

Reporting by New York Post, U.K. Guardian, A&U Magazine, Associated Press, Fox News and AHRP on the Incarnation Children's Center drug trials.

## **SHOCKING EXPERIMENTS: AIDS TOTS USED AS 'GUINEA PIGS' By Douglas Montero**

"I took the girls out of hell—and the city stole them back" <http://www.leftgatekeepers.com/articles/AIDsTotsUsedAsGuineaPigsByDouglasMontero.htm> February 28, 2004

Jacqueline Hoerger will never forget the raid of her Nyack home by foster-care social workers who snatched the two HIV-positive sisters she was trying to adopt.

Her crime: She was accused of neglect by the girls' doctor of because she refused to give them a potentially dangerous cocktail of high-powered AIDS medications that she felt made them sicker.

Hoerger, a pediatric nurse who spent two years as the girls' foster mother, got the children from Manhattan's Incarnation Children's Center, a foster home for HIV-infected kids, where she worked from 1989 to 1993.

There, she watched an array of researchers experiment on HIV-infected children, some as young as 3 months.

She did her job, and figured the doctors at Columbia Presbyterian Medical Center, which is affiliated with ICC, knew what they were doing. It wasn't until she was allowed to take the sisters, ages 6 and 4, home in late 1998 that she began questioning the doctors and suspected that they were conducting research.

"They were given to me as total wrecks.," Hoerger said, describing how the oldest was hyperactive and sickly and the youngest was lethargic, extremely overweight and could barely walk.

She learned the drug cocktails were highly toxic and mostly untested in children after listening to a speech by Dr, Philip Incao, of Denver, who travels across the country questioning current HIV medical practices.

She decided to wean them off the drugs with Incao's help.

That's when the brow-beating began. The Administration for Children's Services, which has admitted to allowing researchers to conduct medical experiments on HIV infected children, and the Catholic Home Bureau, the adoption arm of the Archdiocese of New York, became the doctors' enforcers.

When Hoerger refused to relent, social workers came and took the girls away.

ACS refused to comment about the case, citing the privacy of the two sisters.

"I gave my blood, sweat and tears to help these children, and we turned them into real kids," said Hoerger, who cared for the girls with her husband, a schoolteacher. "They were just taken away—two healthy kids---taken away."

"I spent a couple of days in total shock," said Hoerger, who despite her run-in the ACS maintains her license as a nurse. "I didn't do anything for two days—I was in total, complete shock."

That was in 2000. She hasn't seen the kids since.

### **AIDS TOTS USED AS 'GUINEA PIGS' By Douglas Montero**

The state Health Department has launched a probe into potentially dangerous drug research conducted on HIV-infected infants and children at a Manhattan foster-care agency, The Post has learned.

Some 50 foster kids were used as "guinea pigs" in 13 experiments with high doses of AIDS medications at Manhattan's Incarnation Children's Center, sources said.

Most of the ICC experiments were funded by federal grants and in some cases, pharmaceutical companies. They used city foster children, who were sent to the Catholic Archdiocese-run facility by the Administration for Children's Services.

ICC was involved in 36 different experiments, according to the National Institutes of Health Web site. One study researched "HIV Wasting Syndrome," which studied how a child's body changes when his medication is altered.

A handful of the experiments involved combining up to six AIDS drugs - so-called "cocktails" - in children as young as 3 months, and another explores the reaction of not one, but two doses of the measles vaccine in kids ages 6 to 7 months.

Other studies tested the "safety," "tolerance" and "toxicity" of AIDS drugs.

"They are torturing these kids, and it is nothing short of murder," said Michael Ellner, a minister and president of Health Education AIDS Liaison, an advocacy group for HIV parents.

Biochemist Dr. David Rasnick, a visiting scholar at the University of California at Berkeley and an expert in AIDS medication, was outraged because the drugs, alone or combined, have "acute toxicity which could be fatal."

He said the drugs' side effects include severe liver damage, cancerous tumors, severe anemia, muscle wasting, severe and life-threatening rashes and "buffalo hump," where fatty tissues accumulate behind the neck.

Housed in a former convent and run by the Archdiocese of New York's Catholic Charities, the foster-care agency described the experiments on its own Web site, which was abruptly shut down after The Post began making inquiries.

Archdiocese spokesman Joseph Zwilling said experiments at ICC were halted in 2002. He said he did not know why. Zwilling also said he did not know if any children had died.

An ACS spokeswoman said the agency hasn't approved any new experiments since 2000 because the "risks outweighed the benefits." She declined to explain further. That agency is also reviewing its files on the case.

Jacqueline Hoerger was a pediatric nurse at ICC from 1989 to 1993 and said the experimentation was going on even back then. "We were taught that any symptom we saw was HIV-related," said Hoerger, 43. "The vomiting, diarrhea, wasting syndrome, the neurological side effects - they were dying. There was death."

She didn't think doctors were doing anything wrong, however, until years later, when she tried to adopt two of the foster girls. When she refused to give the kids the center's high-powered AIDS cocktails for fear it was making them sicker, ACS had social workers take the children away from her.

Advocates for children question the ethics of experimenting on foster kids - especially those too young to know what's happening to them.

"The most vulnerable, disadvantaged children are being exploited by powerful entities and used as guinea pigs as if they were not human beings," said Vera Sharav from the Alliance for Human Research and Protection.

The tests were conducted by doctors from Columbia Presbyterian Medical Center, which was affiliated with ICC until 2002 and reaped the financial benefits of the research.

"Through these trials, children at the ICC outpatient clinic gained access to state-of-the-art treatments for HIV," said Annie Bayne, a Columbia spokeswoman.

ACS policy states it seeks parental consent before a child is enrolled in a study. If the parents cannot be found, ACS's medical and legal divisions, and its commissioner, must all approve.

The condition, however, is that the experiment "offer each participating child a significant potential benefit, a concomitant minimal risk of injury or harm," ACS spokeswoman MacLean Guthrie said.

Fire Commissioner Nicholas Scoppetta, who headed ACS at the time of the experiments, refused comment.

Officials at ICC, which was established in 1989 to house and care for HIV-infected "boarder babies" left stranded in city hospitals, refused to talk to The Post.

### **Some of the medical experiments conducted at Incarnation Children's Center:**

No. 254 WHAT: Study and compare anti-bacterial drugs on kids between the ages of 3 months and 3 months. WHY: To study the long-term safety and tolerance of a combination of three different bacteria fighting drugs. DRUGS USED; Azithromycin, Atovaquone and Sulfamethoxazole-Trimethoprim (SMX/TMP). SIDE EFFECTS: Azithromycin—fever, joint pain, swelling of face, stomach pain, vomiting. Atovaquone—fever, skin rash, vomiting. SMx/TMP—hallucinations, sensitivity to sunlight,, allergic skin reaction.

No. 299 WHAT: testing the safety of AIDS drug Recombinant Interleukin-2 or Aldesleukin on kids ages 3 to 12 years old. WHY: AIDS medicine was never tested on kids, and adult's immune system reacted positively to the drug. SIDE EFFECTS: Fever, nausea, heart, kidney and liver problems. Used to treat kidney cancer and can only be administered in a hospital setting.

No. 333 WHAT: Comparing the effects of new anti-HIV drug combinations on kids between the ages of 2 and 17 years old. WHY: Researchers want to test the safety and tolerance level of the AIDS medicines when two or more are combined. DRUGS USED: Indinavir; Ritonavir; Nevirapine; Lamivudine; Stavudine Zidovudine (AZT). SIDE EFFECTS: Indinavir—blood in urine, kidney stones, abdominal bloating, muscle wasting. Ritonavir—diabetes, abdominal pains, stomach bleeding, skin disorders. Nevirapine—liver damage, headaches, nausea, fatal skin rashes, fever, yellow eyes or skin. Lamivudine—hair loss, fatigue, body and stomach pain. Stavudine—tingling, burning or pains on hands and feet, skin rash, muscle and severe stomach pain. AZT—bone marrow problems, seizures, abdominal discomfort.

## **DEFENSELESS KIDS' GUARDIAN AGENCY WON'T COME CLEAN Douglas Montero**

The city's Administration for Children's Services is so busy protecting the privacy of foster kids it won't talk about how those kids were used as HIV guinea pigs.

My questions were simple: How many HIV foster kids have they allowed to be used in experiments? Whom could they call for relief if researchers prodded too hard, hurt them, made them cry or made them sick?

These defenseless kids couldn't run home and cry to mommy—their “mother” is the ACS bureaucracy

From 1998 until 2002, ACS allowed HIV-positive foster kids to be used by scientists trying to solve the mysteries of the scourge illness. About 50 of them at Manhattan's Incarnation Children's Center were used as guinea pigs in the late 1990s.

Scientists push the limit—that's how they discovered penicillin, a researcher once told me. And that's fine when we're talking about kids whose parents are looking over the doctor's shoulder.

The city's Public Advocate's Office, which looks over the shoulder of ACS, said it was surprised to hear of the policy that allowed HIV infected children to be used as guinea pigs.

“We're concerned because clinical trials are risky and we're concerned ACS just unilaterally signed up these kids,” said Advocate's Office spokeswoman Anat Jacobson.

Vera Sharav, the president of the city's Alliance for Human Research Protection, who reviewed 10 of the studies, said some of the studies were purely experimental.

One experiment states the combination of two drugs “has not been approved for use in children and the doses for the combination of the two drugs has not been studied in children.” Another study with three drugs flatly states, “This study also evaluates the long-term safety and tolerance of these different drugs.”

“This is not for the children’s treatment, it’s to test experimental drugs,’ said Sharav, who questioned ACS’s decision to give consent for children whose parents can’t.

On paper, the 1998 ACS policy sounds strict. The question is whether ACS’s case- workers, who oversee 14,000 kids, were in a position to hear the cries of the HIV guinea pigs at night—when there’s only a nurse or a \$10.75-an-hour Spanish-speaking matron around.

In an e-mailed statement, ACS spokeswoman Maclean Guthrie says that over the past decade a “great number” of advancements have been made in HIV treatment that prolongs the life of infected children.

“Our goal is to ensure that children in foster care have the same access as other children to these treatments, “ she said.

OK, now show us the proof. Reveal the fate of all the foster children involved in the secret HIV experiments. We don’t want their names, Social Security numbers or date of birth—we just want to know how many of them came out alive.

## **HIV-BABY PROBE**

**By DOUGLAS MONTERO**

March 1, 2004 -- Stunned City Council members yesterday called for an investigation into the use of HIV-infected foster children in potentially dangerous experiments involving high doses of AIDS drugs.

The reaction comes after The Post reported that some 50 children, some as young as 3 months old, were involved in 13 studies at Manhattan's Incarnation Children's Center, a foster care agency run by the Archdiocese of New York.

Three lawmakers, all members of the council's General Welfare Committee, which oversees the city's Administration for Children Services, said they plan to demand an answer on the fate of the children used in the experiments.

"It's crucial that we get full disclosure," said Councilman Bill DiBlasio, the committee chairman, who plans to reach out to ACS Commissioner William Bell today.

"We need to find out what happened to these kids," he said, adding that he may hold public hearings on the matter.

Advocates are concerned some children in the experiments, one which included giving kids a combination of six high powered AIDS medications, were injured during the studies conducted in the late 1990s by doctors from Columbia-Presbyterian Medical Center.

Some, like Vera Sharav from the Alliance for Human Research and Protection, are wondering why the experiments were abruptly halted in 2002 and why Columbia-Presbyterian pulled its clinical operation out of ICC.

No one from ACS, Columbia-Presbyterian and the Archdiocese of New York could say if any children were hurt or killed in the experiments. ICC, which was established in 1989 to house and care for HIV-infected children left at city hospitals, has refused to talk.

Some side effects to the drugs used include severe liver damage, tumors, anemia and life-threatening rashes.

Councilman Bill Perkins said he's concerned because of the rumblings he's heard in the "black community" about children being taken away from their parents by ACS and used in research studies.

ACS Spokeswoman MacLean Guthrie was unavailable for comment.

"I think the council needs to take aggressive steps to put this in check," he said. "Clearly, no one knows what's going on . . . We need to call for a public hearing on this."

Councilman José Serrano Jr. wondered about the consent process and how the "defenseless" children could have fought off researchers.

"It's an outrage to think that they would use children in foster care who have already come from abusive situations," he said. "It's disturbing."

This article was posted on 3.6.04

## **AHRP:**

An ongoing investigation by the Vera Institute of Justice, has uncovered 59 additional New York City foster care children—between July and September—who may have been used in AIDS drug / vaccine trials in violation of federal regulations. This brings the tentative total number of mostly minority children involved, to 773.

These children were enrolled in the risky experimental trials in violation of federal regulations. They were used as experimental subjects without legal informed consent and without an independent advocate authorized to serve the children's best interest. The Vera Institute investigation is charged with finding out not only how many children were involved in the experiments and to ascertain what happened to those children.

The investigation by the Vera Institute follows an investigation by the federal Office of Human Research Protections which was initiated by a complaint filed by The Alliance for Human Research Protection March 10, 2004:

The investigation, however, is being hampered by administrators of Columbia Presbyterian hospital, which had a major involvement in the experimental drug and vaccine trials. Despite repeated requests by the Vera Institute, Columbia administrators have thus far refused to provide access to the medical records of the foster care children who were enrolled in the trials. This is a demonstration of abuse of power by medical institutions that hugely benefit from taxpayer support.

In February, 2006, OHRP found Columbia University Medical Center (CUMC) New York /Presbyterian Hospital in non-compliance with federal research protection regulations. See OHRP letter at:

**NEW YORK POST**  
**MORE HIV 'GUINEA PIG' KIDS**  
**By DAVID SEIFMAN December 29, 2007**

The number of HIV-infected foster kids under the city's care who may have been steered into experimental drug trials in the 1990s has grown to 773, a report says.

The Vera Institute of Justice, which is probing the clinical trials, says 59 potential cases were added between July and September in response to data found in old case files. When the review began in 2005, the caseload was estimated at 465.

The Administration for Children's Services hired Vera in response to 2004 Post articles exposing the practice in 2004. Public Advocate Betsy Gotbaum, who's called for independent oversight over ACS, says the new numbers prove her point.

Vera is preparing a report on whether proper enrolling and monitoring procedures were followed.

## **Drug Tests on Foster Kids Spark Scandal in NYC**

**Published March 10, 2004**

**FoxNews.com**

Were HIV-positive infants and children in the Manhattan foster care system (search) used as guinea pigs in medical experiments? That question is at the heart of a potential scandal that could propel child welfare systems in North America toward greater transparency and accountability.

On Feb. 29, The New York Post exposed the problem in three articles by Douglas Montero (search): The first, "AIDS Tots Used as 'Guinea Pigs,'" claimed that about 50 children had been used in 13 medical experiments, some involving high doses of AIDS medications, at Manhattan's Incarnation Children's Center (search). The Post later revised the number to 100 in the light of data released on March 1 by New York City's Administration for Children's Services, following a review of their files.

The second article, "I Took Girls Out of Hell and City Stole Them Back," was the story of Jacqueline Hoerger, a pediatric nurse and foster mother to two girls from ICC, where she had worked from 1989 to 1993. Social workers took the girls from Hoerger because she refused to administer AIDS medications that she learned were "highly toxic and mostly untested in children."

At ICC, Hoerger says she witnessed experimental treatment "on HIV-infected children, some as young as three months."

In the third piece, an op-ed entitled "Defenseless Kids' Guardian Agency Won't Come Clean," Montero posed his questions for the ACS: For example, "how many children were involved?" And, to whom could the children "call for relief if researchers prodded too hard, hurt them, made them cry or made them sick?"

In other words, what authority supervised the treatment of children who had no parent or foster parent to render consent?

The ACS assigned the children to the studies, but the agency lacks the medical expertise to evaluate whether the application of an experimental treatment is appropriate or abusive. Moreover, according to Anat Jacobson, a spokeswoman for the Public Advocate's Office that serves as a watchdog to the ACS, her agency had no knowledge of the experimental treatments.

Jacobson expressed concern that the ACS might have "just unilaterally signed up these kids."

The ACS could answer Montero's questions, but instead, it seems to be invoking privacy concerns in order to remain silent. When questions involve aggregate numbers and protocol, however, there is no privacy issue. And there are well-established methods for discussing medical studies that preserve the anonymity of subjects.

In the presence of official silence, the facts alleged gain credibility. What are they? A good place to begin is with the ICC, which is run by the Archdiocese of New York's Catholic Charities and was opened in 1989 to provide residential and outpatient medical care for HIV-infected children. The ICC has conducted dozens of experimental medical studies, most of which were funded by federal grants or — more controversially — by pharmaceutical companies.

One of the ICC's experimental studies, sponsored by the National Institutes of Health, was entitled "HIV Wasting Syndrome." Its purpose was "to see how beginning or changing anti-HIV medications affects the body composition ... of HIV-infected children."

No one could fault researchers for administering appropriate drugs to sick children and monitoring the results, especially when the children might not otherwise receive treatment. But questions immediately arise concerning studies that purportedly tested the "safety," "tolerance" and "toxicity" of AIDS drugs. Or one that tested the reaction of HIV-positive children, ages six to seven months, to the injection of two doses of measles vaccine. The ICC used to offer descriptions of such experiments on its web site, which became abruptly inoperative in the wake of the Post's investigation. Without data, how can the validity be judged?

News of the experiments is already fueling outrage. "They are torturing these kids, and it is nothing short of murder," Michael Ellner of Health Education AIDS Liaison declared of the experiments that ended in 2002.

Biochemist Dr. David Rasnick, an expert in AIDS medication, reviewed the AIDS drugs administered to the children and concluded that alone, or in combination as they often were administered, the drugs had "acute toxicity which could be fatal."

ACS must be forthcoming. Silence or bureaucratic answers aren't going to work this time. Driven by criticism by officials such as New York City Councilman Bill DiBlasio, the New York Health Department is beginning to investigate.

Moreover, the "scandal" has hit the international press. A headline in last week's Japan Today announced, "HIV-infected kids in New York used as 'guinea pigs.'" Newspapers in France and the U.K. echoed the accusation. Too many eyes are watching.

It is usually parents who look out for children — comfort their tears, shield them from abuse, and make wrenching decisions about their welfare. Who comforted and protected the parent-less, HIV-positive infants and children at ICC? I hope there were hospital staff who held each sick child in their arms and wanted nothing more than to heal the pain.

But data has disappeared. Archdiocese spokesman Joseph Zwilling reportedly told journalists that he did not know why the experiments stopped in 2002 or whether any of the children had died. Nicholas Scoppetta, who headed ACS during the experiments and has since left the agency to become New York City's current fire commissioner, will not comment.

Hopes are not enough. For once, a child welfare system must have the courage and decency to open itself to public scrutiny.

Wendy McElroy is the editor of [ifeminists.com](http://ifeminists.com) and a research fellow for The Independent Institute in Oakland, Calif. She is the author and editor of many books and articles, including the new book, "Liberty for Women: Freedom and Feminism in the 21st Century" (Ivan R. Dee/Independent Institute, 2002). She lives with her husband in Canada.

