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## Belated Charge Ignites Furor Over AIDS Drug Trial

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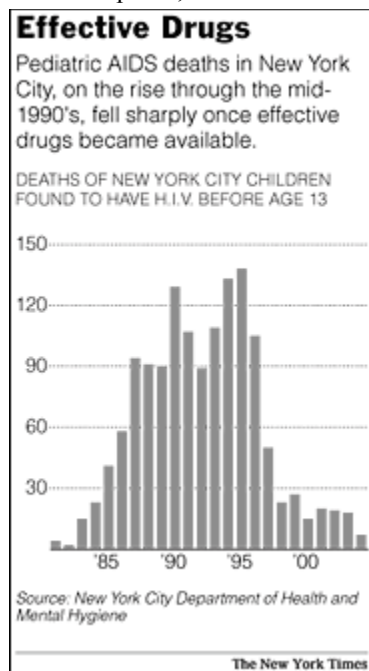
It was seen as one of the great successes of AIDS treatment. In the late 1980's and early 1990's, hundreds of children in New York City were dying of AIDS. The only approved drugs were for adults, and many of the patients were foster children. So doctors obtained permission to include foster children in what they regarded as promising drug trials.

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Edward Keating/The New York Times

In a 1994 photo, one of the babies with AIDS who were at the Incarnation Children's Center in Manhattan.





Ashley Gilbertson for The New York Times

Vera Hassner Sharav filed complaints with federal agencies over AIDS drug testing on children.

By 2000, the number of children under 20 who died of AIDS in the city that year dropped to 13 from more than 100 per year less than a decade before.

But now, just as the trials are receding into history, they are coming under intense scrutiny. A federal agency is investigating whether guidelines for including foster children in trials were violated. The city's child welfare administration has opened an independent inquiry into whether children were harmed.

And when the head of the child welfare system testified about the trials at a City Council hearing in May, angry spectators shouted him down.

All this is happening despite the fact that there is little evidence that the trials were anything but a medical success. Most of the questions have arisen from a single account of abuse allegations - given by a single writer about people not identified by real names, backed up with no official documentation as supporting proof, and put out on the Internet in early 2004 after the author was unable to get the story published anywhere else.

The story accused doctors of brutally experimenting on foster children, most of them black, Latino or poor. It said they had poisoned them with toxic drugs, sometimes against their parents' will and without even being certain they were sick.

The charges jumped from Web site to Web site, then into The New York Post and into a documentary shown on the BBC. The documentary alarmed black civil rights activists and City Council members, who charged racism.

Physicians and federal health officials involved in the trials have strongly defended their work. They say hundreds, perhaps thousands, of children benefited; many of those were children not in foster care. To have withheld promising drugs from sick children just because they were in foster care would have been inhumane, the doctors say.

They say they obtained legal permission for the children's participation, either from the biological parents or child welfare officials, in all but a small number of cases. Numerous doctors interviewed said they knew of no foster child who died as a result of the trials.

"For those people who believe that these kids were harmed, I'd like to say, 'What is the evidence?' " said Dr. William Borkowsky, a pediatrician at Bellevue Hospital Center who took part in the trials. "And better yet, 'Is there evidence that they were helped?' There is very impressive evidence that they were helped."

#### Missing Records

The most thorough of the investigations will not be completed for months. In the meantime, some critics' suspicions have been stoked by admissions by city officials that their own records are inadequate or missing. The city's child welfare agency, the Administration for Children's Services, which has been

through four changes in administration since the trials began, cannot even say conclusively how many foster children were involved.

More worrisome, the agency now expects that the current independent investigation will find that there are inadequate records of parental consent.

"We don't believe we have all the permissions by any means," said Sharman Stein, director of communications for the children's services agency.

Already, one federal agency, the Office of Human Research Protections, found in June that one New York hospital had approved four of the trials without gathering enough information about the selection of foster children as subjects, or about the process for getting their parents' or guardians' permission. It made no finding as to whether any children were harmed or selected improperly.

Whatever the outcome, the controversy has already demonstrated the power of a single person armed only with access to the Internet and an incendiary story to put major institutions on the defensive. The story taps a combustible mix of fears: the suspicions of some activists that AIDS is not necessarily caused by H.I.V. and that AIDS drugs do not necessarily help, and the belief of some black people that the medical establishment does not always have their interests at heart.

The controversy extends back to a bleak period in New York City history when well over a hundred children a year were dying of AIDS, most under the age of 5. As many as one in every five children infected with H.I.V. were dead by 2, doctors now say; up to 50 percent were dead by 4.

There were no AIDS drugs approved for children in those years. The first AIDS drug, AZT, was approved for adults in 1987. Babies were being abandoned in hospitals, their mothers unable to care for them and with no foster homes available. About 40 percent of the children with H.I.V. were in foster care.

