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HIV Study Raises Ethical Concerns for the Treatment of Pregnant Women

David Lowet†

In February 1994 the National Institute of Allergy and Infectious Diseases ("NIAID") abruptly halted a key medical study. NIAID wanted to determine whether administering a powerful, virus-fighting drug to pregnant women who were infected with the Human Immunodeficiency Virus ("HIV") would prevent transmission of the virus to their babies. To that end, NIAID was conducting the world's only clinical trial evaluating the effects of antiretroviral treatment on perinatal transmission of HIV. Then the scientists stopped the study.

Why would the government interrupt a study designed to test the efficacy of zidovudine ("ZDV") (more commonly known by its brand name, AZT) in preventing transmission of HIV from pregnant mothers to their newborn children? Did the drug prove dangerous to the mother or the infant? Was ZDV found to be ineffectual in preventing transmission of HIV? On the contrary, the researchers found that a regimen of antepartum, intrapartum, and neonatal ZDV therapy reduced the rate of vertical (mother-to-child) HIV transmission by approximately two-thirds. Further, the treatment did not appear to pose any immediate threat to the health of the mothers or the infants. In fact, NIAID stopped the study so that all of the patients enrolled could be offered ZDV. "This recommendation was based on the demonstration of efficacy of zidovudine [ZDV] in reducing the risk of maternal-infant transmission of HIV."

The success of this clinical trial, known as AIDS Clinical Trial Group ("ACTG") protocol 076, has sparked excitement in the medical community. The chairperson of the Food and Drug Administration's ("FDA") Antiviral

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1 NIAID to Reassess Clinical Trial Protocols in Light of ACTG 076 Maternal-Fetal Results, THE BLUE SHEET 37(8) (F-D-C Reports, Inc., Chevy Chase, MD), Feb. 23, 1994, at 8.
4 See id. at 1177.
5 Id. at 1174.
Drugs Advisory Committee announced that protocol 076’s results were “compelling like no other.” In addition, an FDA Division of Antiviral Drug Products medical officer claimed that “[t]he results from ACTG 076 are probably the most clinically significant thing to date we’ve seen in any study of [an HIV-fighting] drug.”

In response, the Centers for Disease Control and Prevention recently called for the voluntary HIV testing of all pregnant women. In fact, protocol 076’s success has prompted some doctors to call for mandatory HIV testing of all pregnant women. Dr. Philip Pizzo, the chief of pediatrics at the National Cancer Institute, insists that mandatory testing is necessary to identify every pregnant woman with HIV. Indeed, it is indisputable that pregnant women who do not know that they are HIV-positive are unlikely to seek ZDV treatment to prevent transmission to their infants. The issue has thus been presented: Is requiring women to take a simple blood test a greater evil than increasing the risk that an infant will be born HIV-positive? The answer to this question poses many ethical, medical, legal, political, and practical dilemmas.

Some doctors find no ethical dilemma in this situation. Dr. Arthur Caplan, one of the world’s leading bioethicists and the director of the Center for Bioethics at the University of Pennsylvania, endorses mandatory testing. He further states, “[i]t seems to me that despite all the rhetoric, despite all the verbiage, this isn’t such a complicated moral call. 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.”

Dr. Caplan’s reference to “the steps necessary to prevent that harm” conflates the issues of mandatory testing and mandatory treatment. If women are forced to be tested for HIV as a means of protecting their infants, it is a short and slippery slope to the conclusion that women should be forced to undergo treatment toward the same end. Dr. Caplan advocates for HIV testing, but his comment implies that an obligation exists to prevent the harm to the fetus or infant, even if the necessary steps include mandatory treatment.

At least two important suppositions make possible the moral clarity which characterizes Dr. Caplan’s position. First, his position implies that we have the technology to actually prevent the transmission of HIV from mothers to their children. Second, he suggests that the obligation to use that technology to prevent a potential infection is absolute. However, if (1) ZDV does not prevent vertical transmission of HIV or if (2) the value of

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6 Burroughs Wellcome’s Retrovir Reduces Maternal-Fetal HIV Transmission to 8.3% Compared to 25.5% for Placebo; Indication Gets Unanimous Committee Vote, THE PINK SHEET 56(31) (F-D-C Reports, Inc., Chevy Chase, MD), Aug. 1, 1994, at 13.
7 Id.
10 Id.
using ZDV to prevent perinatal transmission must be balanced against other goals, then Dr. Caplan would have to concede that the moral "call" is indeed complicated. In fact, these two suppositions are contestable.

First, the evidence has not proven that ZDV can "prevent a young child from being infected." While the data from protocol 076 suggest that the incidence of vertical transmission can be reduced for a particular population, the results also demonstrate that a substantial proportion of perinatal transmissions were not prevented by the treatment tested. "Although ZDV was successful in reducing perinatal transmission, the study regimen did not completely prevent it." According to the researchers, ZDV therapy reduced the infection rate from 25.5% to 8.3%. The claim that we can prevent any particular infant's infection is speculative, not absolute.