## **UK firm tried HIV drug on orphans**

**GlaxoSmithKline embroiled in scandal in which babies and children were allegedly used as 'laboratory animals'**

**Antony Barnett in New York**

**The Observer, Sunday 4 April 2004 04.35 EDT**

Orphans and babies as young as three months old have been used as guinea pigs in potentially dangerous medical experiments sponsored by pharmaceutical companies, an Observer investigation has revealed.

British drug giant GlaxoSmithKline is embroiled in the scandal. The firm sponsored experiments on the children from Incarnation Children's Centre, a New York care home that specialises in treating HIV sufferers and is run by Catholic charities.

The children had either been infected with HIV or born to HIV-positive mothers. Their parents were dead, untraceable or deemed unfit to look after them.

According to documents obtained by The Observer, Glaxo has sponsored at least four medical trials since 1995 using Hispanic and black children at Incarnation. The documents give details of all clinical trials in the US and reveal the experiments sponsored by Glaxo were designed to test the 'safety and tolerance' of Aids medications, some of which have potentially dangerous side effects. Glaxo manufactures a number of drugs designed to treat HIV, including AZT.

Normally trials on children would require parental consent but, as the infants are in care, New York's authorities hold that role.

The city health department has launched an investigation into claims that more than 100 children at Incarnation were used in 36 experiments - at least four co-sponsored by Glaxo. Some of these trials were designed to test the 'toxicity' of Aids medications. One involved giving children as young as four a high-dosage cocktail of seven drugs at one time. Another looked at the reaction in six-month-old babies to a double dose of measles vaccine.

Most experiments were funded by federal agencies like the National Institute of Allergy and Infectious Diseases. Until now Glaxo's role had not emerged.

In 1997 an experiment co-sponsored by Glaxo used children from Incarnation to 'obtain tolerance, safety and pharmacokinetic' data for Herpes drugs. In a more recent experiment, the children were used to test AZT. A third experiment sponsored by Glaxo and US drug firm Pfizer investigated the 'long-term safety' of anti-bacterial drugs on three-month-old babies.

The medical establishment has defended the trials arguing they enabled these children to obtain state-of-the-art therapy they would otherwise not have received for potentially fatal illnesses.

However, health campaigners argue there is a difference between providing the latest drugs and experimentation. They claim many of the experiments were 'phase 1 trials' - among the most risky - and that HIV tests for babies were not a reliable indicator of actual infection and therefore toxic drugs could have been given to healthy infants. HIV drugs are similar to those used in chemotherapy and can have serious side-effects.

Vera Sharav, president of the Alliance for Human Research Protection, said the children had been treated like 'laboratory animals'.

'These are some of the most vulnerable individuals in the country and there appears to be a policy of giving drug firms access to them,' she said. 'Throughout the history of medical research we have seen prisoners abused, the mentally ill abused and now poor kids in a care home.'

Sharav has urged the US Food and Drug Administration to investigate and has demanded full disclosure of all adverse effects suffered by the children, including deaths. Brooklyn Democrat councillor Bill de Blasio is also demanding that New York's Administration for Children's Services, which approved the trials, reveal who gave consent and on what grounds.

Glaxo has confirmed it provided funds for some of the experiments but denied any improper action. A spokeswoman said: 'These studies were implemented by the US Aids Clinical Trial Group, a clinical research network paid for by the National Institutes of Health. Glaxo's involvement in such studies would have been to provide study drugs or funding but we would have no interactions with the patients.'

'Generally speaking, clinical research is carefully regulated in the US and it would be the responsibility of the appropriate authorities to ensure all subjects in a clinical trial provided appropriate, informed consent to conform with all local laws and regulations regarding legal authority in the case of minors.'

The Incarnation trials were run by Columbia University Medical Centre doctors. Columbia spokeswoman Annie Bayne said there had been no clinical trials at Incarnation since 2000 and that consent for the children was provided by the Administration for Children's Services, which uses a panel of doctors and lawyers to determine whether the benefits of a trial for each child outweighs the risks. 'There are many safeguards in the system. HIV is eventually a fatal disease, but drug therapy has lengthened life significantly,' said Bayne.

A spokesman for Incarnation said: 'The purpose of the trials was to test the efficacy of HIV medication ... These trials were based on scientific evidence of their potential value in the treatment of HIV-infected children.'

**Guinea Pig Kids**  
**BBC/NDR Fernsehen**  
**UK: BBC, Germany: NDR**

Vulnerable children in some of New York's poorest districts are being forced to take part in HIV drug trials.

During a nine month investigation, the BBC has uncovered the disturbing truth about the way authorities in New York City are conducting the fight against Aids.

Regina Mousa and grandson  
Regina Mousa's grandson (left) is HIV positive and in a foster home

[Click here to download View comments about the progamme.](#)

HIV positive children - some only a few months old - are enrolled in toxic experiments without the consent of guardians or relatives.

In some cases where parents have refused to give children their medication, they have been placed in care.

The city's Administration of Children's Services (ACS) does not even require a court order to place HIV kids with foster parents or in children's homes, where they can continue to give them experimental drugs.

Reporter Jamie Doran talks to parents and guardians who fear for the lives of their loved ones, and to a child who spent years on a drugs programme that made him and his friends ill.

### Young lives

In 2002, the Incarnation Children's Center - a children's home in Harlem - was at the hub of controversy over secretive drugs trials.

Jamie speaks to a boy who spent most of his life at Incaranation. Medical records, obtained by the This World team, prove the boy had been enrolled in these trials.

"I did not want to take my medication," said the boy, "but if you want to get out of there, you have to do what they say."

He also conveys a horrifying account of what happened to the children at Incarnation who refused to obey the rules. "My friend Daniel didn't like to take his medicine and he got a tube in his stomach," he said.

## Powerless

Dr David Rasnick from the University of Berkeley who has studied the effects of HIV drugs on patients - particularly children - says these drugs are "lethal".

"The young are not completely developed yet," he says. "The immune system isn't completely mature until a person's in their teens."

So why are these children targeted? Is it simply because they cannot defend themselves?

At the beginning of this investigation, the ACS said that no child was selected for trials without a long process of decision making, but declined to comment further.

For months, the BBC tried to get information from the people responsible for the trials, but none would comment.

The companies that supply drugs for the trials are among the world's largest, including Britain's own Glaxo SmithKline (GSK).

GSK responded to BBC programme makers, saying that all trials follow stringent standards and are compliant with local laws and regulations.

Under federal rules, consent for children to take part in drug trials has to be given by their parents.

But what if that child is in the care of New York City authorities, which volunteered it for trials in the first place?

## **BBC Guinea Pig Kids Transcript**

**Transcript for the BBC documentary “Guinea Pig Kids”, for which I provided research.**

**I have provided a few comments in brackets. The rest is from the BBC transcript of the film.**

**The Narrator throughout is Amanda St John.  
This World – Guinea Pig Kids**

This script was made from audio tape ' any inaccuracies are due to voices being unclear or inaudible

Dr David Rasnick: They were just experimenting, like you had a bunch of lab rats, an unending supply. You had subjects, you had drugs and you were just experimenting, throwing things around.

Boy: [ ed. – this is “Sean” from The House that AIDS Built. He is later called “Carlos” by the film producers. Both are aliases, as per his guardian’s request]

It's just that I don't like it when I see my best friends pass away, you know.

Vera Sharav: Would they have done those experiments to their own children? I doubt it.

Speaker: We have freedom in this country and that's a wonderful thing isn't it? When you can, we have freedom of religion and freedom of speech and that's one of the cool things about being an American.

Narrator: Battery Park, in the heart of downtown New York. And a hymn to America in the last of the summer sunshine. New York is the richest city, in the richest country in the world. But just a few miles uptown live some of the poorest communities in America.

In the Bronx three grandchildren try to bring their grandmother up to date with the latest fashions. But two people are missing from this picture. Veronica Momodu recently died of AIDS.

[ ed. – This is the one piece of the film I think is flimsy. She didn't die of 'Aids', as in a long, debilitating death. She was an African immigrant. Her son had been taken from her by the state, because she did not want him in an AIDS drug trial. I was working with her to appear in the film and tell her story. She was depressed and anxious, and terribly distraught over not seeing her child.

A few weeks before filming, she passed out in her home, again, after months of stress from not being able to see her child, and not knowing where in the city he was. She was brought into the hospital passed out, after having, I was told, a seizure. I believe she was drugged heavily, and with the standard Aids drugs, because she had tested 'HIV positive'. In any case, three weeks after entering the hospital and starting the drugs, she was dead.]

Narrator: It was left to her mother, Regina, to bring up three granddaughters and a grandson, Garfield, who's HIV Positive. Veronica and Regina had wanted to have a say in the treatment Garfield received.

But instead the New York authorities insisted Garfield stay on drugs and medicines, which even the other children could see were making him ill.

Nanju [family member]: When he was drinking the medicine sometimes at night, it was in the summer time too, and he would say, 'mummy I'm cold, I'm cold' or he would itch his body all over, non-stop.

Catherine [family member]: And every time he said he was cold, my aunt would tell my uncle to put the heat up, he put up the heat a lot of times, but he kept saying he was cold.

Interviewer: Is this why your family decided to stop the medicine?

Nanju: Yeah, my aunt stopped it because he wasn't feeling comfortable.

Catherine: And he started to get well, but when she went for a check up, they gave him the medicine again without her knowing it.

Interviewer: And did he get sick again?

Catherine and Nanju: Yeah.

Regina Mousa – Grandmother\*: I don't know what type of medicine they were giving. The boy was allergic to sulphur and they give it to him and he's scratching all over his body and he lost his appetite, he don't eat and he was getting skinny and skinnier.

Narrator: Convinced that the medicines were making things worse, not better, they turned to their hospital doctor for advice. He made an unexpected offer.

Regina Mousa: My daughter told me, she said when she went to see the doctor and that time it was the child's appointment the man said he would be giving her twenty-five dollars a month if they can put the child on experimental basis.

She said 'I will think about it' and she said 'No'. Then the doctor said 'You will regret it'.

Narrator: Regina's daughter took Garfield off all medication. Almost immediately his health improved. Then there was a knock on the door.

Regina Mousa: They came to take the child and they came with police. I think it was three or four policemen.

Narrator: In New York, you don't need a court order to take a child from its parents. The Administration for Children's Services, or ACS, has exceptionally strong legal powers to decide what's best for the city's kids.

David Lansner – Family Lawyer: They're essentially out of control; I've had many ACS case workers tell me; 'we're ACS, we can do whatever we want'. And they usually get away with it.

Narrator: Garfield simply disappeared into the system; one of twenty-three thousand children placed either with foster parents or in children's homes.

This Catholic-run home, the Incarnation Children's Centre in Harlem, is where many HIV children end up if their parents or guardians refuse to medicate them.

For years it was the centre of highly controversial and secretive drug trials on orphans and foster children as young as three months old.

Jacklyn Hoerger -Paediatric Nurse: At the time it did not occur to me that anything was wrong because we were told by the doctors that these were all

steps that were going to happen, to be expected because they were all HIV-positive.

[ ed. – Jacklyn’s story was part of the initial story on ICC, “The House That AIDS Built,” in a segment called The Nurse’s Story. Hoerger has also been interviewed by Essence Magazine and the New York Post.]

Narrator: Jacklyn Hoerger is a paediatric nurse who worked at Incarnation for five years.

Jacklyn Hoerger: If they were vomiting, if they lost their ability to walk, if they were having diarrhoea, if they were dying; that all of this was because of their HIV infection and to be expected and that we were doing the best we could to save them from that.

Narrator: Jacklyn was completely unaware that she was party to experiments on children.

Jacklyn Hoerger: It didn't come as my first thought at all to question the medication and since I had worked with paediatric AIDS for many years and had given the medication, I just faithfully gave it as I was told by the doctors.

Narrator: We found documentation listing some of the experiments carried out on HIV children at the home. One was for treating herpes; another involved giving children double doses of the measles vaccine.

And yet others involved whole cocktails of drugs with side-effects admitted by the manufacturers including: severe stomach pain, muscle wastage, organ failure and many more.

Dr David Rasnick -University of Berkeley: Side-effect is a euphemism for, for undesired direct effects. The effects of the anti-HIV drugs are quite serious, in fact, in fact if you look at the insert that comes with these drugs you'll see virtually all of them will have a black box warning label which is the highest, most severe warning that these drugs can have and still be prescribable to human beings before they're taken off the market. They're lethal.

Narrator: Three thousand miles west of Manhattan, Dr David Rasnick is internationally renowned for his work on numerous diseases, including cancer.

Dr David Rasnick: I'll scroll that up a little so you can see the years and everything. And it's Aids cases, deaths and'

Narrator: He's studied the effects of HIV drugs on patients, particularly children.

Dr David Rasnick: The young are not completely developed yet; the immune system isn't completely mature until a person's in their teens, typically.

Narrator: We asked for his opinion on some of the Incarnation trials.

Dr David Rasnick: We're talking about serious, serious side-effects. Didanosine, all by itself is, is a very dangerous drug. Zidovudine is our famous AZT, which has never been shown to be life saving, it also causes severe anaemia. Nevirapine is the drug that also causes that Stephen Johnson Syndrome, the flaking of the skin and it's very, very dangerous and debilitating, it's horrible and painful and also lethal.

These children are going to be miserable; they're absolutely going to be miserable. They're going to resist taking them after a while, they're going to probably take them when people give it to them, they're going to suffer so much AZT by itself that they're going to have cramps, they're going to have diarrhoea, they're not going to want to eat, they're joints are going to swell up, they're going to roll around on the ground, you can't touch them.

And I understand that the Incarnation Centre, they sent them to the hospitals, these children and they cut a hole in their belly and put a feeding tube in their belly and administer the drugs to the children who don't take these drugs.

Boy: My friend, Jolice, she never, never ever liked to take her medicine. So they used to hold her down and force it down her throat. I tell her'

Narrator: This boy spent most of his life at Incarnation. Aged fifteen, after years on drug tests, he has the physique of a ten year-old.

Narrator: He didn't want to show his face. But he did want to tell the story of what happened to him in the home.

Boy: I did not want to take the medications and I did not want to, you know, do all that stuff.

Interviewer: But they insisted?

Boy: Yeah, if you want to get out of there you have to do what they say or else you're not going anywhere.

Narrator: His medical records, which we've obtained, prove that he was enrolled in drug trials while living at Incarnation. If a child refused to take the medicine, a peg-tube was inserted directly into the stomach; something he warned his friends about.

Boy: And I used to tell her every single day, 'please take your medicine; you don't want a tube in your stomach'. But she didn't listen to me. That's what she got. And my friend Daniel, he didn't like to take his medicine either and he got a tube in his stomach.

Narrator: Under Federal rules consent for children to take part in drug trials has to be given by their parent or guardian. But the kids at Incarnation have no independent voice. The body that is their legal guardian, the ACS, is the same body that makes the children available for trials.

Vera Sharav – Alliance for Human Research Protection: You would not expect too many parents to volunteer their loved children for such experiments. This means that if the researchers want to do the experiment on children, they are going to look for vulnerable children whom they can get. And when you have a city government agency accommodating them; that is the biggest betrayal of those children. They don't have anyone but the city agency that is their guardian on paper but not in human ways.

Narrator: For over ten years, Vera Sharav has battled almost single-handedly with the New York authorities to come clean over the use of children in drug trials.

Vera Sharav: They tested these very highly experimental drugs, Phase One and Phase Two, why didn't they provide the children with the current best treatment; that's the question that we have. Why did they expose them to risk and pain when they were helpless? Would they have done those experiments to their own children? I doubt it.

Narrator: When we spoke to the ACS early in our investigation, they told us that no child was selected for trials without a long process of decision-making.

Vera Sharav: I would absolutely reject the idea that they go through a process. Yes, they go through a process, but it is in, in, on paper only. For example, the city department created a panel, an ethics committee that approved the experiments that were conducted at Incarnation House. There's only one little pesky detail; the panellists all come from hospitals that conduct the trials, so they all are stakeholders in saying that it was perfectly all right.

Narrator: Most of the children in the trials are from New York's poorest districts. Many were born to drug addicted mothers. Over ninety-eight percent of children in foster care in the City are black or Latino.

Narrator: It's a very different story if you're white, middle class and live outside New York City.

Christine Maggiore has been HIV positive for fourteen years and as an adult chose to decline all drugs offered; she's never been sick.

Narrator: She lives in Los Angeles and when her children were born, she refused even to have them tested as she'd no intention of putting them on medication.

Christine Maggiore – Mother: The drugs are very powerful, they're known to be toxic, they can cause everything from liver failure to sudden death, heart attacks, strokes, paralysis, diabetes, pancreatitis. They're, they're devastating and the only reason to take them is the belief that one will die without them. That is something I don't believe.

Narrator: Christine may not believe, but the authorities do. She received a phone call from the Los Angeles Welfare Services threatening to take her children away.

Christine Maggiore: It was the most horrible event of my life, to think that someone who didn't know me, who had no idea of how much I love my children, how I labour over every decision from what they eat to where they got to school and I work so hard to provide them with the best care so they grow into loving, healthy, responsible individuals, that with one phone call they could actually put me at risk of losing my family.

[at restuarant] I would like to order a salad'

Narrator: The difference for Christine was that she could afford lawyers and that the authorities in LA were prepared to listen to what they had to say.

Interviewer: How did you fight it?

Christine Maggiore: Attorneys and excellent medical records. My children see two separate private practice paediatricians, they always have. We take them even though they've never been ill. My children are so gloriously healthy they've never had any of the typical childhood problems from ear infections to respiratory infections, nothing. And so we have excellent medical records and I work with a big team of lawyers and I just prepare myself.

Narrator: Christine fought and won. You can do that in Los Angeles.

[ ed. – Christine Maggiore's daughter Elisa Jane, died in 2005, within a day (but more like hours) of taking an antibiotic for an ear infection. While this looks like antibiotic-induced toxic shock (which is a well-known and overly-common event), this created great controversy, and Maggiore was accused by AIDS activists, essentially, of murdering her child, for not putting the girl on AZT, and other AIDS drugs at or prior to birth.

Prior to these events, however, Maggiore had been accused of faking that she was HIV positive, notably by Jeanne Bergman in a NY Press editorial, in which Bergman also claimed that Maggiore's children were fine because Maggiore had never really been HIV positive. "Maggiore has built a profitable career by combining a gift for self-promotion with a couple of false-positive HIV test results." Wrote Bergman. She later changed her mind, and said that Maggiore's daughter, in fact, "died of AIDS."

In any case, it's a horrible, painful and truly tragic event. I wrote about it here. ]

Narrator: But in New York City, where the ACS was given special powers by former Mayor Rudi Giuliani, even professionals realise they are fighting a losing battle.

Jacklyn Hoerger, the nurse who had once administered the drugs to children at Incarnation, was about to discover just how difficult it really was. She'd decided to add to her existing family by adopting two young girls she'd grown to love at the home.