As a result, pediatricians began pressing pharmaceutical companies to let them try drugs shown to work in adults. "People were clamoring, begging for access to any drug," said Dr. Borkowsky.

Trials began in the late 1980's. Pediatricians asked the city to allow foster children to participate. "To deny these kids the medications would have been a crime," said Dr. William B. Caspe, chairman of pediatrics at Jacobi Medical Center in the Bronx. "Because of what we did, we were able to keep them alive until newer medications became available."

By 1989, the child welfare agency was developing rules for enrolling large numbers of foster children in clinical trials. Carol Marcus, the agency's lawyer in charge of that project, said that the agency had acted slowly and carefully, aware of the need to protect a particularly vulnerable population. In a recent interview, she said that even then she was acutely aware that the agency could be accused of racism and exploitation.

The guidelines required a panel of pediatricians to review all pediatric AIDS trials being sponsored by the National Institutes of Health, and to eliminate those in which there was no "prospect of direct benefit" for each child. The agency required the consent of the child's biological parent or, if no parent could be found, written permission from the commissioner.

Ms. Marcus says that she now believes there could have been more safeguards. The task of matching children to trials was left to each child's physician. She said the agency, which had seen the number of children in their care double in two years to 40,000, was too understaffed to monitor how each child was doing. Nevertheless, she remains proud of the agency's response to the crisis.

In 1990, under the city's first black mayor, David N. Dinkins, the guidelines went into effect. They were being carried out by Barbara J. Sabol, the city's first black commissioner of social services, and by her deputy in charge of child welfare, Robert L. Little. Mr. Little, a younger brother of Malcolm X, died in 1999, and Ms. Sabol did not return phone calls to her office.

One center that took part in the trials was a small boarding home for H.I.V.-infected foster children called Incarnation Children's Center, the brainchild of Dr. Stephen W. Nicholas, now director of pediatrics at Harlem Hospital Center. With as many as 24 infected children abandoned in the hospital in 1988, the idea of finding them a home outside the hospital came to him after a young patient greeted him with, "Hi, Daddy."

Working with Columbia University and the Catholic Archdiocese of New York, Dr. Nicholas became the medical director of Incarnation, on Audubon Avenue in Washington Heights, which opened in 1989 and added an outpatient clinic in 1992. Foster children there and elsewhere were enrolled in trials - at first,

trials of single drugs like AZT, and later, of multiple-drug cocktails and protease inhibitors, which by 1996 were helping turn AIDS into a manageable, if still chronic, disease.

For 14 years, 90 percent of the children infected with H.I.V. in the city, in foster care and not, participated in drug trials, according to estimates by the child welfare administration. Gradually, fewer children became infected and sick. Foster homes were found for many, and many were adopted. In 2000, Incarnation became licensed as a skilled nursing facility under the State Department of Health, opening its doors to children not in foster care. In 2001, Dr. Nicholas left for his current job at Harlem Hospital Center.

The story, however, does not end there.

In the summer of 2003, Incarnation was visited by Liam Scheff, a 34-year-old, self-described "very independent journalist from the 'go out and get the story, don't let the slammed door get in your way' school of journalism" with a longtime interest in what he calls "the other side" of AIDS.

Mr. Scheff had doubts about much of what was known about AIDS. He doubted that H.I.V. was necessarily the cause. He doubted the seeming certainty of an AIDS diagnosis. He doubted the reliability of the H.I.V. test and the usefulness of AIDS drugs in part, he said, because he knew H.I.V.-positive men who had remained healthy on a macrobiotic diet.

Mr. Scheff said he had been put in touch with a New York woman who said her two adopted children had been placed in Incarnation after she had let them stop taking AIDS drugs she believed had made them sick. So Mr. Scheff went to Incarnation, as a friend of the family. He said he was horrified by what he saw.

#### Grim Allegations

In January 2004, he posted an article, "The House That AIDS Built," on [indymedia.org](http://indymedia.org), a Web site that describes itself as an outlet for "radical, accurate and passionate tellings of truth." He chose that approach after trying unsuccessfully to get the article published. "I couldn't get anybody to touch it," he said.

The article made a series of gruesome claims: Among other things, Mr. Scheff wrote that Incarnation had been holding children against their parents' will, in some cases force-feeding them drugs "known to cause genetic mutation, organ failure, bone marrow death, bodily deformations." He wrote that two children had recently died.

The article came to the attention of Vera Hassner Sharav of the Alliance for Human Research Protection, a group she said she had founded to monitor "the underbelly of research" after her schizophrenic son died of a reaction to an approved drug. After his death, she said recently, she realized people must "stop thinking you can trust the men in the white coats."