Further, the genuinely encouraging data collected in protocol 076 cannot be applied beyond the narrow population studied. Only women with mildly or moderately symptomatic HIV-disease and relatively healthy immune systems were enrolled in the study. The clinical trial also generally excluded women who had previously had antiretroviral therapy. "Women with more advanced disease and those who have had prolonged treatment with [ZDV] may have a higher viral burden and may also be infected with [ZDV]-resistant strains of HIV. Thus, it is not clear whether the results of this trial can be extrapolated to these groups." This limitation is particularly relevant for poor women and women of color, who are disproportionately infected with HIV. Because these women traditionally have less access to health care, they are more likely to be in the advanced stages of HIV-disease at the time they are diagnosed.

Second, the suggestion that "you are under an obligation to take the steps necessary" to prevent perinatal transmission of HIV, assumes that this goal is the only consideration or the absolutely overriding interest in the equation. However, there are significant medical considerations which mitigate against requiring mandatory testing or treatment of pregnant women.

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12 See Connor et al., supra note 3, at 1176.
13 The study was restricted to women with CD4+T-lymphocyte counts above 200 cells per cubic millimeter. See id. at 1173, 1178.
14 See id. at 1174, 1178.
15 Id. at 1178.
16 In 1990, women of color comprised 73% of all women diagnosed with AIDS in the United States. See CENTERS FOR DISEASE CONTROL, HIV/AIDS SURVEILLANCE REPORT 1-16 (1990).
ZDV is a powerful drug which may have dangerous or unknown consequences for the mother and her child. "The long-term effects of ZDV treatment during pregnancy solely to reduce perinatal transmission or of fetal and neonatal exposure to ZDV are not known."\(^{18}\) The potential long-term consequences of ZDV may include cancer, as well as adverse effects on certain tissues and the reproductive system.\(^{19}\) Furthermore, "[u]se of ZDV during pregnancy could be associated with the development of ZDV-resistant virus, which may lessen the drug’s therapeutic benefit for the woman when it is needed for her own health."\(^{20}\) Thus, the HIV-positive pregnant woman who subjects herself to ZDV therapy to reduce the risk of transmission to her child may be threatening her own health by risking ZDV toxicity and the development of resistant strains of HIV. By focusing only on ZDV therapy’s potential to reduce the risk of vertical HIV-infection, doctors fail to weigh these risks to the mother’s health in determining the ethical course of action.

Ironically, those who support mandatory treatment overlook the potential negative medical consequences for the child. "Although the trial results indicate that the short-term toxicity of the zidovudine [ZDV] regimen was minimal, the long-term effects on both mother and infant are unknown."\(^{21}\) Considering that only approximately one-in-four children born to HIV-positive women will be infected\(^{22}\) (absent ZDV intervention), it would be perfectly reasonable for a woman to decide that it is in the best interests of her unborn child for her to forego an experimental and potentially risky therapy which, in any event, will only reduce the already unlikely chance that her child will be born infected.

The relative clinical success of ZDV in preventing perinatal transmission of HIV to infants also raises legal concerns for those committed to defending a woman’s right to control her body. "Driving such skepticism has been the fear that the new clinical findings would be used to override the privacy rights of pregnant women at risk for HIV, the vast majority of whom are poor black or Hispanic women."\(^{23}\) This is a legitimate concern given the U.S. Supreme Court’s holding that the state has a compelling interest in protecting the life of the fetus in certain instances.\(^{24}\) This precedent may be used to validate mandatory testing.

\(^{18}\) Mofenson & Balsley, supra note 11, at 5.
\(^{19}\) Id.
\(^{19}\) Mutagenic, carcinogenic, and teratogenic effects are possible consequences of ZDV exposure. See id.
\(^{20}\) Id. at 6.
\(^{21}\) Id. at 1222 (emphasis added).
\(^{22}\) Bayer, supra note 2, at 1224.
\(^{23}\) See Connor et al., supra note 3, at 1176.
\(^{24}\) See, e.g., Roe v. Wade, 410 U.S. 113 (1973). However, the Supreme Court has never held that a pregnant woman’s health may be jeopardized in order to protect her fetus. See Lawrence J. Nelson & Nancy Milliken, Compelled Medical Treatment of Pregnant Women: Life, Liberty, and Law in Conflict, 259 JAMA 1060, 1061-63 (1988).
Moreover, pregnant women in particular have been subjected to shocking violations of their individual autonomy. "[A]lmost half of the [doctors surveyed] thought that judicial force should be used to impose treatment thought to be lifesaving, including surgery, on unconsenting pregnant women for the sake of the fetus." These doctors would jeopardize a woman's health and privacy against her will to protect the potential life of the fetus. Women who belong to marginalized communities are particularly vulnerable to these often paternalistic and misogynist policies of the medical establishment. The history of misogyny and vicious medical paternalism has particular relevance in a context where a drug administered to pregnant women is found to help protect their infants from a fatal infection.