Jacklyn Hoerger: They were half-sisters and the younger of the two was pretty much immobile; didn't know how to walk, didn't know how to play, didn't speak much, didn't know how to show her emotions or feeling whatsoever. And her sister was the opposite; she was hyperactive, couldn't sit for a minute, couldn't be still for a minute and wouldn't eat and the younger of the two overate. So it was a complete mess.

I gave them all that I could, on every level. I gave them the good quality food, the rest, the best private schooling they could get, occupational therapy, physical therapy, speech therapy, tutoring. The best psychologists I could find on all levels and I just didn't seem to be making any headway. And the only thing that was left was the medication that I had been giving them.

Narrator: Jacklyn decided to take the children off the drug regime which Incarnation had insisted upon. The results were almost instantaneous. The older girl began eating properly for the first time.

Jacklyn Hoerger: She would ask for seconds and thirds and it started showing on her body. When we swam at a swim club that we go to she had a swimsuit on about a month or two after I took her off the medication, I just looked at her with those loving mother eyes, just seeing a daughter look beautiful, rounded out, muscular, strong and healthy. It was a wonderful sight.

The younger daughter, I would say, the main change after I took her off the medication, it felt that her nerves became more and more healthy and I taught her how to walk, run, jump on the trampoline, play, ride the bicycle, swim and it was a joy to watch her.

Dirk Hoerger [husband]: I remember the first Christmas when they all got new hats and they sat in the corner all three of them together next to the Christmas Tree in their new hats surrounded with their presents and Ilene had this little shy smile, Olivia beaming from ear to ear and Leah sitting over them.

Daughter [Jacklyn and Dirk's daughter]: And on Christmas morning, I woke and there was the faintest red on the horizon and so I turned on the light and we all got up and we opened our presents, you know, our stockings, and we started yelling out the window; 'thank you Santa Claus!'. And then Mommy came stomping, stomping down the stairs; 'how dare you guys, it's only one o'clock in the morning!'.

Narrator: Not long after those Christmas celebrations, there was a visit; from the ACS.

Jacklyn Hoerger: It was a Saturday morning and they had come a few times unannounced so when I saw them at the door, I invited them in and they said this is not a happy visit and at that point they told me that they were taking the children away. I was in shock; I couldn't believe it and we were, it was a home day and they were in their pyjamas and'

Narrator: The social worker involved in the case was Demetrius Travis. He was on holiday when a temporary case worker arrived at their door with the ACS.

Demetrius Travis – Social Worker: The family did not agree with the drugs that were being given to these children who had HIV and as a result of the parents not agreeing with the, the medicinal, I guess, regimen that was being administered to the children when it was learned that that regimen was not being followed the children were taken back into foster care.

Interviewer: Did that decision upset you?

Demetrius Travis: It bothered me yeah, because I can remember how well off these children seemed to be and, and that just wasn't, that wasn't just my opinion that was the opinion of this mental health professional who had dealt with these children over a period of, I would say, a year and a half, two years.

Narrator: As a result, Jacklyn was taken to court and convicted of child abuse.

Interviewer: Where are they now?

Jacklyn Hoerger: I don't know. I'm not allowed to know.

Narrator: Jacklyn's greatest fear is they've been returned to Incarnation Children's Centre or a similar home in New York where they might be subjected to experimentation.

Bill Perkins – New York City Council: Well it is shocking that in New York City, experimental drug treatments are being used on children who are in foster care.

Narrator: Even senior politicians in the city have found it impossible to get information about the trials. Bill Perkins is Deputy Majority Leader on New York City Council.

Bill Perkins: We do know that several have passed away during the course of these experiments and we know that there are still some involved and there's been somewhat of a secrecy about the whole matter, I must say. It has not been easy to get through the bureaucracy as to exactly what this is all about.

Narrator: In a mass grave owned by the Roman Catholic Church close to Manhattan, over a thousand children's bodies, including some who were enrolled in the trials, lie beneath a tarpaulin. Officially their deaths are recorded only as resulting from 'natural causes'.

For months, we tried to get answers from those behind the trials – from Columbia Presbyterian Hospital, where many of the tests were devised. From Incarnation Children's Centre. From the Catholic Church. And from the ACS; the authority ultimately responsible. None would comment.

The drug companies which have supported trials at Incarnation include some of the world's largest. Among them Britain's own Glaxo Smith Kline.

They also refused to be interviewed for this programme saying only that all trials have stringent standards and are in compliance with local laws and regulations.

In Washington, officials at the National Institutes for Health insist that any participation of children in drug trials should be voluntary in every sense.

Lauren Wood – National Institutes of Health: We let parents know that participation is always voluntary; that they can stop participating in a trial at any time. Many parents need to have that reinforced, that participation is voluntary. We also get the assent of the child, when it's appropriate.

Narrator: But what if that child is in the care of New York City authorities which have volunteered it for the trials in the first place?

David Lansner – Family Lawyer: New York Law hasn't made clear where the boundaries are between the parent's right to provide and control the treatment for the child and the ACS's right. And as a result, the parent loses out and the child loses out because ACS simply says; 'we're going to make all the decisions'.

Narrator: In two thousand and two, the trials at Incarnation were suddenly halted. Attempts to uncover why exactly meet either with silence or a call to the NYPD to have us removed.

During the making of this programme the Food and Drugs Administration announced an investigation into the trials, which we have discovered are continuing at at least six other locations in New York City.

Meanwhile, Regina Mousa from the Bronx is now in contact with her grandson, Garfield. She's won a court order granting her visitation rights.

This is her grandson's new foster home in the Bronx. The boy was hungry and Regina had brought food. Although the house was in poor condition, it was better than his previous one where the foster mother had allegedly beaten him.

Garfield's new foster mother receives six thousand dollars every month for him and three others.

What makes her a better guardian in the eyes of the authorities is that she gives the medicine demanded by the ACS and Regina refuses.

Regina Mousa: I want to get him back. I want to get him back. Because I don't want my child to remain in experimental basis. Not my own grandson. Because we love him.

Narrator: Jacklyn Hoerger has had no news of the two little girls she was adopting since that day when the ACS arrived on her doorstep.

Jacklyn Hoerger: We weren't given any rights whatsoever. I even wrote a letter to the social worker appealing to her humanity, to just let us know something. But I don't know anything.

Interviewer: Did you ever say to the nurses or the doctors that you felt the medicine was wrong?

Carlos: I try; I just try to be me. I don't bother anybody. People do things for, like I said, a reason; good or bad, we have to forgive them for what they do.

[bbc.co.uk/thisworld](http://bbc.co.uk/thisworld)

## Credits

Narrator  
Amanda St John

Reporter  
JAMIE DORAN

Camera  
UNE HERZER  
ANDREW SUHL

Dubbing Mixer  
NICK ROGERS

Original Research  
LIAM SCHEFF

Production Assistant  
TRACEY DORAN

Production Manager  
TOM BATTY

Original Music  
EDWARD GUERTIN

VT Editor  
STEVE GILBERT

Director  
MILENA SCHWAGER

Research  
CELIA FARBER

Assistant Editor  
JOHN MOFFAT

Picture Editor  
ROGER GUERTIN

Executive Producer  
KAREN O'CONNOR

Written & Produced by  
JAMIE DORAN

A PROBE tv Production for  
BBC/NDR FERNSEHEN

thisworld

Series Producer  
SANDY SMITH

BBC  
' BBC MMIV

End

## **New York's HIV experiment**

**HIV positive children and their loved ones have few rights if they choose to battle with social work authorities in New York City. Jacklyn Hoerger's job was to treat children with HIV at a New York children's home. But nobody had told her that the drugs she was administering were experimental and highly toxic.**

Jamie Doran

"We were told that if they were vomiting, if they lost their ability to walk, if they were having diarrhoea, if they were dying, then all of this was because of their HIV infection."

In fact it was the drugs that were making the children ill and the children had been enrolled on the secret trials without their relatives' or guardians' knowledge.

As Jacklyn would later discover, those who tried to take the children off the drugs risked losing them into care.

The BBC asked the Alliance for Human Research Protection about their view on the drug trials.

Spokesperson Vera Sherav said: "They tested these highly experimental drugs. Why didn't they provide the children with the current best treatment? That's the question we have.

"Why did they expose them to risk and pain, when they were helpless?

"Would they have done those experiments with their own children? I doubt it."

Power and authority

When I first heard the story of the "guinea pig kids", I instinctively refused to believe that it could be happening in any civilised country, particularly the United States, where the propensity for legal action normally ensures a high level of protection.

But that, as I was to discover, was central to the choice of location and subjects, because to be free in New York City, you need money.

Over 23,000 of the city's children are either in foster care or independent homes run mostly by religious organisations on behalf of the local authorities and almost 99% are black or hispanic.

Some of these kids come from "crack" mothers and have been infected with the HIV virus. For over a decade, this became the target group for experimentation involving cocktails of toxic drugs.

Central to this story is the city's child welfare department, the Administration for Children's Services (ACS).

The ACS, as it is known, was granted far-reaching powers in the 1990s by then-Republican Mayor Rudi Giuliani, after a particularly horrific child killing.

Within the shortest of periods, literally thousands of children were being rounded up and placed in foster care.

"They're essentially out of control," said family lawyer David Lansner. "I've had many ACS case workers tell me: 'We're ACS, we can do whatever we want' and they usually get away with it."

Having taken children into care, the ACS was now, effectively, their parent and could do just about anything it wished with them.

'Serious side-effects'

One of the homes to which HIV positive children were taken was the Incarnation Children's Center, a large, expensively refurbished red-bricked building set back from the sidewalk in a busy Harlem street.

It is owned by the Catholic church and when we attempted to talk to officials at Incarnation we were referred to an equally expensive Manhattan public relations company, which then refused to comment on activities within the home. Hardly surprising, when we already knew that highly controversial and secretive drug experiments had been conducted on orphans and foster children as young as three months old.

We asked Dr David Rasnick, visiting scholar at the University of Berkeley, for his opinion on some of the experiments.

He said: "We're talking about serious, serious side-effects. These children are going to be absolutely miserable. They're going to have cramps, diarrhoea and their joints are going to swell up. They're going to roll around the ground and you can't touch them."

He went on to describe some of the drugs - supplied by major drug manufacturers including Glaxo SmithKline - as "lethal".

When approached by the BBC, Glaxo SmithKline said such trials must have stringent standards and be conducted strictly in accordance with local regulations.

### Battle of wills

At Incarnation, if a child refused to take the medicines offered, he or she was force-fed through a peg-tube inserted into the stomach. Critics of the trials say children should have been volunteered to test drugs by their parents.

When Jacklyn Hoerger later fostered two children from the home where she used to work with a view to adopting them, she discovered just how powerful the ACS was.

"It was a Saturday morning and they had come a few times unannounced," she said. "So when I opened the door I invited them in and they said that this wasn't a happy visit. At that point they told me that they were taking the children away. I was in shock."

Jacklyn, a trained paediatric nurse, had taken the fatal step of taking the children off the drugs, which had resulted in an immediate boost to their health and happiness.

As a result she was branded a child abuser in court. She has not been allowed to see the children since.

In the film Guinea Pig Kids, we follow Jacklyn's story and that of other parents or guardians who fear for the lives of their loved ones.

We talk to a child who spent years on drugs programmes which made them and their friends ill, and we discover that Incarnation is not an isolated case.

The experiments continue to be carried out on the poor children of New York City.

## **An interview with Jamie Doran on "Democracy Now," with Amy Goodman Guinea Pig Kids: How New York City is Using Children to Test Experimental AIDS Drugs**

**Wednesday, December 22nd, 2004**

A new BBC documentary exposes how the city of New York has been forcing HIV positive children under its supervision to be used as human guinea pigs in tests for experimental AIDS drug trials.

All of the children in the program were under the legal guidance of the city's child welfare department, the Administration for Children's Services. Most live in foster care or independent homes run on behalf of the local authorities and almost all the children are believed to be African-American or Latino.

The BBC identified pharmaceutical giant GlaxoSmithKline as one of the companies that provided the experimental drugs for the tests. In an email to Democracy Now! GlaxoSmithKline stated "pharmaceutical companies are not directly involved in the recruitment, enrolment or participation of patients in such trials." GSK went on to say "the FDA encourages studies in pediatric patients. Clinical trials involving children and orphans are therefore legal and not unusual."

In the documentary, parents or guardians who refused to consent to the trials claim that children were removed by ACS and placed in foster families or children's homes. Then, acting over their objections, ACS authorized the drug trials. We called the Administration for Children's Services to respond to the allegations but they declined to join us on the program but did send us a written statement.

To talk about this story we are joined by award-winning documentary filmmaker Jamie Doran who made the film "Guinea Pig Kids." He joins us on the line from London. And here in New York we are joined by Vera Sharav of the Alliance for Human Research Protection.

AMY GOODMAN: To talk about the story, we are joined by an award-winning documentary filmmaker, Jamie Doran, who made the film Guinea Pig Kids. He joins us on the phone from London. Here in New York we're joined by Vera Sharav of the Alliance for Human Research Protection and we welcome you both to Democracy Now! Jamie Doran, let's begin with you. Tell us the story of your documentary, Guinea Pig Kids.

JAMIE DORAN: Basically, it began when someone told me about -- I was given a very rough version of the story, and I took it for granted that we were talking about some developing country or whatever -- I couldn't believe when it was New York City, and what happens was that I discovered that the ACS were -- incidentally, I'm terribly sorry they refused to appear. They also refused to appear in my film which only tells you how much they have to hide. But I discovered the ACS were basically providing children on a conveyor belt process, into children they've taken into care. Many of the children incidentally had been taken by force from their parents or guardians and put into either foster homes or children's homes in the city. One particular home we concentrate on is the Incarnation Children's Center in Harlem. And we discovered they were carrying out tests which even under federal rules are certainly illegal. You have to be clear, to use foster children in experimentation, it's prohibited unless there is a direct benefit to those children. You know, what I would have liked to have asked the ACS had they appeared today was what was the benefit of the herpes experiment at Incarnation all about? Why did they give double doses of the measles vaccine in another experiment and why won't they publish the results? This is the real question. Why won't they publish the results? The answer we can all guess at.

AMY GOODMAN: On the issue of the herpes experiment, what was it?

JAMIE DORAN: They were actually carrying experiments out on children with HIV linked to herpes, and with absolutely no clear explanation as to any benefit whatsoever it would be to the children. Why were they giving children -- the key here is that these children have no -- they have been taken from their parents or guardians, and put into the system -- effectively, their legal parent is now the ACS. And it's the ACS that then volunteers them for this program of experimentation, and this is absolutely shocking.

AMY GOODMAN: Tell us about Jacqueline Herger.

JAMIE DORAN: Jacqueline had actually worked at the home -- for the Incarnation -- for about five years. She simply, you know, loyally carried out giving the drugs to kids, et cetera, never questioned the doctors. The only time she ever questioned it was when she decided to adopt two kids she had grown to love at the home, and she was told she had to carry on the medication that had been insisted upon by Incarnation. She saw them getting more and more sick, more ill, and decided one day simply to take them off the medication. Of course, the results were astonishing. They became healthy, they became vibrant, great little

kids. The results of that, the ACS discovered that she had taken them off the medication, and there was a knock on the door, and the next thing she knew, the children were taken away. Now this despite the fact she brought in private doctors, given them private health care, she'd given them fantastic education. They were taken away, and either put into some foster care home or some children's home. She doesn't know. They won't tell her, and lord knows her biggest fear is that they have been put back on experimentation.

AMY GOODMAN: In your piece, you talk about how her job was to treat the kids with HIV at a New York children's home. Nobody had told her the drugs she was administering were experimental or highly toxic. And you quote her saying, "We were told that if they were vomiting, if they lost their ability to walk, if they were having diarrhea, if they were dying, then all of this was because of their HIV infection."

JAMIE DORAN: Yes.

AMY GOODMAN: In fact, it was the drugs, you write, that were making the children ill, and the children had been enrolled in the secret trials without their relatives' or guardians' knowledge.

JAMIE DORAN: There are enormously serious side effects from these drugs. You should also be clear that we're talking about up to 20 drugs in a single cocktail given to individual children. We're talking about drugs like didanosine, which is a very toxic drug; zidovudine, which is the famous azt which can cause severe anemia; nevirapine, that's the drug that's been known to cause Steven Johnson's Syndrome, which is an enormously painful flaking of the skin. I mean, I've seen pictures myself, and it's as if a young child has just been pulled from a terrible fire. And they're giving these cocktails of drugs to these kids, and when a researcher pushes too far, who do these kids turn to? They don't have any parents. Their parent is the ACS. This is the horrific side of it all. They have -- they're totally and utterly vulnerable.

AMY GOODMAN: We're also joined by Vera Sharav, who has been looking at the whole issue of trials and issues of consent. Now, some might say that these drugs may make people very sick, but ultimately, they'll make them better. What is your response?

VERA SHARAV: That's the hope, of course, but these children are not consenting adults. They cannot evaluate the risks and benefits, and whether they have

something to gain for them. They require a personal advocate. Because they have no parents, it makes them doubly vulnerable. The federal law or regulations, really, mandate that children in foster care may only be used in experiments involving greater than minimal risk, only if there is a direct benefit to them, or if the study examines their situation as foster care children. Now, these were drug trials. These had nothing to do with being in foster care. The trials were phase one and phase two. That means they are highly experimental safety studies. They're examining the safety of the drugs in children, often testing them in children for the first time. Our question, and we filed a complaint both with the FDA and with the federal office of human research protection. Those two investigations are ongoing. Our question was, why did these children not receive the best standard care that was available at the time? That is their right. They should not because they're vulnerable, because they're wards of the state be simply taken and used as a means to an end. The end being, as you said, potentially, perhaps, possibly improved treatment. That -- the skip and jump between a clinical trial and clinical care -- there is a huge gap there because the unknown is there. Secondly, many of these drugs, and we have, you know, the adverse effects are as Jamie said, quite horrendous.

AMY GOODMAN: I'm sorry ACS wouldn't join us. We even asked them if they would join separately from Jamie Doran and they said no. But they sent a statement that said the single case used to build the story was described in a way that was blatantly inaccurate. They're talking about your BBC documentary, Jamie, Guinea Pig Kids. They say part of a foster parent's job is to ensure child safety including routine medical checks as well as following doctor-prescribed medication and treatment. Should a foster parent fail to live up to these responsibilities, we have to intervene. If we find that the foster parents are endangering the child's health or not meeting the child's needs, removal of the child from his or her home may be necessary and appropriate for the best interests of the child. Jamie Doran.

JAMIE DORAN: I have heard this claim. I'm wondering if the ACS have actually watched the film. They keep referring to this single case. There are three, clear, specific cases in that film. I also spoke to numerous children and guardians, most of whom were too frightened to appear on the program. If you want your kids back out of foster care or one of these children's homes, the last thing you do in New York City is take on the ACS. But I think they should be aware, the BBC film was actually the shop version, the 28-minute version of my film. Okay. I hope the ACS is looking forward to seeing the longer version, of which there are more cases, additional to that. I have statements written and verbal statements,

recorded statements from other children and parents. So, they're not going to get away with that.

