

**U.S. House of Representatives
Committee on Ways and Means
Subcommittee on Human Resources**

Testimony—May 18, 2005

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Mr. Chairman and Committee members, thank you for inviting me to share my views with the Committee on the issue of **Protection of Foster Children Enrolled in Clinical Trials**. My name is Alan Fleischman; I am a physician, pediatrician and medical ethicist. I am Senior Advisor at The New York Academy of Medicine and Ethics Advisor to the National Children's Study at the National Institute of Child Health and Human Development, as well as Clinical Professor of Pediatrics and Clinical Professor of Epidemiology and Population Health at the Albert Einstein College of Medicine in New York. **I speak today as an individual, the opinions I will express represent my own and do not represent the views or opinions of any organization or institution with which I am or have been affiliated.**

In the late 1980s and the early 1990s I was Professor of Pediatrics and Professor of Epidemiology and Social Medicine at the Albert Einstein College of Medicine in New York and served as Director of the Division of Neonatology at the Montefiore Medical Center, that included responsibility for the newborn services at the voluntary hospital, Montefiore, and two public hospitals operated by the New York City Health and Hospital Corporation, Jacobi Medical Center and North Central Bronx Hospital. I was also a member of the two Institutional Review Boards for research involving human subjects that was responsible for approval of all research involving humans conducted at each of

these hospitals.

I was a member of the American Academy of Pediatrics National Bioethics Committee from 1983-1989, and a member of the American Academy of Pediatrics AIDS Committee from 1993-1999. In New York State, I was a member of the Department of Health, AIDS Advisory Council Work Group on Ethical Issues in Access to Treatment. In addition, I was asked, in 2001, by the Secretary of the U.S. Department of Health and Human Services (DHHS) to serve as a member of the National Human Research Protections Advisory Committee to the Office for Human Research Protections and to chair the review of the federal regulations that govern research involving children. I have also served as an expert advisor to the Institute of Medicine's Committee on Ethical Conduct of Clinical Research Involving Children.

I am currently a member of the New York State Governor's Task Force on Life and the Law, the New York City Mayor's Commission on Women's Issues, the DHHS Secretary's Advisory Committee on Human Research Protections' Subcommittee on Research Involving Children, and the Institute of Medicine Committee on Ethical Issues in Housing-Related Health Hazard Research Involving Children Youth, and Families.

I am here today to express my strong belief that clinical research with therapeutic intent involving children in foster care is an ethical imperative and can be performed in an appropriate manner fully consistent with good ethical practice and compliant with federal regulations that govern research.

In order to understand the issue of the enrollment of foster children in AIDS clinical trials, you need to have a picture of AIDS care for children in the late 1980s and the early 1990's:

- 25% of babies born to women who were HIV infected developed HIV through viral transmission in utero;

- AIDS was a universally fatal disease in children, with 25% of infected children dying by 5 years old;

- many of the young children with HIV were "boarder-babies" who stayed in hospitals or were placed in foster care because they had become orphans due to the death of their mothers from AIDS, or because their mothers were too ill or impaired to care for them;

- great strides were being made with new drugs developed for the treatment of HIV and AIDS and its complications, but initial trials of these drugs included only adults; multiple drug therapy was shown to save lives, and reverse some of the major life-threatening illnesses associated with AIDS, but these new treatments were not available to children;

- in fact, pediatric formulations of these drugs were not available to physicians caring for young children with HIV and AIDS;

- the National Institutes of Health developed clinical research trials in order to study the effectiveness of various new treatments in children; Some of the drugs had the potential for side effects, but those possible risks were viewed by doctors to be far out

weighed by the potential therapeutic benefit of the new drugs against AIDS, then a uniformly and often rapidly fatal disease.

A large percent of the children with HIV and AIDS in the late 1980s and the early 1990s in New York City and other parts of the country were poor, minority children, and many of these children required foster care. It would have been unconscionable and unjust, not to offer these children the very best prospect of life saving and life-enhancing treatment. Enrollment in clinical trials was the only way to accomplish that goal. If the agencies responsible for supervising the care of foster children in the early 1990s refused to allow children to be enrolled in treatment trials, I and many other clinicians would have demanded action in the interests of those children.

In New York, the Administration for Children's Services, the agency responsible for supervision of foster children, developed mechanisms that made enrollment of foster children in clinical trials possible. Local Institutional Review Boards for research involving human subjects, like ours in the Bronx, approved the NIH treatment trials for use in all children infected with HIV and helped investigators and the Administration for Children's Services to develop mechanisms to allow enrollment of children in foster care. The consent of biologic mothers was obtained when possible, agency permission on an individual basis was obtained, and foster parents were involved in these discussions because of their need to administer treatments and bring children back for follow up visits to the hospital.

Let me also comment on the federal regulations that govern research involving children with a specific emphasis on the section on “wards” in the regulations (§45CFR46.409). I took the opportunity last week to clarify the regulations with a senior member of the Office for Human Research Protections at the U.S. Department of Health and Human Services and I believe that my views of the regulations are consistent with his.

Clinical trials that include treatment with the prospect of direct benefit to the individual child are governed by section §45CFR46.405 of the federal regulations. This section requires the permission of the parent or legal guardian in order to enroll any child in a study. It does not require the creation of an advocate for each child that is a ward or in foster care. This approach is based on a clinical treatment model. Only if the proposed research does NOT provide the prospect of direct benefit for the individual child AND has a level of risk greater than minimal is the creation of an advocate required by the regulations (§45CFR46.409).

Let me add that virtually all of the research projects involving foster children in New York City were treatment trials with therapeutic intent. The individual institutions conducting the trials had an Institutional Review Board that had to prospectively approve the studies and may or may not have created special advocates or processes for enrolling foster children. We did in the Bronx, but it was not mandated by the regulations. What was required was the permission of the biologic parent or of the guardian, either the legal guardian or the agency fulfilling that responsibility for the child.

Today, Pediatric AIDS treatment in the U.S. is different. Because of clinical trials conducted in the 1990s, there are effective treatments to prevent children from becoming infected in utero and standard treatments for the small number of children who are infected. AIDS in children has become a chronic disease with less than 1% mortality each year for children treated in AIDS centers in the U.S. Children in foster care infected with HIV are getting standard treatment and are rarely participating in clinical trials because it is no longer a matter of life and death. But there may be a time in the future, perhaps with the emergence of a new dreaded disease, when we will once again be faced with the critical need to enroll foster children in clinical trials in order to provide needed life saving treatments. The present federal regulations allow us to do that, if we had to.

In conclusion, those of us involved in the treatment of children infected with HIV in the late 1980s and 1990s knew that a large percentage of our patients were poor, minority children and many of those children were in foster care. We demanded the very best treatment for these vulnerable children. The only way to provide the best treatment to any child with HIV at that time was through clinical trials—the drugs were just not available any other way. We enrolled children in treatment trials and gathered information on the effects of the new drugs on children, while we attempted to save and enhance the lives of our patients. It would have been unethical to have behaved in any other way; if we denied those new treatments to children in foster care we would stand today open to severe criticism for having allowed our most vulnerable children to have suffered or even die rather than offer them the best chance of survival and the possibility of a good future quality of life. Thank you.