She added, "It's a business now."

Ms. Sharav forwarded Mr. Scheff's article to the 3,500 people she said receive her e-mail "infomails" daily. She then looked into Incarnation on the Internet. She came to suspect that children had died there, and that this was what ended the trials and led to the license change and Dr. Nicholas's departure. In March 2004, Ms. Sharav filed a complaint with the federal Office for Human Research Protections and with the Food and Drug Administration.

At the same time, The New York Post published several articles about Incarnation under headlines like "AIDS Tots Used as Guinea Pigs." Soon, an independent film director enlisted Mr. Scheff and Ms. Sharav to help with a documentary, paid for and shown by the BBC, entitled "The New York Experiment - Guinea Pig Kids."

The reports alarmed African-American activists and politicians in the city. The accusations resonated in particular with Omowale Clay, a leader of the December 12th Movement, a Brooklyn-based group that campaigns for reparations for slavery, and acts as a watchdog group for civil rights violations against blacks.

Mr. Clay said he had conducted his own research and concluded that trials were done on black infants who did not even have H.I.V. He offered no evidence of his claims.

"What we know already," he said, "is that 98 percent of the children experimented on were black and Latino and that the fundamental basis of why they chose those kids was racism. They have the arrogance to say it was for their own good, but we know it was racism."

Last fall, Mr. Clay began showing the documentary film, which had aired only on BBC, in churches, block association meetings and private gatherings. He campaigned to make the child welfare agency's records public.

At the same time, two Democratic city councilmen, Charles Barron of Brooklyn and Bill Perkins of Manhattan, also were calling for Council hearings and an investigation by the city.

In March, the child welfare agency handed its critics new ammunition. It revised its count of the number of children in the trials, to 465 from 89, saying it had discovered an additional box of documents in the basement.

The news prompted a new round of scrutiny. The child welfare agency responded by hiring the Vera Institute of Justice, an independent nonprofit research group, to conduct an in-depth investigation at an initial cost of \$1.5 million. The move hardly tamed the fury.

#### Demanding Answers

In May, the City Council held a hearing and a mostly black audience booed John B. Mattingly, the child welfare commissioner, who had been appointed in 2004, more than three years after the last foster child was enrolled in the drug trials.

Councilman Barron invoked the specter of the infamous Tuskegee experiments, in which black men with syphilis were studied for 40 years, beginning in 1932, but were neither treated nor told they had the disease. Councilman Perkins warned, "This has deep racial connotations."

After the Council hearing, the Black Equity Alliance, a group of African-American leaders, started contacting the news media to demand a better accounting by the city. Dr. Billy E. Jones, a former president of the city's Health and Hospitals Corporation, who is black, said, "Nobody who has the history that our community has, has the luxury of not being concerned."

Pediatricians involved in the trials say they are mystified by the onslaught. While powerful drugs do have side effects, many said, they remembered no fatal reactions. At Incarnation, Dr. Nicholas said, no child had died of a reaction and "no child ever had an unexpected side effect."

He said that, with one exception, no children had been included in the trials without "absolute proof" by advanced testing methods that they were infected and not simply carrying their mother's antibodies. He said the exception was a trial that proved that by giving AZT to pregnant, infected women and then to their newborns in the first six weeks of life it was possible to sharply reduce the rate of H.I.V. transmission from mother to child. He called that study "the most important clinical trial in the history of AIDS."

In response to the charge by some critics that hospitals should have appointed independent guardians for each child, doctors said the federal regulations require advocates only when a trial holds "no prospect of direct benefit" for the child. Several said their hospitals appointed advocates anyway.

"This isn't Tuskegee, it never was Tuskegee, it never will be Tuskegee," Dr. Borkowsky said. "This is something that has been blown totally out of proportion by, I think, people who are vying for office and looking for something to get them into the news."

Columbia University Medical Center, which was found by federal officials to have "failed to have obtain sufficient information" in approving the participation of foster children in four trials, has acknowledged what it called a need to improve "how information is collected and decisions documented." But it said investigators had not questioned the appropriateness of enrolling children, the care they received, the research's value or the scientists' conduct.

As for the city's child services agency, officials say that in all the years since the drug trials, no family has sued or come to them with evidence of mistreatment. Staff members, past and present, expressed pride in what they had done; the worst thing that could have happened, they said, would have been for the agency to have done nothing.

Mr. Mattingly, the agency's commissioner, said, "I would far rather be having this dialogue than one in which we tried to explain why my predecessors - confronted by a medical epidemic of unforeseen magnitude - did not do everything possible to get these children access to promising medication because they were in foster care. Or because the rules and regulations designed to protect their interests were so complicated that no children got the lifesaving help."