## **Guinea Pig Kids** **by Celia Farber**

The fanatic fringe of what was once the AIDS “establishment,” and is now a Trotskyite splinter group that even the AIDS lobby fears, have launched one of their frightfully grave missives, demanding repentance for crimes of moral defect —this time against none other than the BBC. Given that the BBC has just aired a four part investigative report exposing the pharmaceutical industry’s fraudulent and perhaps criminal conduct in the sordid story of Paxil and suicide in children, and that the first of those four reports elicited more than 65,000 reader emails, it is unlikely that the BBC will roll over and start erasing Pharma-critical films from its archives at the present moment. Undoubtedly, they have been inundated with similar crow-screeching over Paxil—how it saved countless lives of children who would have otherwise killed themselves etc etc.

I worked as a researcher on the Jamie Doran/Milena Schwager film “Guinea Pig Kids,” for over four months in 2004, and what I found is detailed in the article below. I can attest categorically that among the many lies in the inquisitor generals' letter is the charge that the makers of the film are “AIDS denialists.” Doran made it very clear to me on many occasions that he had no stake in whether HIV was pathogenic—that the film as he saw it cut to the heart of essential human rights of both the children and their parents and/or guardians. Most people who have seen the film are devastated by it in ways that have no bearing on their views about HIV’s pathogenicity.

None, except possibly the seven signatories of that letter, could be proud of a medical ethos in which children are sedated and have feeding tubes for drugs operated into their stomachs. This is what Charles Ortleb refers to as the “abnormal science” culture of HIV/AIDS. In the wake of the global outcry against the forced feeding by tubes and pipes of geese, everybody from Sir Roger Moore, a.k.a. James Bond to Pope Benedict XVI denounced the practice as being, in the words of the latter, “in violation of Biblical principles.” But as you will see as the details of this deep and labyrinthine story begin (only now) to truly unfurl, forced feeding was only one part of the debasement of human life that transpired at reincarnation hell house.

The first and most elemental matter that I address, is the claim made by Jeanne Bergman (the lead signatory of the letter) and others that “no children died,” during the course of the experiments. The information I have received is that the

ICC children themselves told Scheff and Schwager that seven of their friends had died on the drugs. It took me about six months to obtain death certificates for the only two children whose names I had. A characteristic of ARV zealots that you will see very clearly in the BBC complaint letter is a refusal to deal in hard facts or figures. It is always viscous claims about widely known truths a slight distance ahead on the road. Then they make people feel ashamed for wondering what people would naturally wonder, namely, not how safe the drugs are in theory but rather, a simple and singular question: How many of these kids did in fact die?

They don't know. Why? There was a "warehouse fire" in which all the children's medical records were destroyed.

The following was originally published by RedFlagsDaily.org in 2004

### The Continuing Heartbreak of our Human Experimentation Culture

I have in front of me two certificates of death. Both were children. Both died in the autumn of 2004, while partaking in what some call a clinical trial, and others call a medical experiment, under the auspices of a well-funded "nursing facility" in Harlem for HIV-positive orphans called Incarnation Children's Center (ICC). According to the AIDS orthodoxy, these children died of AIDS. There is no reason to believe anybody wanted them to die, least of all those who knew them and cared for them. But serious questions remain unanswered about these and other deaths that have occurred in the course of ongoing clinical trials involving foster children in the United States.

About two years ago, freelance journalist Liam Scheff went undercover as a party-line AIDS journalist "visiting" ICC and broke the story about children being forcibly treated with powerful AIDS drugs, experimental AIDS vaccines and other drugs, as part of a vast network of pediatric "trials" that used foster kids who had been signed on by the ACS (Administration for Children's Services).

Some children in the trials were as young as three months old. Those who refused, or tried to refuse, the medications had gastronomy tubes inserted into their abdomens, which dispensed the drugs straight into their digestive tracts. When I first heard this, I thought it had to be an isolated and bizarre departure from common practice — some kind of freak occurrence at a primitive facility. But soon I learned that this is a new draconian development in the treatment of pediatric "AIDS" — code for mere HIV antibodies, which do not signal either true "infection" with HIV, nor inevitable progression to AIDS.

A 2004 paper in the journal *Pediatric*, titled *Gastronomy Tube Insertion for Improvement of Adherence to Highly Active Antiretroviral Therapy in Pediatric Patients with Human Immunodeficiency Virus*, describes 17 children who had tubes inserted after they refused drugs. "Reasons for non-adherence," the paper states, "include refusal, drug tolerability and adverse reactions."

The paper includes a picture of a child in a diaper with what looks like the plastic twist-cap from a gallon of juice protruding from under his ribcage. The authors found that after the tube insertions, for which eight children required general anesthesia, "adherence" to the drug regimens was 100 percent.

AIDS professionals love acronyms. Everything that happens in their world gets an acronym, which has the effect of making it sound routine, clinical and rational. Gastronomy tubes for children and babies are now simply "GT."

"GT placement," the authors wrote, "allowed for the use of more potent antiretroviral drugs, e.g., Ritonavir, which are often unpalatable and difficult to administer to younger children." They also found that there were no significant differences in virologic response (viral load and CD4 counts), but gave no other clues about how the children had fared, healthwise, after a year of follow-up. All they were really looking at was whether "adherence" had been improved, which one would expect from feeding drugs straight into children's stomachs through a device they cannot remove.

Jeanne Bergman, a "human rights and AIDS activist" who has recently devoted her time to "beating back the HIV denialists" (those who question HIV's pathogenicity and raise alarm about AIDS drug toxicities) through "grassroots activism," is also a writer and editor for the AIDS journal of *Housing Works*, one of the most well-funded of all AIDS organizations. Bergman documented her enthusiasm for the pediatric trials in a widely circulated piece from *Housing Works Update* published in late May of 2005, and again in late June in *New York Press*. In the former, Bergman's title was "Denial=Death: Defend Incarnation Children's Center and Access to HIV Treatment," and in it she called what ACS did, "really wonderful. It put kids with HIV/AIDS who had no other home into a cozy, first-rate specialized care facility, where they had access to state-of-the-art combination anti-viral therapy under the expert supervision of a brilliant and compassionate staff. That's not a scandal to be investigated; it's an incredible accomplishment to be celebrated."

Bergman went on with characteristic AIDS authoritarianism: "Should children of three, six, or even 12 years get to decide if they will or will not take their medicine? Of course not, particularly when irregular dosing may result in multiply drug-resistant HIV. All responsible parents and caregivers understand that children can't make crucial life and death decisions for themselves, and the law recognizes this fact, too, such that children can neither give nor withhold medical consent. Columbia University ran the clinical trials the only way the kids could get the drugs that kept them alive."

Bergman seems to have lost the capacity to differentiate between "life and death." The now global outcry over these experiments begins with the indisputable fact that several of the children died during the experiments. She even has the ruthless, indeed racist, audacity to refer to the many African-American activist groups and state politicians who have objected to the situation as "deluded," and called the May 5 New York City Council Hearing on the matter "bizarre" and even "a spasm of misinformed grandstanding from a few City Council members."

Bergman went on record with a milder version of this patronization in 1997 in a New York Times article that bemoaned the black community's resistance to AIDS drugs in general. Throughout the article, African-Americans were depicted as conspiracy loons, yet their comments are remarkably prophetic to today's reality. One HIV-positive woman is quoted as saying, "I'm not taking anything. If its not broke, don't fix it. Everything is going OK with me."

"Who's better to be a guinea pig than us?" said another, describing quite accurately AIDS drugs as "tearing down your liver," and pointing out that long-term tests had not been done and that there seemed to be a great zeal to get blacks and Latinos to take these untested drugs. "Doctors say such attitudes are simplistic," the Times reporter wrote, adding that the New York State Health Department "now funnels \$25 million annually to minority community organizations" in an effort to "combat the distrust."

Jeanne Bergman, then a senior policy analyst at Housing Works, is cast in the article as somebody who felt the "challenge in minority neighborhoods was not just to make drugs available, but to build trust." Speaking as the voice of Caucasian Reason, she said: "I have been struck by our clients' extraordinary cynicism about the possibility that these drugs could work, and the absolute conviction that, like Tuskegee, the AIDS drugs are part of a giant conspiracy."

The patronization is staggering, and the message is clearer today than it ever has been: AIDS treatment activists will dictate all terms of what is right, wrong, objectionable or praiseworthy, and no rogue reactions will be permitted or cast as anything less than denialist fringe lunacy, even "murderous."

They will insist that AIDS is "everybody's disease," but the protest chants, the anger, the emotions - those are their exclusive domains. They alone will parcel the outrage and it will never, repeat never, be directed at AIDS drugs or the many violent, even lethal, scenarios set into motion by AIDS culture.

Robotically invoking the catechism of the HIV faith, Bergman writes: "We must fight back with the trust: HIV causes AIDS. Antiretroviral treatments save lives."

"Fighting back," is standard AIDS-speak, as is the by-now bankrupt phrase, "saving lives." You'll note that their organizations all tend to have the word "act" or "action" in them. They also love words like "information," "inform," "disinform," "awareness" and "compassion." Another favorite is "access" and the word for the evidence that HIV "causes" AIDS is of course "overwhelming."

Bergman's hysteria is directed at all sources in media and politics who have objected to the experiments - from "African-American nationalists" and the now "HIV denialist infiltrated WBAI and Pacifica radio to the "extremist right" - The Traditional Values Coalition.

Boasting of her recent NY Press attack on Scheff, myself (calling me an "HIV denialist") and even Christine Maggiore, who tipped off Scheff to the story and who Bergman calls an "HIV imposter" because Maggiore is healthy and long-term HIV-positive, Bergman elicited an excited response from an AIDS activist named George Carter, who wrote in reply to her email alert, "Hi Jeanne! Doesn't it just make ya feel CLEAN???"

This is the moment in history where mainstream AIDS activists have abdicated all credibility, all reason and, I would say, all sanity. History will record that they were not given pause even at such a point of medicinal depravity as this. They feel not even a pang of disturbance or "compassion." They have alienated themselves from all reasonable factions of society and identified themselves as fanatics - lost in the fever of their revolutionary war against what they think is HIV "infection." but what is really constellations of proteins with supernatural, unsubstantiated beliefs projected onto them.

Where does the border for their "outrage" begin? They are outraged about almost everything but not that black and Hispanic orphans in the custody of an AIDS "charity" and kept behind bars were force fed, via feeding tubes, a barrage of highly toxic AIDS drugs, experimental vaccines, and other untested drugs, as human test subjects in National Institutes of Health (NIH) sponsored clinical trials, obviating all known standards and conventions established in the wake of Nuremberg and Helsinki, which assure protection for human test subjects.

The Code of Federal Regulations prohibit the use of children who are wards of the state from being subjected to experiments involving "greater than minimal risk," and mandate that each child must have an advocate who fights for the best interests of the child. The Associated Press (AP) has reported that of 465 New York City children in the experiments, only 142 had an advocate. ACS - New York City's child welfare agency - lied about the number of children involved in the experiments; first they claimed it was only 76, but eventually admitted it was 465.

On June 16, AP reported that the government - specifically the Department of Health and Human Services Office of Human Research Protections - had concluded after an investigation that NIH and Columbia Presbyterian Hospital "acted unethically," and that "at least some AIDS drug experiments involving foster children violated federal rules designed to ensure vulnerable youths were protected from the risks of medical research."

Again, Bergman and her ilk are factually wrong - but undeterred. Children's true HIV infection status cannot be known until they are at least 18 months old, and yet infants as young as 3 months were given the drugs. It is not known how many children died during the course of the "trials" because ACS and ICC have refused to turn over the data. AP reported, "Some foster children died during the studies, but state or city agencies said they could find no records that any deaths were directly caused by experimental treatments."

This brings me back to the two certificates of death I have in front of me, which I obtained during the course of a four-month research stint last summer as a researcher on the film "Guinea Pig Kids," based on Scheff's original research. It aired on BBC and across Europe, but never in the United States.

One child was 11 at the time of death and the other was two. Each certificate is signed by a physician and states that the deaths were due entirely to "natural causes."

Having interviewed several people who work in the funeral and burial field, I learned this is the standard form that is filled out when there is no autopsy. I find it staggering that NIH and major hospitals would fail to perform autopsies on children who died in the course of multi-million-dollar clinical trials. Why does the research path go cold here? Why is there no information about what exactly killed these kids? How many entered the trials, and how many died?

Objectors and politicians at City Council, in activist groups and elsewhere are asking for the records. The indefatigable Vera Hassner Sharav of AHRP (The Alliance for Human Research Protection) in New York has fought tirelessly and thus far in vain for information about the lost records. As long as those records do not surface, people like Jeanne Bergman can continue to insist that the trials and the drugs only "saved" children's lives, as opposed to ending them.

I spent last summer trying to get answers and, like all others, ran into a labyrinth of silence. No answers, no communication, no accountability.

We knew that ICC buries its dead children at a Catholic mass grave in Hawthorne, New York, called Gates of Heaven Cemetery, so I was sent up there.

The grave is a large hole in the ground covered by Astroturf. It is not known how the children are buried, but it is certain that they are not embalmed and that their bodies cannot be exhumed. (The cemetery's director told me this.) Around the mass grave are six large tombstones in a semi-circle with the names of about 1,000 children engraved along with their dates of birth and death. These are not only ICC children - by far - but mostly indigent Catholic babies, children and even fetuses, whose parents could not afford a proper burial. I stood on that burial plot and wrote down the name of every last child, which took almost four hours.

I took that list and narrowed it down to the years the ICC experiments were taking place. Then I took those names to the Department of Health's birth/death archives and searched for matches. My colleague on the project, Milena Schwager, had been given some names of children who were rumored to have died during the experiments from foster parents inside ICC.

We ended up with the names of a handful of kids who had died at ICC and I set about trying to find out what their cause of death was listed as. This is where the trail went cold; unless an immediate blood relative demands an autopsy, none is done in situations like this and the cause of death is simply listed as "natural."

For two of the kids, I managed to get a friend of a friend who is a funeral director to send for their death certificates, and he told me in advance to expect them to say "natural causes." The system is designed that way, he said, so that the paperwork moves quickly and the burial happens fast.

These children were disposed of as though they were garbage. One father of a dead ICC child was in prison when the boy died. He searched high and low for any information about what had happened to the boy or where he was buried. ICC told him that they were very sorry, but all the medical records had been "destroyed in a warehouse fire" in New Jersey.

How all this makes AIDS activists feel "clean" is a mystery.

Can we say for sure that these children died of the known and potentially lethal toxicities of anti-HIV drugs? No. But the reason we can't know that, or say that, is that it has been arranged that all data reach a vanishing point at death. Why is that? The NIH puts about \$10 billion per year into HIV research. Why are we all being told there is no data about these experiments, these kids - how they fared, what precisely they died of? HAART (Highly Active Antiretroviral Therapy) deaths, after all, are distinguishable from what used to be known as "AIDS" deaths, and if we knew what symptoms the children had, we would know if the drugs killed them.

During the course of the documentary, I was contacted by a nurse who worked at a summer camp where her sole job was to administer the drugs to the ICC kids. She was instructed to make sure they got the drugs - no matter what, and this was in fact, her entire job for the duration of the kids' stay. She told of children screaming, running, scaling walls, charming and cajoling - anything to be spared the drugs. She repeated the testimony of so many who have seen these kids both on the drugs and off them; when they are on the drugs they are as good as dead - listless, vomiting, unable to walk - and as soon as they go off them (in the words of one former ICC nurse, Jacqueline Hoerger, who testified at the May 5 City Council Hearings on this matter, which Bergman called "misinformed grandstanding"), "they become children again, right away." Hoerger had her two foster daughters seized on a Saturday morning, while they were still in their pajamas, because authorities learned that she had taken them off the drugs. They became healthy right away when she did so, but she still lost all rights. To this day she does not know what happened to the two girls she loved, cared for and wanted to adopt.

The nurse who came forward (anonymously) said that all the ICC kids spent the entire 10-day camp stay in the infirmary, lying in beds, lifeless. There was one little boy from West Africa who was clever, charming and determined enough to wear her down, and she eventually allowed him to miss a few doses. She said she had been told the drugs were in the best interests of the kids but she decided to speak out because she knew "something was wrong."

The City Council Hearing on May 5 in New York was packed and the air was electric. It felt like an historic event. ACS Commissioner John Mattingly started out fairly arrogant but quickly became deferential when the rage in the largely black crowd in the room became almost tangible. He had made the mistake of calling those who were furious about the trials "fringe groups" and was put in his place, as though by the swipe of a mighty lion paw, by Councilman Bill Perkins who said in a low, rich voice: "An apology is in order, I believe, for your use of this phrase 'fringe groups.' To use that phrase diminishes the substance of what we are talking about. There is nothing of greater concern to communities of color than what we are talking about here today. This has grave racial and historical connotations, and you, sir, have opened a real can of worms."

The audience roared. After that Mattingly was meek and contrite, vowing to "find out what happened to these children. Every one of them."

Is that so much to ask? Why is everything in HIV research simultaneously so ultra-funded, so high tech, and yet so trapped in factual viscosity that prohibits ever getting simple, clear, hard data?

Public Advocate Dr. Betsy Gotbaum, who had written letters to ACS and ICC inquiring about details of the trials and the children in them, all of which were unanswered, said: "This is so outrageous. It is literally unbelievable."

The meeting went on for about five hours, concluding with three-minute testimonies from dozens of people, including parents whose children had been taken into custody by ACS for little or no reason then swept into the medical experiments.

The film "Guinea Pig Kids" was shown - depicting a world that looked more like apartheid era South Africa than post Civil Rights America. Many people cried openly. The black community - represented by several groups that Bergman dismissed as "denialist" and "grandstanding," including the Dec. 12th Movement

and Parents in Action - made it very clear that this "issue" is to them, "bigger, even, than police brutality," and likened it to the Tuskegee syphilis experiments.

A final note: Every Saturday there are protests outside ICC. A couple of months ago, I attended one. Several times, cars pulled up and staff members brought ICC kids from the vehicles into the building. Not one of them could walk. They were all vegetables. Several were in wheelchairs; others had to be carried. This is not what HIV "infection" looks like - in children or young adults. The "denialists" collect stories and footage of children whose parents have successfully fought off the enforcement of drugs, and those kids are happy and healthy as a rule. Case in point: remember those Romanian "AIDS babies" who got HIV through blood transfusions in the mid-1980s? An article in The New York Times reported they've now become young adults, and (gasp) sexually active. Remember Romanian born Lindsay Nagel, whose adoptive parents were accused of murder for taking her off AZT? She is now a healthy teenager. These are the stories that rarely get told.

The natural history of HIV in children is virtually impossible to decipher because of the way the system is designed. It is extremely difficult for any parent or guardian to fight for the legal right to keep custody of their kids and keep them off the drugs. Those who aren't giving their kids the drugs usually have to pretend they are, to keep their kids from being taken away. This is the brutal reality and the horrific choice parents are faced with: keep your children with you and poison them or give them up and let the state poison them.