The political dimension to the debate over mandatory testing, mandatory treatment, or both is the fight over who gets the power to make medical decisions for pregnant women. "The philosophical question confronting society is whether it wishes to enforce a policy that would entail on an unprecedented scale serious invasions of a woman's privacy, restriction of her civil liberties, and interference with her religious and personal beliefs." The political implications revolve around who has the power to make decisions and what weight is accorded to (and who defines) the mother's interests, the infant's interests, and society's interests.

According to Dr. Ruth Macklin, an ethicist at Albert Einstein College of Medicine, mandatory treatment or testing of pregnant women privileges the interests of the fetus or child over those of the pregnant woman. "What we're talking about here is requiring a test to diagnose something not for the sake of the patient, not for the sake of the general public, but for the sake of a future child." Poor women and women of color, women whose interests have historically been ignored or trammeled outright by the medical establishment, will almost certainly bear the brunt of the political subjugation of pregnant women in general.

In addition to the medical and political issues, calls for mandatory testing and treatment raise a host of practical concerns. "The pragmatic aspects alone of the treatment regimen defined in Protocol 076 make the prospect of therapy without the full cooperation of infected pregnant women difficult to contemplate. . . . Would anything short of incarceration make such treatment possible?" Compulsory treatment of pregnant women appears to be practically unfeasible.

Mandatory testing alone has huge practical difficulties. "[E]laborate requirements for extensive counseling before testing" are mandated by law.

25 Nelson & Milliken, supra note 24, at 1060 (citing V.E. Kolder et al., Court-Ordered Obstetrical Interventions, 316 New Eng. J. Med. 1192, 1196 (1987)). For a discussion of the First Amendment right to decline medical treatment, see Application of the President and Directors at Georgetown College, Inc., 331 F.2d 1000 (D.C. Cir. 1964).

26 Id. at 1065.

27 Kolata, supra note 9, at A15.

28 Bayer, supra note 2, at 1225.
in some states.\textsuperscript{29} States simply cannot afford the time and effort it would take to counsel and test every pregnant woman. Furthermore, people testing positive for HIV often face discrimination and stigma from those who know about their infection. As a practical matter, "confidentiality is rarely, if ever, absolute," according to Dr. Macklin.\textsuperscript{30} Although these concerns are pragmatic, they obviously carry ethical implications as well.

The availability of treatment is a prime example of the nexus between practical and ethical problems for a regime of mandatory testing. [N]o recommendation for HIV-testing would be ethical if access to the needed therapy and support was not ensured. Given the failure of the American health care system to guarantee access to health care, given that too many women at risk for HIV receive either no perinatal care or inadequate care, and given the poverty of the overwhelming majority of women who are infected, it is by no means certain that the scientific breakthrough represented by Protocol 076 will evoke the necessary social response.\textsuperscript{31}

Dr. Mervyn Silverman, the president of the American Foundation for AIDS Research observed, "[i]t would be a cruel hoax to test someone, find out they're positive and not be able to offer . . . [ZDV] and other clinical follow-up."\textsuperscript{32} Again, these consequences are amplified with respect to poor women and women of color who are disproportionately deprived access to health care. Will ZDV be made available to these women if they test positive for HIV? Who will pay for their treatment if they develop complications as a result of the ZDV therapy? Who will make available alternative drugs for treatment of HIV infection if the therapy causes them to develop a viral strain resistant to ZDV? These practical considerations compound the ethical implications of requiring mandatory testing and treatment of pregnant women.

While the goal of obstetrics should continue to be "the birth of a healthy baby to a healthy mother,"\textsuperscript{33} it is unethical for a physician to substitute his or her ethical determination for that of the mother where there are potential conflicts between the mother's interests and the infant's or fetus' interests. "[I]t is not feasible to determine in a just and fair manner which actions or inactions of a pregnant woman should warrant interventions as drastic as involuntary treatment. . . . It is also not possible to enforce such a policy effectively without extensive . . . intrusion into the private lives of pregnant women . . . ."\textsuperscript{34} Despite the promising results of protocol 076, the medical uncertainties and the political, ethical, and practical considerations all militate against invading the "ethical principle of patient autonomy and the legal right to self-determination and bodily integrity for . . . pregnant

\textsuperscript{29} Id.
\textsuperscript{30} Kolata, supra note 9, at A15.
\textsuperscript{31} Bayer, supra note 2, at 1225.
\textsuperscript{32} Neergaard, supra note 8, at A15.
\textsuperscript{33} Nelson & Milliken, supra note 24, at 1060.
\textsuperscript{34} Id. at 1065.
women.” Rather, the government and the medical community should focus on outreach and counseling to enable women to make informed decisions about their health and the health of their children.

In addition, the medical establishment should work with communities to resolve the practical obstacles to treatment which particularly plague poor women and women of color. “If society and the medical profession are truly interested in enhancing fetal health, their efforts should be directed toward increasing the availability and quality of voluntary prenatal care for all pregnant women...” The failure to address these practical concerns, coupled with the medical, political, and ethical concerns outlined above, operates to limit severely the benefit of protocol 076’s findings, particularly for poor women and women of color.

35 Id.
36 Id. at 1066.