People like Bergman refuse to look into the now voluminous and (to borrow their favorite word) "overwhelming" evidence that HIV antibodies do not mean surefire death or even sickness. They cannot bear for this to be true because if it is true, the mistake, to use the gentlest word possible, amounts to almost incalculable and unnecessary destruction of life.

Bergman's email address reflects a macabre desperation: [HIVkills@earthlink.net](mailto:HIVkills@earthlink.net). She invites you to write to her if you want to help her beat back the "denialists." I invite her and her fellow pharma-funded AIDS professionals to come to the next City Council Hearing and do nothing except listen, hear, look into eyes, watch faces and glean.

\*To "glean" means to gather grain left behind by reapers, or "facts in small amounts or from places widely scattered by searching here and there."

## **Foster child drug trials**

### **From SourceWatch**

Jump to: navigation, search

Foster child drug trials. In the nightmarish, surreal world of pediatric clinical trials, infants, toddlers, children and teenagers are forced to ingest dangerous, toxic pharmaceuticals. In 2004, a shocking series of expose's revealed this horrifying practice in at least seven U.S. states. The National Institutes of Health (NIH) clinical trial scandal originally broke in January of 2004. Government funded researchers were using New York city orphans in trials for combinations of highly toxic drugs. [1]

The tragedy became the basis for the British documentary "Guinea Pig Kids", which aired on November 30, 2004 on British Broadcasting Corporation (BBC).[2]

#### **Contents**

- 1 Incarnation Children's Center
- 2 Primary drugs used (antivirals)
  - 2.1 AZT (Retrovir)
  - 2.2 Nevirapine (Viramune)
  - 2.3 Nucleoside analogues & protease inhibitors
  - 2.4 Summary of side effects & inefficacy
- 3 Toxic trials
  - 3.1 Case studies
  - 3.2 Description of drug trials
- 4 HIV tests: highly inaccurate
- 5 Inside ICC
  - 5.1 Illegal non-drugging
  - 5.2 AZT children
  - 5.3 Interview with Medical Director
- 6 Complaint prompts nationwide investigation
  - 6.1 1983 federal protection for child wards
- 7 Links to NIH/ICC investigation & participating drug companies
- 8 Interviews
  - 8.1 NPR interview (audio & transcripts)
  - 8.2 Democracy Now! (video/audio & transcripts)
  - 8.3 Torsten Engelbrecht (notated transcripts)
  - 8.4 Liam Scheff (audio & transcripts)
- 9 Articles & sources

- 9.1 SourceWatch articles
- 9.2 References
- 9.3 External articles
- 9.4 External resources

## Incarnation Children's Center

In June, 2003, investigative journalist Liam Scheff got a call to investigate Incarnation Children's Center (ICC), a Catholic orphanage for HIV-positive children in New York City. He was told that "terrible things were happening there." Some of the children were orphans. Others have parents who are drug users and unable to care for them. Still others have parents and families whose parents cannot or will not enforce a heavy AIDS drug regimen. That is when city agencies bought the children to ICC, where their drug regimens are carried out without fail.

In 1992, ICC established an outpatient clinic for HIV-positive children, funded by the National Institute of Allergy and Infectious Diseases (NIAID), a division of the NIH. That year, the clinic became also became a a sub unit of the Columbia University Pediatric AIDS Clinical Trials Unit. By 1996, under the direction of Dr. Stephen Nicholas, thirty-four children were participating in seven clinical trials. Dr. Nicholas was listed as one of the "Best Doctors in New York" in New York Magazine's 1996-97 edition of The Best Doctors in America. ICC received government trial funding through 2002. After Dr. Nicholas moved to Harlem Hospital, Dr. Katherine Painter became Medical Director. According to Dr. Painter:

"Children participating in a drug trial undergo monitoring, testing, and supply of an experimental drug through their outpatient clinic, and we maintain that treatment here."<sup>[3]</sup>

### Primary drugs used (antivirals)

Drugs used to treat HIV and AIDS are various classes of toxic chemotherapies known as "antivirals" or "antiretrovirals".

ICC is a foster home administered by the Catholic Home Bureau under the Archdiocese of New York. According to its website, ICC was established in 1987 to deal with the boarder baby crisis (children abandoned at the hospital.) In 1992, ICC established an outpatient clinic for HIV-positive children, with funding from

the NIAID as well as a subunit of the Columbia's Pediatric AIDS Clinical Trials Unit. ICC went from being a home for poor children of drug-addicted mothers to a recipient of funds allowing the NIH to use foster children in drug tests. The ICC web page listed dozens of trials with AZT and Nevirapine conducted through the late 90s. The NIH site recently listed "five studies currently recruiting for drug trials", and "27 studies ongoing or recently completed"; all on ICC children. It also listed over 200 at Columbia Presbyterian, ICC's parent hospital. The studies are sponsored by NIH subdivisions and many are cosponsored by the companies which manufacture the drugs. The studies used the standard AIDS drugs: nucleoside analogues, protease inhibitors and Nevirapine.[4]

### AZT (Retrovir)

The primary drug used in trials at ICC was AZT, developed in 1964 in a cancer research lab. AZT is a chemotherapy drug used to kill the cells that make up living tissue and blood. It works by disrupting cellular replication at the genetic level. DNA is comprised of four bases that combining in pairs. The pairs line up and spiral into a double helix. AZT stops the spiral, breaks the chain and kills the cell. Considered too dangerous even for short term use, AZT was shelved and a patent was never filed. However, over 20 years later in 1986, Burroughs Wellcome (now GlaxoSmithKline) recycled AZT into an AIDS drug. Testing labs received the drug in a package bearing a skull and crossbones on a bright orange background with a "TOXIC" label and warnings against swallowing, inhaling and skin contact. Today, GSK sells AZT under the brand name "Retrovir" and as an ingredient in "Combivir" and "Trizivir." According to the warning label:

"Retrovir (AZT) has been associated with Hematologic Toxicity (blood toxicity), including Neutropenia (loss of neurophils, an essential component of blood) and Severe Anemia (potentially fatal lack of blood production). Prolonged use of Retrovir has been associated with Symptomatic Myopathy (muscle wasting), Lactic Acidosis and Severe Hepatomegaly (liver swelling) with Steatosis (fat degeneration). Fatal Cases have been reported with the use of Nucleoside Analogues (AZT, 3TC, ddl, D4T) alone or in combination, including Retrovir and other Antiretrovirals."

Worse yet, AZT doesn't even claim to work:

"Retrovir is not a cure for HIV infection ...The long-term effects of Retrovir are unknown at this time ...The long-term consequences of in utero and infant exposure to Retrovir are unknown, including the possible risk of cancer."

Drugs containing AZT as an ingredient accounted for about one billion British pounds (over 1.5 billion dollars) in GSK's 2002 sales alone. Other nucleoside analogues provided another 470 million pounds (750 million dollars) in sales. In 1986, AZT was rushed through its Food and Drug Administration (FDA) approval trials in record speed. Overseen and funded by Burroughs Wellcome (now GSK), the trials were marred by false reporting and a total breakdown of study controls. Nevertheless, the drug was released to the market. Subsequent independent AZT studies revealed the obvious deadly nature of the drug. In English, Australian, and Dutch studies, AZT patients developed severe anemia, requiring multiple blood transfusions just to stay alive. In the Dutch study, three-quarters of the AZT patients died.

AZT has been given to hundreds of thousands of gay men in the US who tested HIV-positive, whether they were sick or not. U.S. deaths attributed to AIDS increased by thousands annually after the mass introduction of AZT in 1987, from 11,000 in 1986 to nearly 50,000 in 1994, the height of AZT use. Sharp criticism of AZT began appearing in the press. Patients and physicians complained openly and cut doses or discontinued it. Subsequently, the death rate declined (prior to the introduction of protease inhibitors, which the industry likes to credit.)[5], [6]

Nevirapine (Viramune)

The other drug used at ICC was Nevirapine, marketed under the brand name "Viramune" by German based drug giant Boehringer Ingelheim. Nevirapine functions similarly to AZT in that it interferes with the essential movement of genetic information in the cell. It blocks an enzyme which translates RNA into DNA. One alarming side effect of this drug is called Steven-Johnson Syndrome, which causes the skin to literally come off of the body. In pathetic images of the unfortunate sufferers, hands, abdomens, faces, and mouths are bursting with blood and flesh comes off like old paint steamed off a wall. According to its label:

"Severe, life-threatening skin reactions, including fatal cases, have occurred in patients treated with Viramune (Nevirapine). These have included cases of Stevens-Johnson syndrome, toxic epidermal necrolysis, and hypersensitivity reactions characterized by rash, constitutional findings, and organ dysfunction.

Patients developing signs or symptoms of severe skin reactions or hypersensitivity reactions must discontinue Viramune as soon as possible."

"Severe, life-threatening and in some cases fatal hepatotoxicity (liver damage), including hepatic necrosis (liver death) and hepatic failure, has been reported in patients treated with Viramune." [7]

### Nucleoside analogues & protease inhibitors

Nucleoside analogues, like AZT, work by stopping cell division. They stop the formation of new blood in the bone marrow; in some cases causing anemia and bone marrow death. They've caused death in pregnant mothers, spontaneous abortion, birth defects, liver failure, pancreatic failure, muscle wasting, developmental damage and death in children and adults. They also may cause cancer. Protease inhibitors interfere with the body's ability to build new proteins. Since we're made of protein, they have pronounced effects on physical appearance and organ function. The side effects can be bizarre, grotesque and often fatal: wasting in the face, arms and legs; fatty humps on the back and shoulders; distended belly, heart disease, birth defects, organ failure and death.

### Summary of side effects & inefficacy

Almost all of this is found on warning labels. The first AIDS drug, AZT, was designed in the 60s as a chemotherapy drug for cancer patients, but never approved. Critics declared it too toxic even for short-term use. Yet, in 1987 it was pushed through for lifelong use in HIV-positive people. Although the trials were later revealed to be fraudulent, AZT remains on the market. Finally, there's Nevirapine, which also interferes with normal cell function. In test trials, it caused severe liver damage and death in dozens of patients. Most die from organ failure due to drug toxicity. Nevirapine can also cause a violent skin disorder called Steven-Johnsons Syndrome (SJS), a horrifying condition in which the skin blisters and ruptures or peels off in large swaths, leaving bloody, exposed flesh. Nevirapine is the main drug distributed in Africa for pregnant women who test HIV positive. In spite of serious medical issues, AIDS drugs don't even claim to work. Every AIDS drug label bears a version of this caveat:

"This drug will not cure your HIV infection. Patients receiving antiretroviral therapy may continue to experience opportunistic infections and other complications of HIV disease. Patients should be advised that the long-term effects are unknown at this time." [8]

## Toxic trials

According to ICC's published history:

"Early in the epidemic, HIV disease of childhood was considered to be a downhill course leading to death. But in the late 1980's, before AZT was available, many very ill children admitted to ICC got dramatically better with proper nurturing and high-quality medical and nursing care."

According to ICC's Medical Director, Dr. Painter, children who "can't take" or refuse the drugs have a tube surgically implanted in their abdomens through which the drugs are administered, regardless of the child's wishes.[9]

ICC is run by Columbia University's Presbyterian Hospital, in affiliation with Catholic Home Charities through the Archdiocese of New York. It is a 4-story brick former convent in the Washington Heights area of New York city. The children have been removed from homes by the Agency for Child Services. They are black, Hispanic and poor and many have mothers with histories of drug abuse who have died. Once taken into custody, they become subjects of NIAID sponsored drug trials sponsored by the NIAID and the National Institute of Child Health and Human Development (NICHD) in conjunction with some of the world's largest pharmaceutical companies. The drugs given to the children are toxic, known to cause genetic mutation, organ failure, bone marrow death, bodily deformations, brain damage and fatal skin disorders. If the children refuse the drugs, they're held down and force fed. Should they continue to resist, they're taken to Columbia University Presbyterian hospital, where a surgeon puts a plastic tube through their abdominal wall into their stomachs. The drugs are injected directly into their intestines. In 2003, two children, ages 6 and 12, had debilitating strokes due to drug toxicities. The 6-year-old went blind and they both died shortly after. Another 14 year old died later and an 8-year-old boy had two plastic surgeries to remove large, fatty, drug-induced lumps from his neck.

Children at ICC tested HIV positive or were born to were born to mothers who tested HIV positive. However, neither parents nor children were informed of the critical fact that HIV tests are extremely inaccurate.[10], [11] The HIV test cross reacts with nearly seventy common conditions, giving false positive results. They include common colds, herpes, hepatitis, tuberculosis, drug abuse, inoculations and most troublingly, current and prior pregnancy.[12], [13], [14]

Factors that cause false positives in pregnant mothers can be passed to their children, who may also be given a false diagnosis. Most people have never heard of this undoubtedly best kept secret in medicine, though it is well known to HIV researchers. Researchers don't tell the doctors. They certainly don't tell unwilling child subjects for the next generation of profitable drugs. [15]

## Case studies

When Christine Maggiore tested HIV-positive in 1992, her doctor told her to "get ready to die." She was told that AIDS drugs would make her sick, so she skipped them and used natural methods to support her health. A year and a half later, she was so healthy that her doctor told her she should retest. The tests came back negative, indeterminate and positive. After investigating medical literature, Ms. Maggiore discovered that HIV testing was highly inaccurate. She also found "gaping flaws in the HIV hypothesis itself." She later founded Alive & Well AIDS Alternatives and had two children who were never tested for HIV. They were raised on organic food and naturopathy and were healthy, intelligent, active and drug free. They regularly saw a pediatrician. They were two of the thousands of healthy HIV-positive people on natural immune system support regimens.

Mona is a great aunt and guardian raising two children, Sean and Dana, who tested HIV-positive. As her niece was unable to care for them, the children were remanded to state foster care before she took them back to raise as her own. However, when the city agencies found out that the children weren't on the drugs, they took them away for mandatory treatment at a clinic and then back to ICC. She had been taking them to a naturopath. It didn't seem to matter that the children were healthy. At ICC, they were locked up and pumped full of drugs day and night. "AZT, Nevirapine, Efavir, Zerit. All kinds of drugs."

## Description of drug trials

To read the list of drug studies conducted at ICC and sponsored by government agencies is to take a trip through the nightmare of pediatric drug research:"

"The Effect of Anti-HIV Treatment on Body Characteristics of HIV-Infected Children" is looking for the causes of "Wasting and Lipodystrophy (fat redistribution)" by using drugs known to cause wasting and lipodystrophy.

"The Safety and Effectiveness of Treating Advanced AIDS Patients between the Ages of 4 and 22 with Seven Drugs, Some at Higher than Usual Doses." The

seven drugs in the study are all known to cause debilitating, potentially fatal side effects, yet they are administered at "higher than usual doses" in four-year-olds.

"Stavudine Alone or in Combination with Didanosine." (Stavudine plus Didanosine has killed pregnant women.)

A vaccine study to be administered to children "12 months to 8 years" using "live chicken pox virus." (One consequences of a live virus vaccine can be the disease itself.)

"HIV Levels in Cerebrospinal Fluid." (Cerebrospinal fluid can only be gathered from a spinal tap, a dangerous and invasive procedure.)

A study on HIV-negative children born to HIV-infected mothers that uses an experimental HIV vaccine.[16]

HIV tests: highly inaccurate

HIV and the AIDS myth. - Black History Channel - April 2008

People take AIDS drugs because they are "HIV-positive". However, HIV tests are highly inaccurate. Most of them are antibody tests, meaning they can cross-react with normal proteins in human blood. There are nearly 70 commonly occurring conditions known to cause these tests to come up as positive. They include yeast infections, colds, flus, arthritis, hepatitis, herpes, recent inoculations, drug use and pregnancy. The remaining HIV tests, called viral load tests, can produce dozens of conflicting results, even from the same blood sample. In fact, HIV tests are so unreliable that they all bear a disclaimer, such as:

"At present there is no recognized standard for establishing the presence or absence of HIV-1 antibody in human blood."

"The AMPLICOR HIV-1 MONITOR (Viral Load) test is not intended to be used as a screening test for HIV or as a diagnostic test to confirm the presence of HIV infection."

"Do not use this kit as the sole basis of diagnosis of HIV-1 infection" [17]

Positive test results can occur due to "prior pregnancy, blood transfusions...and other potential nonspecific reactions" [18], [19]

## Inside ICC

### Illegal non-drugging

Mona's son Sean was put on AZT in infancy and has lived in a virtual coma his entire life. He was fed by a tube through his nose until he was three. The drug made him ill and lethargic. He could not play without becoming exhausted. Sean became sicker every time Mona gave him the drugs, so she cut down the doses. His energy level began to improve as she continued to wean him off the drugs and started taking him to a naturopath:

"For the first time in his life, he became a normal boy. He could play with the other children, he could walk, he could run. He smiled and laughed. He was normal."

The Administration for Children's Services (ACS) came down hard on Mona for not drugging Sean. She was sent to an "AIDS specialist" at Beth Israel. Sean was put on a "miracle drug," Nevirapine. Within six months, he was on life support due to organ failure. At this point, the ACS decided that Sean should be put into ICC for four months. The child was imprisoned there for a year before Mona hire a lawyer to get him back. According to his medical records, he had been put administered AZT, Nevirapine in the Intensive Care Unit. Then they put Dana on drugs. At 13 years old, Sean was He was 4 feet tall, weighed 50 pounds and walked with a shuffle. He was an "AZT baby". He was stunted with cells damaged from the inside out.

A nurse, Jacqueline Hoerger tried to adopt two little girls from ICC to raise and care for with her husband. She administered the drugs "by the book" for about a year, watching them get steadily sicker. After much research and consultation, she discontinued the drugs. They girls improved remarkably and she documented their improvement with her doctor. When it was revealed to the adoption agency that she wasn't drugging the girls, the New York Administration for Children's Services returned them to foster care.

### AZT children

ICC is a four story, brick, converted convent with barred windows. The children ranged in ages from a couple years old to almost adult. Except for a few Hispanic kids, the children are African American, with a number of children in wheel chairs. The wheelchair-bound kids are being fed or drugged, or both, with a milky-white fluid dispensed through tubes coming out of hanging plastic packs. The tubes disappeared beneath their shirts. Inside, children in wheelchairs stared ahead, unable to focus. One wheelchair bound child was about 12. His head was oddly shaped and his eyes were widely spaced. His limbs and torso were slightly warped, shortened and weak-looking. He was an "AZT baby". Other children had similar faces, arms and legs. Amir, boy of about 6 sat at one of the tables. He had a stomach tube. He had also undergone multiple surgeries to remove "buffalo humps", what AIDS doctors call large, fatty growths from the necks and backs of people who take protease inhibitors. Five months later, he died in a hospital.

#### Interview with Medical Director

According to Dr. Painter in October of 2003, the "biggest problem facing families with HIV-positive children is adherence." (A code word for people who don't take their medication). It does not mean illness, but obedience to a drug regimen. Even the Center for Disease Control (CDC), agrees that the majority of people with HIV aren't sick. Most AIDS patients are given the diagnosis because of a T-cell count rather than an actual illness. There are dozens of drug studies in which patients have died, specifically because of the drugs. According to the drugs own warning labels, risks include: heart attack, organ failure, wasting, bone loss, anemia, birth defects, skin loss, bloody rashes, deformation and death. [20]

#### Complaint prompts nationwide investigation

On March 10, 2004, The Alliance for Human Research Protection (AHRP) filed a complaint with the FDA and the federal Office of Human Research Protection. That complaint prompted two separate investigations by the FDA and AHRP. Articles in the New York Post and a BBC documentary raised the alarm among the African-American and Latino community in NY; some of whom had already been protesting weekly in front of ICC. The complaint prompted an Associated Press (AP) investigation into over four dozen studies being conducted in "at least seven states." In Illinois, Louisiana, Maryland, New York, North Carolina, Colorado and Texas, the investigation found that 13,878 children had been enrolled in pediatric AIDS studies funded by the government since the late 1980s. Of these, officials estimated 5 to 10% were foster children from infants to late teens. According to AHRP, "the institutional culture of arrogance is

demonstrably in evidence at both medical research centers and government agencies", as evidenced by Marilyn Castaldi, spokeswoman for Columbia Presbyterian Medical Center:

"Our position is that advocates weren't needed."

The children are reported to have suffered painful side effects, such as:

"such as rashes, vomiting and sharp drops in infection-fighting blood cells as they tested antiretroviral drugs to suppress AIDS or other medicines to treat secondary infections."

In one study testing the drug dapsone:

"at least 10 children died from a variety of causes, including four from blood poisoning, and researchers said they were unable to determine a safe, useful dosage. They said the deaths didn't appear to be 'directly attributable' to dapsone but nonetheless were 'disturbing'. ...overall mortality while receiving the study drug was significantly higher in the daily dapsone group. This finding remains unexplained."

Another study involving foster children in the 1990s treated children with different combinations of adult antiretroviral drugs. Out of 52 children, 26 had moderate to severe reactions, nearly all infants. Side effects included rash, fever and a major drop in infection fighting white blood cell counts.

At least three states declined to use children in foster care in medical experiments: Tennessee, California and Wisconsin. [21]

See also testimony of Vera Hassner Sharav, President of AHRP, at a hearing of the New York State Assembly Committee on Health and the Committee on Children and Families on September 8, 2005. [22]

1983 federal protection for child wards

Since 1983, the government has required "special protections" for child wards. Oversight boards are required to appoint independent advocates for any foster child enrolled in a narrow class of studies that involve "greater than minimal risk and lacked the promise of direct benefit." Some foster agencies require the protection regardless of risks and benefits. Advocates must be independent of

foster care and research agencies, have some understanding of medical issues and "act in the best interests of the child" for the duration of the research. However, foster children in the AIDS drug trials often weren't given advocates, after research institutions promised to do so in order to gain access to them. Illinois officials believe none of their nearly 200 foster children in AIDS studies had independent monitors. New York City records revealed that less than a third of the children involved in clinical trials (142 out of 465) had monitors required by city policy. Other facilities, including Chicago's Children's Memorial Hospital and Johns Hopkins University in Baltimore, concluded that foster children were not provided with advocates.[23]

Links to NIH/ICC investigation & participating drug companies

See also NIH/ICC investigation for links to media coverage, follow up coverage, documentation and images related to the NIH clinical trial scandal. [24]

Eight clinical trials were conducted at ICC between 1997 and 2004, all funded by NIAID and NICHD and co-sponsored by the following drug companies: GlaxoSmithKline, Pfizer, Bristol-Myers Squibb, Merck, Genentech, Biocine and MicroGeneSys. [25]

Interviews

NPR interview (audio & transcripts)

National Public Radio (NPR)'s Ed Gordon interviewed Dr. Jonathan Fishbein of the NIH and Baylor College of Medicine's Dr. Mark Kline on May 27, 2005. [26]

Democracy Now! (video/audio & transcripts)

Amy Goodman of Democracy Now! interviewed Guinea Pig Kids filmmaker Jamie Doran and Vera Sharav of the Alliance for Human Research Protection on December 22, 2004.[27]

Torsten Engelbrecht (notated transcripts)

After the NIH/ICC scandal broke, German journalist Torsten Engelbrecht requested an interview with Columbia Presbyterian. He was answered by a public relations firm. In notated transcripts, their answers were compared with

NIH documents, records from clinical trials, interview material, Medline articles and Department of Health statistics and published in July 2004. [28]

Liam Scheff (audio & transcripts)

Series of five excerpts of Liam Scheff's an October, 2003 interview with ICC's medical director Dr. Katherine Painter. [29]

**Hearing of the NYS Assembly Committee on Health and Committee on  
Children and Families  
Testimony  
by Vera Hassner Sharav, President**

**Alliance for Human Research Protection (AHRP)  
[www.ahrp.org](http://www.ahrp.org)  
September 8, 2005  
New York City**

I speak on behalf of the ALLIANCE FOR HUMAN RESEARCH PROTECTION (AHRP), the organization that filed the federal complaint about the enrollment of foster care children as experimental subjects of Phase I and II trials of AIDS drugs, vaccines, and drug/vaccine combinations. See: <http://www.ahrp.org/ahrpspeaks/HIVkids0304.php>

AHRP wholeheartedly agrees with the committees' moral position: "Children placed in the State's custody should be protected by placing the physical, mental and emotional needs of the children above all else." Indeed, the overriding issue is whether the welfare of vulnerable infants and children in foster care was sacrificed to facilitate AIDS drug research?

Phase I and II are the first two rounds of testing done on an experimental drug, which means they pose the highest level of risk without a foreseeable benefit for the children. The primary objective of Phase I and II tests is not to provide therapy to the patient-subjects. Rather,

- The objective of a Phase I test is to assess the toxicity of a drug (i.e., how poisonous is the drug).
- The objective of a Phase II test is to assess whether a drug has any impact whatsoever on the intended disease (i.e., does it do anything vis-à-vis AIDS).

To paraphrase bioethicist, Dr. Arthur Caplan: if a phase I trial proved beneficial to a human subject, it would be reported as "a miracle!" These experiments were NOT conducted to save the children's lives. The facts contradict the claims made by the NYC Administration of Children's Services and the researchers involved. At the time the children were enrolled in these high risk experiments, there was no scientific basis for anyone to claim that:

1. the drugs were safe and not dangerous to the children; or that
2. the drugs held the promise of any therapeutic value whatsoever.

The AHRP complaint led to several federal investigations - and these have validated the concerns raised.

(1) The Associated Press report, "Researchers Tested AIDS Drugs on Children" by John Solomon, May 5, 2004: <http://www.ahrp.org/infomail/05/05/04.php>;

(2) OHRP letter, May 23, 2005: ([http://www.hhs.gov/ohrp/detrm\\_lettrs/YR05/may05c.pdf](http://www.hhs.gov/ohrp/detrm_lettrs/YR05/may05c.pdf))

Children in foster care are "wards of the state." Federal law protects wards from being exploited as research guinea pigs by restricting their inclusion in research that does not offer a reasonable "prospect of direct benefit" to the child. If research involves even "a minor increase over minimal risk," federal regulations mandate the appointment of "an advocate for each child who is a ward. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way with the research, the investigator(s), or the guardian organization." [45CFR 46.409(b)]

The nature and level of risk involved in these Phase I and II experimental trials dictated that the agencies responsible for the care of these foster children - such as the City Administration for Children's Services (ACS) - were REQUIRED to provide the mandated federal protection of an independent advocate for each child.

This case demonstrates that underprivileged children of color are continually made to bear the burden of dubious medical experiments that are not expected to offer a therapeutic benefit to the children. This case serves as a lightning rod for public debate about the approval of ethically questionable pediatric research by an institutional system that operates in secret and is not held accountable.

As we discovered on the website of the National Institutes of Health (NIH) ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) Incarnation Children's Center, which was the site of 36 trials, was the only non-medical facility in the country that received federal research grants from NIH-AIDS division. The grants were for testing experimental AIDS drugs and vaccines - even on infants and children who were only "presumed" to be HIV-infected. In fact, the principle investigators have written

that "The incidence of transmission of HIV from an infected mother to her offspring is estimated to be in the range of 5%--40%. [1]

This presumption gave rise to our concern that children who might never have developed AIDS were unjustifiably exposed to lethal risks and the horrific adverse effects of highly toxic drugs for non-therapeutic purposes. As we have recently discovered, these concerns were justified.

After a year of denial by ACS, the Associated Press uncovered evidence revealing that 465 NYC foster children were subjects in these trials and less than one third (142) of those children were provided with an advocate. ACS failed to provide the minimum protections afforded by law. The AP investigation uncovered evidence that elevated the issue to national prominence: at least 48 AIDS experiments had been conducted on foster children in seven states - mostly in violation of the federal requirement of an advocate. And the AP report confirmed that children had suffered severe adverse effects, and some died.

In one study testing the drug dapsone, "at least 10 children died from a variety of causes, including four from blood poisoning," and researchers said they were unable to determine a safe, useful dosage. They said the deaths didn't appear to be "directly attributable" to dapsone but nonetheless were "disturbing." In another study testing combinations of adult antiretroviral drugs, AP reported that of the 52 children in the trial, "there were 26 moderate to severe reactions - nearly all in infants. The side effects included rash, fever and a major drop in infection-fighting white blood cells."

A Freedom of Information request by AHRP to the National Institutes of Health, for adverse event reports from the trials was rejected by claiming the information falls under "trade secrets" and "privacy" exemptions.

**THE FOLLOWING FACTS SHOW THE EXPERIMENTS ARE INDEFENSIBLE:**

First, NO HIV vaccine has ever been found to be safe or effective for human use.

Fact: Infants and children - 1 month to 18 years old - were subjected to unjustifiable risks of harm and discomfort in Phase I vaccine tests.

For example, published reports between 1998 and 2002 acknowledge that ACTG # 218 a multiple vaccine trial co-sponsored by NIH (NIAID) and the vaccine

manufacturers, Genentech, MicroGeneSys, and Chiron/Biocene. Not only did the vaccines show

"no clinical benefit to vaccine recipients" - the trial resulted in the:

"unexpected inverse association between viral diversification and [vaccine-associated immune] response." This, the researchers acknowledge, "raises the possibility that these RGP vaccines may have had a deleterious impact on antiviral effector mechanisms." [1]

There also seems to be a discrepancy between the inclusion criteria and the number of children involved. The ACTG #218 protocol states: "Patients must have: Documented asymptomatic HIV infection" and the "Expected Total Enrollment" was 72.

However, the published reports show that "HIV-Uninfected subjects" were used. According to one report: "125 immunized children proved to be HIV uninfected." [3]

Another HIV Phase I vaccine trial, ACTG #230, tested two experimental vaccines, one by Genentech, another by Chiron/Biocine. The protocol stated: "Accepts Healthy Volunteers." The subjects, who were randomized to one of three doses of either experimental HIV vaccine or placebo, were newborn infants aged 3 days or less. A published report describes the extensive biochemical response of uninfected infants to an experimental vaccine that never made it through advanced trials: "Responses to heterologous HIV antigens by treatment group (HIV-uninfected subjects only). The number given is 157. [1]

These reports validate concerns raised by AHRP about the possibility that infants and children who were not even at risk of AIDS were exposed to unjustifiable risks and discomfort in speculative, non-therapeutic drug and vaccine experiments that offered absolutely no potential benefit for them.

Second, most of the drugs that were approved for adults with AIDS and tested in these children carry Black Box warnings because of potentially lethal side effects:

\*Aldesleukin, \*\*Dapsone, Didanosine, Lamivudine, \*\*\*Nevirapine, Ritonavir, Stavudine, Zidovudine. See warnings: <http://www2.kumc.edu/druginfo/drugsafety/BLACK%20BOX.htm>

Third, those who argue that the trials were the children's only available access to "life-saving" drugs are not telling the truth.

Fact: Under state law physicians and the state had a duty to provide "life-saving" treatment to wards of the state, if need be, to provide treatment "off-label." It cannot, therefore, be argued that foster children were enrolled as test subjects to gain access to "life-saving" treatments.

Fourth, physicians who have a stake in the enterprise deliberately blur the distinction between treatment and research.

Fact: The purpose of clinical trials is to gain safety and efficacy information that may prove helpful for subsequent patients. Clinical trials are NOT designed to benefit the individual subjects. Furthermore, not all subjects get the "most promising" drug in a trial, some get placebos.

Fifth, federal regulations restrict the inclusion of children who are wards of the state in greater than minimal risk research - so that their vulnerability will not be exploited by those who seek human subjects.

Sixth, Those who argue that research presents an acceptable means for disadvantaged populations to obtain essential treatment, are trying to legitimize an immoral quid pro quo that collides with fundamental ethical principles of research which are enshrined in the Nuremberg Code: "The voluntary consent of the human subject is absolutely essential·the person should be so situated as to be able to exercise free power of choice·without any element of force·or coercion."

Seventh, contrary to the assertions made by the physicians and institutions involved, the experimental phase I and II AIDS drug and vaccine trials tested on foster children, did NOT offer the children a benefit justifying the risks - as is required under federal regulations.

Indeed, the evidence reveals that many (if not, most) of the experimental drugs and vaccines tested on foster children presented an UNFAVORABLE risk/ benefit ratio.

That means the trials were not in the children's best interest: they should, therefore, not have been approved. Indeed, the significant unfavorable risk / benefit ratio in these phase I and II trials should have precluded the inclusion of

ANY children in the trials. The full extent of harm resulting from the unlawful enrollment of children in these exploratory medical experiments is not yet fully known.

Finally, the physicians and institutions who failed to provide children with an advocate had a financial stake in the trials - they received federal and pharmaceutical company grants. Inasmuch as they sought to secure subjects for clinical trials in which the risk/ benefit ratio for the children was UNFAVORABLE, their failure to provide foster children with an independent advocate may have been motivated to protect their self-interest. An independent advocate would be duty-bound to say, NO, to such experiments.

In January, 2004, "The House that AIDS Built," by Liam Scheff, ignited the controversy on the internet. A recent follow up report by Liam Scheff, "Inside Incarnation," was published by New York Press Volume 18, Issue 30, July 29, 2005. See complete article: <http://www.nypress.com/18/30/news&columns/liamscheff.cfm>

Incarnation Children's Center acknowledges on its website:

"before AZT was available, many very ill children admitted to ICC got dramatically better with proper nurturing and high quality medical and nursing care."

How then, can anyone justify exposing non-symptomatic, "presumed" HIV infected infants to the horrific side effects and risks of experimental AIDS drugs?

An investigation must address the following:

How many children who were not ill - non-symptomatic - and how many infants, who were not HIV-infected, were used like guinea pigs - to test AIDS drug and vaccines? How many died? How many suffered severe adverse effects?

References:

1. Borkowsky W; Wara D, et al. "Lymphoproliferative responses to recombinant HIV-1 envelope antigens in neonates and infants receiving gp120 vaccines. AIDS Clinical Trial Group 230 Collaborators". J. of infectious Diseases. 2000; 181:890
2. Essajee, SM, Borkowsky,W. et al. "Recombinant Glycoprotein Vaccines for Human Immunodeficiency Virus-Infected Children and Their Effects on Viral

Quasispecies," Clinical and Diagnostic Laboratory Immunology, January 2002, p. 79-82, Vol. 9, No. 1

3. Borkowsky W; Wara D et al "Lymphoproliferative responses (LP) to receive HIV-1 envelope antigens in neonates & infants receiving gp120 vaccines [abstract]" Conference on Retroviruses & Opportunistic Infections, 1998 Feb 1-5;5():129 (abstract no. 268)

A detailed chronology of the facts is posted on the AHRP website: <http://www.ahrp.org/ethical/incarnation/timeline0805.php>.

FDA required Black Box WARNINGS for drugs tested in foster children:

\* Aldesleukin: manufacturer's warning: "Aldesleukin is not approved for the treatment of HIV. Aldesleukin is a highly toxic drug. Adverse effects associated with aldesleukin therapy are common, often serious, and sometimes fatal. Aldesleukin is approved for the treatment of metastatic renal cell carcinoma and metastatic melanoma in patients 18 years and older."

\*\* Dapsone: manufacturer's warning: "Deaths associated with the administration of Dapsone have been reported from agranulocytosis, aplastic anemia and other blood dyscrasias." Indeed, the Associated Press reported that 10 children died in the Dapsone trials: "overall mortality while receiving the study drug was significantly higher in the daily dapsone group. This finding remains unexplained."

\*\*\* Nevirapine new 2005 label warnings 2005: "Patients should be informed of: the possibility of severe liver disease or skin reactions associated with Viramune / Nevirapine that may result in death." See: <http://www.hivdent.org/drugs1/drugNNLC0105.htm>

Nevirapine is a controversial drug: its clinical trials in Africa have been the subject of investigation. See: AP reports, for example: <http://www.ahrp.org/infomail/05/07/04a.php>

The Alliance for Human Research Protection (AHRP)  
[www.ahrp.org](http://www.ahrp.org)

Contact: Vera Hassner Sharav  
212-595-8974

## **NYC Commissioned Investigation Absolves NYC of 80 Deaths FosterChildren AIDS Trials**

Tuesday, 27 January 2009

The VERA Institute acknowledges that its staff never gained access to the children's primary medical clinical trial records--which the hospitals conducting the trials kept sealed under a shield of confidentiality.

The final report of the VERA Institute investigation commissioned in 2005 by the NYC Administration of Child Services will hardly put to rest the controversy surrounding a 20-year period during which children in foster care were subjected to toxic Phase I and Phase II AIDS drug and vaccine experiments--mostly without parental consent and without the protection of an independent advocate--as mandated by federal regulations in force then and now.

The VERA Institute report findings:

532 children in NYC foster care were enrolled in the AIDS clinical trials or observational studies.

80 of the 532 children who participated in clinical trials or observational studies died while in foster care; 25 of them died while enrolled in a medication trial.

64 children participated in 30 medication trials that were NOT REVIEWED by a special medical advisory panel, as the city's policy required.

And 21 children participated in trials that the panel had REVIEWED BUT had NOT RECOMMENDED.

(In both cases, 13 of the enrollments occurred before the children were placed in foster care.)

The authors of the report "concluded" that the deaths were "not a direct result of the medications."

However the validity of that conclusion is highly questionable inasmuch as the VERA Institute reached that "conclusion" on the basis of (admittedly) incomplete, therefore unreliable records.

**MOST IMPORTANT:** The VERA Institute acknowledges that its staff never gained

access to the children's primary medical clinical trial records--which the hospitals conducting the trials kept sealed under a shield of confidentiality.

"citing confidentiality laws, the New York State Department of Health (NYSDOH) refused multiple requests from Children's Services that it use its supervisory authority to allow Vera Institute of Justice staff from Vera or Children's Services to review clinical trial research or medical records.

This limited Vera's review in several ways, including the ability to fully document the frequency and severity of toxicity (side effects), the individual outcomes of trial participation for the children in the review, and the existence of valid, signed informed consent documents." [Executive Summary ]

The Vera Institute did not have access to minutes from medical center research review boards where the trials were conducted.

"Vera could not identify the trials in which an IRB approved a trial under 5 CFR 46.406 or .407. HRA/Children's Services' policy required that each institution produce proof of IRB approval, but the policy did not require that the institution identify the category under which the IRB approved the research"

**DENIAL OF ACCESS TO THE PRIMARY RECORDS EFFECTIVELY UNDERMINED THE VALIDITY OF THE VERA INSTITUTE INVESTIGATION** which was charged with fact-finding about these highly controversial experiments.

The foster children in the experiments--94% children of color--were enrolled, mostly in violation of federal informed consent requirements.

The VERA Institute relied on secondary, child welfare files and Pediatric AIDS Unit (PAU) records both of which are notoriously incomplete.

"Although state regulations mandated that Children's Services ensure the retention of most of the child welfare files that Vera was asked to review, for 30 percent of the children, some part of the child welfare file was lost, destroyed, or otherwise unavailable."

"the records of the Pediatric AIDS Unit (PAU) were incomplete, especially after 1995. Problems with the PAU's record keeping after 1995, including defects in

the unit's electronic database, were noted in the unit's quarterly reports to supervisors and state officials, including the AIDS Institute."

Even those incomplete welfare files provide a hint of the adverse effects suffered by children who had been subjected to the experimental trials:

"The child welfare files contained information indicating that some children experienced serious toxicities, or side effects, from trial medications, such as reduced liver function or severe anemia. These toxicities were consistent with toxicities described in published articles about the trials."

Background:

In 2004, after ascertaining that there were legitimate issues of concern and the possibility of child abuse--some of which were enumerated in a report by Liam Scheff, *The House that AIDS Built*, the Alliance for Human Research Protection filed a complaint with the federal Office of Human Research Protection (OHRP). The AHRP complaint focused on the enrollment of particularly vulnerable foster children in AIDS drug / vaccine experiments and system wide institutional failure to protect the individual child's best interest in accordance with Federal regulations mandating an independent advocate for each child.

The foster children enrolled in the AIDS trials were denied their human right: they were enrolled in the trial in accordance with New York City ACS guidelines which waive a foster child's right to individual consent. ACS guidelines stated: "Separate consent need not be obtained for each child."

This waiver, we believe, denies these children their basic human dignity and ascribes to them the status of guinea pigs .

The VERA Institute report confirms that the AHRP letter of complaint was the cornerstone for OHRP's investigation of Columbia University Medical Center's HIV-AIDS clinical trials, followed by a nationwide investigation:

"OHRP issued determination letters to 19 institutions across the country for violations related to the enrollment of foster children in the HIV/AIDS clinical trials originally cited in the AHRP letter.<sup>366</sup> The 19 institutions included the New York City medical centers Bronx-Lebanon and Bellevue Hospital Centers. <sup>367</sup> The SUNY Health Science Center at Stony Brook had also received a determination letter in February 2006 regarding two of the clinical trials cited.<sup>368</sup> Each of these

letters refers to an IRB's apparent failure to categorize the research as 404, 405, 406, or 407 studies and/or to obtain sufficient information regarding the selection of foster children as participants in the trials. At each of the 19 other sites that received the June 2006 determination letters, OHRP approved corrective action plans aimed at preventing future violations." Links to the 19 letters .

The VERA Institute report makes some cogent critical observations about the shortcomings of the OHRP investigation:

" The OHRP investigations indicate that IRBs at many institutions across the country did not properly document their activities and did not take the special circumstances of children in foster care into consideration. As is its mandate, OHRP focused its activities on compliance with federal regulations. The investigation at CUMC, however, left many other questions unanswered."

"OHRP did not seek to make determinations on how many children in foster care participated in clinical trials or whether the person who signed the consent form had the legal authority to do so, nor did it examine what adverse events or benefits occurred to the children, if any, due to trial participation.

"The investigation did not examine whether foster children made up a disproportionate number of children in HIV/AIDS clinical trials or specify the policy of New York City's child welfare agency for enrolling and monitoring foster children in clinical trials."

Evidence previously uncovered by the Associated Press, confirmed AHRP's concerns: most of the foster children in the AIDS trials were denied the protection of an independent advocate charged with ensuring that a foster child's best interest is served by participating in a research project--as mandated by federal regulations.

Because the facts do not refute our complaint about the failure to provide NYC foster children the protection of an independent advocate--who may have refused consent for the AIDS drug / vaccine trials in which 80 children are confirmed to have died, the VERA report attempts to whitewash the violations by claiming that:

"The role and requirements of the independent advocate described in federal research regulations were not well understood by clinical trials researchers and, in some cases, child welfare staff...."

It boggles the imagination that institutional review boards at premier medical research centers could claim ignorance about a glaring conflict of interest:

"In at least six instances where Vera reviewers found that an independent advocate had been appointed, the person appointed had relationships to the institution conducting the trial or a child welfare agency that the federal regulations specifically bar."

The ACS Press Release claimed: "evidence that child welfare officials followed then-current written policies to obtain parental consent for nearly 80 percent of children participating in the trials" when in fact, the child welfare agency changed its enrollment policy to speed up the enrollment process.

The New York City ACS guidelines waived a foster child's right to individual consent in direct violation of federal regulations:

"Separate consent need not be obtained for each child."

This waiver denied foster children their basic human dignity and cast them to the status of guinea pigs.

Oddly, The New York Times did not consider 80 children's deaths worthy of mention in its news report!

See: AHRP complaint: <http://www.ahrp.org/ahrpsp>

See: The Associated Press report, "Researchers Tested AIDS Drugs on Children" by John Solomon, May 5, 2004, whose investigation found that less than a third of the children in the AIDS trials :

See: AHRP Testimony

posted by Vera Hassner Sharav

**THE VERA INSTITUTE OF JUSTICE  
THE EXPERIENCES OF NEW YORK CITY  
FOSTER CHILDREN IN HIV/AIDS CLINICAL TRIALS**

EXECUTIVE SUMMARY ---EXCERPT

The Vera review also found evidence that supported some concerns about the participation of foster children and their families in clinical trials. This evidence includes violations of state regulations, Children's Services' own policies for clinical trial review and enrollment, and federal regulations for protecting human subjects.

1. Child welfare agency policy after 1991 called for a review of clinical trials by a Medical Advisory Panel and approval by the commissioner. However, twenty-one children participated in three medication trials that the MAP reviewed and did not recommend and the commissioner did not approve. Thirteen of these enrollments took place before the children entered foster care.

- Thirteen children participated in four medication trials that the MAP had reviewed but for which no recommendation had been forwarded to the commissioner. Two of these enrollments took place before the children entered foster care.

- Sixty-four children participated in 30 medication trials that were not reviewed by the MAP. Thirteen of these enrollments took place before the children entered foster care.

2. Regulations and policy required the child welfare agency to retain signed informed consent forms, commissioner approval documents, and other documentation for each trial and each enrollment. For 21 percent of enrollments in medication trials that took place while the children were in foster care, signed informed consent forms were not found in the child welfare files.

3. Trials sponsored by the National Institutes of Health were monitored by an organization charged with ensuring that an informed consent document was present in the research records for each enrolled child. Without access to clinical trial research records, Vera cannot say whether or not a valid informed consent document existed in every case.

4. In at least 16 cases, Vera staff found that children in foster care appeared to

have been enrolled in trials prior to the commissioner's approval of the trial. In some instances, HRA/ACS took several months to approve a trial.

5. In at least seven enrollments, the person who signed an informed consent form was not legally authorized to do so. Kinship foster parents, parents without parental rights, and child welfare staff signed the consents in these cases.

6. Federal regulations required informed consent forms to be written in accessible language.

Many informed consent forms contained technical language difficult for people without a medical background to understand.

7. The role and requirements of the independent advocate described in federal research regulations were not well understood by clinical trials researchers and, in some cases, child welfare staff. In at least six instances where Vera reviewers found that an independent advocate had been appointed, the person appointed had relationships to the institution conducting the trial or a child welfare agency that the federal regulations specifically bar.

8. In several situations, child welfare files described deviations from the processes required by federal regulations and Children's Services policy. These include handwritten notes for informed consent in lieu of official documents, consent accepted over the phone, and consent sought or obtained from parents who may not have been competent to provide it. In at least two instances, the files indicate that parents' wishes were ignored. In other situations, consent was requested in ways that parents might have perceived as coercive.

9. Although state regulations mandated that Children's Services ensure the retention of most of the child welfare files that Vera was asked to review, for 30 percent of the children, some part of the child welfare file was lost, destroyed, or otherwise unavailable.

10. Available records often did not contain documentation required by state regulations.

11. Though required to collect information related to HIV testing, HIV-related medical care, and clinical trials enrollment, the records of the Pediatric AIDS Unit (PAU) were incomplete, especially after 1995. Problems with the PAU's record keeping after 1995, including defects in the unit's electronic database, were noted in the unit's quarterly reports to supervisors and state officials, including

the AIDS Institute.

12. Foster care agency staff approved at least 14 enrollments of children who were in the joint guardianship of the commissioner and the foster care agency. Although conforming to the technical requirements of the policy, this resulted in the enrollment of several foster children in trials the commissioner had not approved. Three of these children were enrolled in a phase I clinical trial even though Children's Services' policy barred participation in phase I trials.

~~~~~

THE NEW YORK TIMES

January 28, 2009

Study Refutes Claims on AIDS Drug Trials

By LISA W. FODERARO

An investigation into the participation of New York City foster children in clinical drug trials for H.I.V. and AIDS over a nearly 20-year period has found no evidence that any children died as a result of the trials or that the foster children were selected because of their race.

In the late 1980s, as the AIDS epidemic intensified, the city's child-welfare agency developed a policy to allow foster children to enroll in drug trials at a time when there were no approved treatments for children infected with H.I.V. and AIDS. Hundreds of children received medication in scores of trials conducted from the late 1980s to 2005.

But after charges by a freelance journalist that children were put in trials without their parents' knowledge and given medications known to cause death, some civil rights activists and City Council members expressed angry concern.

As a result, in 2005 the city commissioned the Vera Institute of Justice, an independent nonprofit group, to investigate the claims. That study, which is to be released on Wednesday, determined that city officials had acted in good faith and in the interests of the children, many of whom were seriously ill.

But it also found that the agency had not always followed its own protocols and kept poor records.

After interviewing dozens of people involved in the trials and reviewing hundreds of thousands of pages of case files, documents and correspondence, the Vera Institute concluded that none of the 532 children in the trials died as a direct result of the medications. (Twenty-five children receiving treatment as part of the trials died during the trial years.)

The report also found that foster children were not removed from their families by the city because a parent had refused to consent to a child's treatment, as some had alleged.

In addition, the study said that researchers did not specifically select foster children for enrollment in the trials. And while the foster children were overwhelmingly black and Hispanic, as some critics emphasized, that profile mirrored the demographics of children with H.I.V. infection in the city at the time.

"When we read through an amazing volume of material, we found that Children's Services were aware that this was a very sensitive issue for a lot of important historic reasons," said Timothy A. Ross, the co-director of the project at Vera.

"Children's Services did research on the rules and regulations that applied, and developed a reasoned policy in the late 1980s," he added. "The standard for enrolling kids in foster care that the child welfare agency used was higher than the federal standard."

However, the institute also discovered problems. "There were clearly breakdowns in the implementation of this policy," Dr. Ross said.

Sixty-four children participated in 30 medication trials that were not reviewed by a special medical advisory panel, as the city's policy required. And 21 children participated in trials that the panel had reviewed but had not recommended. (In both cases, 13 of the enrollments occurred before the children were placed in foster care.)

Moreover, the informed consent forms from biological parents or guardians were missing from the child-welfare files in 21 percent of cases, even though regulations and the city's own policies mandated that they be kept, Mr. Ross said. The state's Department of Health refused Vera's request to review medical records, which might have included some additional consents.

"We found a disturbing lack of medical consent forms," he said. "In some cases

we found handwritten consents instead of the official consent forms." Mr. Ross added that such makeshift permissions violated both city policy and federal regulations.

The commissioner of the Administration for Children's Services, John B. Mattingly, said in an interview about the report: "In very general terms, it puts to rest the most egregious charges that were being made by a few people three or four years ago. No children were yanked from their homes. That is all completely false."

Liam Scheff, the journalist in Boston who first made the alarming charges about the trials, questioned that finding.

"Now they admit that the children died, but, oh, it couldn't have been the drugs," Mr. Scheff said in an e-mail message. "How do they know? How do they tell the difference?"

He said that the drugs in question had Food and Drug Administration warnings on them and that they had "caused permanent injury and painful death in adults who have taken the exact same drugs at normal prescribed doses. These children died, and countless others were made sick while taking these drugs, because of a diagnosis that is itself overly harsh, overly deterministic" and, he said, based on faulty H.I.V. testing technology.

Mr. Mattingly said the agency had already taken steps to ensure that policies are properly enforced in any future clinical trials involving foster children. Today, no children are involved in medication trials.

One change involved the revamping of the way the agency catalogues and maintains archived case records; an electronic system established in 2004 allows for prompt retrieval of all case files. Another new policy calls for more review by Family Court when a parent is not available to provide consent.

Copyright 2009 The New York Times Company

## **A National Scandal: AIDS Drug Experiments on Foster Care Children - Assoc Press. Wed, 04 May 2005**

On March 10, 2004, The Alliance for Human Research Protection filed a complaint with the FDA and the federal Office of Human Research Protection about a series of AIDS drug experiments conducted on New York City children in foster care. That complaint prompted two separate investigations by the FDA and OHRP which are still on-going.

Articles in The New York Post and a documentary by BBC raised the alarm among the African-American and Latino community in NY-some of who have been protesting weekly in front of Incarnation Children's Center, the site of some of the drug experiments.

The Associated Press AP has just released its investigative report: the problem is a national scandal--the experiments were conducted in "at least seven states -- Illinois, Louisiana, Maryland, New York, North Carolina, Colorado and Texas -- and involved more than four dozen different studies.

AP's investigation found that 13,878 children had been enrolled in pediatric AIDS studies funded by the government since the late 1980s. Of these, officials estimated that 5 percent to 10 percent were in foster care. Their age ranged from infants to late teens.

"More than two dozen Illinois foster children remain in studies today."

Those who conducted the experiments in violation of federal regulations, are supported by taxpayers - thus they have a public responsibility which they violated. The children who were targeted to serve as human drug testing subjects - mostly poor children of color - were not afforded the protection of a personal advocate - as is mandated by federal regulations. (45 Code of Federal Regulations 46.409)

The institutional culture of arrogance is demonstrably in evidence at both medical research centers and government agencies: "Our position is that advocates weren't needed," said Marilyn Castaldi, spokeswoman for Columbia Presbyterian Medical Center in New York.

And officials of NYC Administration of Child Services "defend the decision to enlist foster children en masse, saying there was a crisis in the early 1990s and research provided the best treatment possibilities."

The children are reported to have suffered painful side effects "such as rashes, vomiting and sharp drops in infection-fighting blood cells as they tested antiretroviral drugs to suppress AIDS or other medicines to treat secondary infections."

In one study testing the drug dapson, "at least 10 children died from a variety of causes, including four from blood poisoning, and researchers said they were unable to determine a safe, useful dosage. They said the deaths didn't appear to be "directly attributable" to dapson but nonetheless were "disturbing." "overall mortality while receiving the study drug was significantly higher in the daily dapson group. This finding remains unexplained," the researchers concluded.

"Another study involving foster children in the 1990s treated children with different combinations of adult antiretroviral drugs. Among 52 children, there were 26 moderate to severe reactions -- nearly all in infants. The side effects included rash, fever and a major drop in infection-fighting white blood cells. At least three states declined to use children in foster care in medical experiments: Tennessee said its foster care rules generally prohibit enlisting children in such trials. California requires a judge's order. And Wisconsin "has absolutely never allowed, nor would we even consider, any clinical experiments with the children in our foster care system," spokeswoman Stephanie Marquis said.

Not addressed in the AP report is the amount of money that these trials generated for the institutions involved in the experiments.

\*\*\*The NYC Council, general welfare committee is holding a hearing about the unethical experiments conducted in NYC. The hearing will take place at City Hall at 11:15.

For information and to register to speak, call: Ms. Jackie Sherman at  
212-788-7015  
Contact: Vera Hassner Sharav  
212-595-8974

[http://www.latimes.com/news/nationworld/wire/ats-ap\\_top13may04,0,7330019.story](http://www.latimes.com/news/nationworld/wire/ats-ap_top13may04,0,7330019.story)

## **Researchers Tested AIDS Drugs on Children**

**By JOHN SOLOMON**

**Associated Press Writer**

**11:08 AM PDT, May 4, 2005**

WASHINGTON - Government-funded researchers tested AIDS drugs on hundreds of foster children over the past two decades, often without providing them a basic protection afforded in federal law and required by some states, an Associated Press review has found.

The research funded by the National Institutes of Health spanned the country. It was most widespread in the 1990s as foster care agencies sought treatments for their HIV-infected children that weren't yet available in the marketplace.

The practice ensured that foster children -- mostly poor or minority -- received care from world-class researchers at government expense, slowing their rate of death and extending their lives. But it also exposed a vulnerable population to the risks of medical research and drugs that were known to have serious side effects in adults and for which the safety for children was unknown.

The research was conducted in at least seven states -- Illinois, Louisiana, Maryland, New York, North Carolina, Colorado and Texas -- and involved more than four dozen different studies. The foster children ranged from infants to late teens, according to interviews and government records.

Several studies that enlisted foster children reported patients suffered side effects such as rashes, vomiting and sharp drops in infection-fighting blood cells as they tested antiretroviral drugs to suppress AIDS or other medicines to treat secondary infections.

In one study, researchers reported a "disturbing" higher death rate among children who took higher doses of a drug. That study was unable to determine a safe and effective dosage.

The government provided special protections for child wards in 1983. They required researchers and their oversight boards to appoint independent

advocates for any foster child enrolled in a narrow class of studies that involved greater than minimal risk and lacked the promise of direct benefit. Some foster agencies required the protection regardless of risks and benefits.

Advocates must be independent of the foster care and research agencies, have some understanding of medical issues and "act in the best interests of the child" for the entirety of the research, the law states.

However, researchers and foster agencies told AP that foster children in AIDS drug trials often weren't given such advocates even though research institutions many times promised to do so to gain access to the children.

Illinois officials believe none of their nearly 200 foster children in AIDS studies got independent monitors even though researchers signed a document guaranteeing "the appointment of an advocate for each individual ward participating in the respective medical research."

New York City could find records showing 142 -- less than a third -- of the 465 foster children in AIDS drug trials got such monitors even though city policy required them. The city has asked an outside firm to investigate.

Likewise, research facilities including Chicago's Children's Memorial Hospital and Johns Hopkins University in Baltimore said they concluded they didn't provide advocates for foster kids.

Some states declined to participate in medical experiments. Tennessee said its foster care rules generally prohibit enlisting children in such trials. California requires a judge's order. And Wisconsin "has absolutely never allowed, nor would we even consider, any clinical experiments with the children in our foster care system," spokeswoman Stephanie Marquis said.

Officials estimated that 5 percent to 10 percent of the 13,878 children enrolled in pediatric AIDS studies funded by NIH since the late 1980s were in foster care. More than two dozen Illinois foster children remain in studies today. Some foster children died during studies, but state or city agencies said they could find no records that any deaths were directly caused by experimental treatments.

Researchers typically secured permission to enroll foster children through city or state agencies. And they frequently exempted themselves from appointing

advocates by concluding the research carried minimal risk and the child would directly benefit because the drugs had already been tried in adults.

"Our position is that advocates weren't needed," said Marilyn Castaldi, spokeswoman for Columbia Presbyterian Medical Center in New York. If they decline to appoint advocates under the federal law, researchers and their oversight boards must conclude that the experimental treatment affords the same or better risk-benefit possibilities than alternate treatments already in the marketplace. They also must abide by any additional protections required by state and local authorities.

Many of the studies that enrolled foster children occurred after 1990 when the government approved using the drug AZT -- an effective AIDS treatment -- for children.

Arthur Caplan, head of medical ethics at the University of Pennsylvania, said advocates should have been appointed for all foster children because researchers felt the pressure of a medical crisis and knew there was great uncertainty as to how children would react to AIDS medications that were often toxic for adults.

"It is exactly that set of circumstances that made it absolutely mandatory to get those kids those advocates," Caplan said. "It is inexcusable that they wouldn't have an advocate for each one of those children.

"When you have the most vulnerable subjects imaginable -- kids without parents -- you really do have to come in with someone independent, who doesn't have a dog in this fight," he said.

Those who made the decisions say the research gave foster kids access to drugs they otherwise couldn't get. And they say they protected the children's interest by carefully explaining risks and benefits to state guardians, foster parents and the children themselves.

"I understand the ethical dilemma surrounding the introduction of foster children into trials," said Dr. Mark Kline, a pediatric AIDS expert at Baylor College of Medicine. He enrolled some Texas foster kids in his studies, and doesn't recall appointing advocates for them.

"To say as a group that foster children should be excluded from clinical trials would have meant excluding these children from the best available therapies at the time," he said. "From an ethical perspective, I never thought that was a stand I could take."

Illinois officials directly credit the decision to enroll HIV-positive foster kids with bringing about a decline in deaths -- from 40 between 1989 and 1995 to only 19 since.

NIH, the government health research agency that funded the studies, did not track researchers to determine if they appointed advocates. Instead, the decision was left to medical review boards made up of volunteers at each study site.

A recent Institute of Medicine study concluded those Institutional Review Boards (IRBs) were often overwhelmed, dominated by scientists and not focused enough on patient protections. An ethicist who served 22 years on such boards said they lack the resources to ensure the safety of foster children.

"Over the last half century, IRBs have basically broken under the strain of some of the structural changes in research," said Gregory E. Pence, a University of Alabama-Birmingham bioethicist.

The U.S. Office for Human Research Protections, created to protect research participants after the infamous Tuskegee syphilis studies on black men, is investigating the use of foster children in AIDS research. The office declined to discuss the probe.

NIH said it considers patient safety its top priority and awaits the outcome of the investigation. "If we find that patient protections need further strengthening, we will take action to do so," spokesman John Burklow said.

AP's review found that if children were old enough -- usually between 5 and 10 -- they also were educated about the risks and asked to consent. Sometimes, foster parents or biological parents were consulted; other times not.

"Our policy was to try and contact the (biological) parents because it was fairly common when we got done the foster kid would go back to the parents," said Dr. Ross McKinney, a pediatrics AIDS expert at Duke University.

Research and foster agencies declined to make foster parents or children in the drug trials available for interviews, or to provide information about individual drug dosages, side effects or deaths, citing medical privacy laws.

Other families who participated in the same drug trials told AP their children mostly benefited but parents needed to carefully monitor potential side effects. Foster children, they said, need the added protection of an independent advocate.

"I don't believe a foster care parent can do it," said Vinnie DiPoalo, a New Jersey woman whose 10-year-old adopted son has participated in three AIDS drug trials. "There are informed consents that have to be signed. There are follow-up blood appointments.

"I think that's the role the advocate should take, because a foster parent may only have this child for three months and then the child moves on and someone needs to be watching all the time," she said.

Many studies that enlisted foster children involved early Phase I and Phase II research -- the riskiest -- to determine side effects and safe dosages so children could begin taking adult "cocktails," the powerful drug combinations that suppress AIDS but can cause bad reactions like rashes and organ damage. Some of those drugs were approved ultimately for children, such as stavudine and zidovudine. Other medicines were not.

Illinois officials confirmed two or three foster children were approved to participate in a mid-1990s study of dapsone. Researchers hoped the drug would prevent a pneumonia that afflicts AIDS patients.

Researchers reported some children had to be taken off the drug because of "serious toxicity," others developed rashes, and the rates of death and blood toxicity were significantly higher in children who took the medicine daily, rather than weekly.

At least 10 children died from a variety of causes, including four from blood poisoning, and researchers said they were unable to determine a safe, useful dosage. They said the deaths didn't appear to be "directly attributable" to dapsone but nonetheless were "disturbing."

"An unexpected finding in our study was that overall mortality while receiving the study drug was significantly higher in the daily dapsone group. This finding remains unexplained," the researchers concluded.

Another study involving foster children in the 1990s treated children with different combinations of adult antiretroviral drugs. Among 52 children, there were 26 moderate to severe reactions -- nearly all in infants. The side effects included rash, fever and a major drop in infection-fighting white blood cells.

New York City officials defend the decision to enlist foster children en masse, saying there was a crisis in the early 1990s and research provided the best treatment possibilities. Nonetheless, they are changing their policy so they no longer give blanket permission to enroll children in preapproved studies.

"We learned some things from our experience," said Elizabeth Roberts, assistant commissioner for child and family health at the Administration for Children's Services. "It is a more individualized review we will be conducting."

Researchers likewise defend their work, saying they often sat with foster families to explain the risks and benefits, and provided them literature and 24-hour phone numbers.

"We talk about it. Then they come the next time. There is no rush," explained Dr. Ram Yogev, the chief pediatric AIDS researcher in Chicago whose patients include a large number of foster children.

Kline, the Texas researcher, added: "I never wanted a parent or guardian to ever say 'yes' simply because they thought that it was what I wanted them to do. I wanted it to be the right choice for them. I think there is not any single right answer for any family."

\* \_\_\_\_\_

Researcher Rachel Landau in Washington and reporter Carla K. Johnson in Chicago contributed to this story. On the Net:

Documents associated with this story are available at:

<http://wid.ap.org/inv/foster.html>

National Institutes of Health: <http://www.nih.gov>

FAIR USE NOTICE: This may contain copyrighted (C ) material the use of which has not always been specifically authorized by the copyright owner. Such material is made available for educational purposes, to advance understanding of

human rights, democracy, scientific, moral, ethical, and social justice issues, etc. It is believed that this constitutes a 'fair use' of any such copyrighted material as provided for in Title 17 U.S.C. section 107 of the US Copyright Law. This material is distributed without profit.

## **Asking the Questions**

**What does it mean when a story about possible clinical trial abuses hits the wire, but most news media ignore**

### **Patricia Nell Warren's Left Field**

For years, CNN's Christiane Amanpour has been saying—not on CNN, of course—that courageous reporting is vanishing from the U.S. major media. In a recent interview, the distinguished anchorwoman stressed the importance of “really asking the questions.” When it comes to AIDS, media often run from the questions. Many TV networks, wire services, and big print publications obediently regurgitate what's hand-fed to them by the AIDS establishment.

Example: the story about New York City's Incarnation Children's Center. ICC is a Catholic-owned group home near Harlem—the city's only group home exclusively for HIV-positive foster children. Opened in 1989, ICC once enjoyed warm fuzzy media coverage and visits from Princess Diana. Now it's hit with allegations that, between 1995 and 2002, more than 100 ICC children were illegally used and abused in AIDS research. Black and Latino babies and children from poor families were used as test subjects in Phase I and II clinical trials funded by the NIH and administered by Columbia-Presbyterian Medical Center doctors.

It's nothing new for children to participate in AIDS trials, with parental consent. But Incarnation is a foster home—the kids are all wards. Evidently many were seized from their HIV-positive mothers by the city's Administration for Children's Services. The ACS then “volunteered” at least 100 children for these trials of vaccines and drugs, including AZT, protease inhibitors, and combinations supplied by GlaxoSmith-Kline, Pfizer, Biocine, Roche, Genentech, and other firms. Some children were shuffled to ICC from area hospitals that were also participating in trials.

In January 2004, the first allegations came from freelance reporter Liam Scheff, who'd been writing about AIDS for Boston's Weekly Dig. He interviewed ICC's medical director, a former ICC pediatric nurse, and several worried parents whose children were at the home. Scheff wrote: “When the children refuse the drugs, they're force-fed. If the kids continue to refuse, they're given a surgery to implant a plastic tube through their abdomen into their stomach. The drugs are

then injected directly into their stomachs—no refusing.” Scheff alleged that several children had died as a result of treatment side effects.

There are other “real questions.” Phase I and II trials involve the highest risk, because they do the first explorations of safety, toxicity, dose tolerance. In 1989 the FDA approved the highly toxic AZT for children under thirteen on a “compassionate use” basis, though clinical trials were still in progress. Yet just a few years later, it was mandatory for HIV-positive mothers to allow their children to be treated, or face loss of custody, even criminal charges. How was this policy shift justified, when Phase I and II drug trials were still ongoing? Even today, government officials admit at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) that they still don’t know the long-term effects of HIV drug treatments on infants and growing children. Why have major media parroted the government reassurances instead of asking real questions about children’s treatment safety?

Was the ACS acting in the best interest of its ICC wards when it consented to these experiments? More and more, medical research is riddled by conflict of interest. New York City’s child-welfare agency has already been under fire for tolerating child abuse and mismanagement, and was being monitored to improve performance. Was a conflict of interest created when ACS, which gets federal funding, obligingly granted federally funded researchers the access to its vulnerable child clients?

Medical research is also more commercially driven today. Don’t billions in profits stand to be made from global use of AZT and nevirapine, the drugs of choice for use in developing countries, mostly on people of color? Is this why researchers and pharmaceuticals were so interested in the black and Latino foster children at ICC? Were the kids, in effect, a handy pool of potential subjects—over 700 of them since ICC opened—whose parents couldn’t make waves because they lacked custody and money for lawyers? Would the media have asked questions sooner if middle-class white foster kids were “studied” without their parents’ consent?

Scheff’s story made a low-profile debut on [www.AltHeal.org](http://www.AltHeal.org), and hit an instant nerve. According to Scheff, indie media grabbed the story and reposted it around the world, translating it into several languages. In Britain, where media are more gutsy about AIDS controversy, The Observer and The Guardian ran their own stories. But in the U.S., only the conservative New York Post did significant coverage. On February 4, the Post ran a tabloidy headline: AIDS TOTS USED AS GUINEA PIGS. The paper revealed that state health department officials

were launching a probe, and they interviewed Scheff but failed to credit him for breaking the story.

The next real question exploded from the Alliance for Human Research Protection, a national network concerned with ethical conduct of scientific experiments. AHRP contacted the city, alleging that the ICC trials “may violate federal regulations that restrict the use of children who are wards of the state as experimental subjects.” By March 1, the shocked City Council was finally asking its own questions. They wanted to know if any children had died during the trials. They asked why the studies suddenly shut down in 2002 and Columbia-Presbyterian doctors pulled out. There was talk of public hearings.

At the moment, all parties involved in the studies must be considered innocent unless found guilty. But if the allegations prove true, what might constitute “justice” for dozens of children and families whose lives may have been negatively impacted by this research? And my final question: Will the major media finally “discover” this story, and all its explosive issues—a story that has been breaking right under their noses for several months now?

Further reading:

Liam Scheff story: [www.altheal.org/texts/house.htm](http://www.altheal.org/texts/house.htm)

Alliance for Human Research Protection statement: [www.ahrp.org/ahrpspeaks/HIVkids0304.html](http://www.ahrp.org/ahrpspeaks/HIVkids0304.html)

Government listing of current pediatric AIDS trials: [www.clinicaltrials.gov/ct/show/NCT00006304?order=2](http://www.clinicaltrials.gov/ct/show/NCT00006304?order=2)

Patricia Nell Warren, author of fiction bestsellers like *The Front Runner*, also writes provocative commentary. Her writings are archived at [www.patricianellwarren.com](http://www.patricianellwarren.com). Reach her by

e-mail at [patriciawarren@aol.com](mailto:patriciawarren@aol.com).

May 2004

Copyright © 2004 by Patricia Nell Warren. All rights reserved.

## **Banana Ethics**

### **Why does corruption in AIDS research continue to go unpunished? Left Field by Patricia Nell Warren**

As Congress dithered on what to do about Tom DeLay, the United States sank to new lows on the ethics front. Americans love to point fingers at corruption in little countries we term “banana republics,” yet we ourselves are a dismal example of public ethics.

What do I mean by public ethics? Regardless of whether conservatives or liberals are running the country, there ought to be enough agreement on what’s wrong with an official or corporation for Congress to investigate without delay. Yet we have the spectacle of our highest legislative body arguing for months over whether to scrutinize DeLay.

Banana ethics has spread its gangrene deep into biomedical research. Over the last six months, Americans are confronted by growing revelations that corporations and government agencies often collude to hide toxicity of drugs and abuses of human subjects in clinical trials.

Ever since I began covering the AIDS political front in 1998, there have been muffled noises about the ethics of how some trials are conducted, both in the U.S. and developing countries. Americans are finally learning that (for example) a high NIH official rewrote the results of an AIDS drug trial in Uganda, in an effort to hide several deaths and toxic reactions to nevirapine. Some conscience-stricken government workers were harassed when they tried to bring these problems to public attention.

The most pathetic example of ethics rot: Officialdom stonewalled for well over a year before the Incarnation Children’s Center case finally got budged from media coverage to actual investigation.

Children are a knee-jerk issue in the U.S. Let a single child be murdered by a sex offender, and the whole country is baying like bloodhounds. Any prosecutor who knew the suspect’s identity, but delayed action for a whole year, would be strung up by the heels by an outraged public. But here is a case where hundreds of HIV-positive foster children in a Harlem group home might have been subjected to criminal abuse as research subjects of drug trials involving the NIH, the State of New York, the NYC child-welfare agency, big corporations, and prominent

hospitals, with alleged suffering and possible deaths of some children. And investigation was delayed. And most of the public simply shrugged. Why? Because most people are brainwashed into believing that “the AIDS authorities know what they’re doing and no one should challenge them or question them.” Indeed, some individuals who did speak out about ICC are being labelled “AIDS dissenters.”

In January 2004, the ICC story first broke in Boston Dig and altheal.com, written by investigative reporter Liam Scheff. It leaped to the London Times, New York Post, other papers around the world, the AP, even a BBC special. According to charges filed by the Alliance for Human Research Protection, the ICC trials may have violated federal regulations, which restrict the research use of children who are wards of the state. As early as spring 2004, a few New York City council members were demanding investigation. Yet it took till April 2005 to get the investigation rolling.

Most of these ICC children were black and Latino, both infants and young teens. When the headlines of “guinea pig kids” hit the Post, I kept expecting to see news reports of widespread protests. Governments of big cities have learned the hard way that a single instance of police brutality against a kid of color can fill the streets with noisy demonstrators. But let the kids of color be “subjects of legitimate AIDS research,” and suddenly the protesters on the street in front of the ICC were ignored by officialdom.

Hopefully federal investigators will finally deal with these children’s real lives—their identities, their histories. How legitimate were the reasons that they were torn from their families and crammed into these experiments? If any died, will there be autopsies? Will the autopsy reports be made public?

A&U readers can study the many cases piling up on the Alliance for Human Research Protection’s Web site ([www.ahrp.org](http://www.ahrp.org)). The same nation that jailed Martha Stewart for “lying to the feds” about a stock-market trade is—so far—letting corporate executives and government officials go unpunished for these crimes. We have finally met the banana republic, and it is us.

**Author of fiction bestsellers and provocative commentary, Patricia Nell Warren has her writings archived at [www.patricianellwarren.com](http://www.patricianellwarren.com). Reach her by e-mail at [patriciawarren@aol.com](mailto:patriciawarren@aol.com).**

**Copyright © 2005 by Patricia Nell Warren. All rights reserved.**

## What Were They Thinking?

### **Inspired by lax oversight in the world of medicine, a new watchdog fights for ethical standards.**

There's no doubt that ethics are collapsing in our country. Policies and laws based on accepted ethics of the past are either openly flouted, or used as a smokescreen to mask actions that are anything but ethical. Every week Americans find themselves staring at ugly situations in the news, especially the growing scandals around pharmaceutical drug testing and safety, and asking, "What were they thinking?" Notable example: the AIDS-drug experiments on foster children at the Incarnation Children's Center in New York, which is going into a new round of revelations as I write this.

What is ethics and why should we care about it?

The word goes back to the Greek *ethos*, meaning "moral character." By extension it means "custom," the collective morals of a people as agreed on and lived by them. Some civilizations' rules seem bizarre or nonsensical to us—yet these systems were the glue that held an ancient people together. Ethics called on individuals to be responsible for each other, and accountable to each other. In the West's medical tradition, which began with the Greeks, *ethos* was summed up in the Hippocratic oath, "Do no harm." No doubt this oath was born when leading physicians looked at some treatment done irresponsibly, or some doctor's infamous greed, and cried out, "What were you thinking?"

When Christianity came along, it evolved its own "morality" (it didn't like the pagan word "ethics"). Christian ethics could be shaded greatly. Catholic inquisitors who had dissenters burned at the stake believed they were acting ethically. Protestants who aimed to reform Catholic corruption disagreed—yet Protestants were willing to burn each other at the stake, too. In short, the history of Christianity shows us how authority can skew "ethics" to serve its own purpose. Yet sensibilities about "right and wrong" remained powerful even in post-Reformation philosophers who returned to old ideals of the ancient Greeks. Men and women with this liberated philosophy were among the colonists of North America, along with colonists whose ethics were more churchy.

Today the religious right call it "morals," while liberals prefer the older word "ethics." Whatever you call it, things have clearly gone horribly wrong and scandal is overwhelming our country.

Several years ago ethics controversy in medical research sparked the founding of a new watchdog organization. The Alliance for Human Research Protection (AHRP) was inspired by a mother's experience—Vera Hassner Sharav watched her son die from a side effect of pharmaceutical drugs, one that she says she wasn't told about. Headquartered in New York City and run by prominent professionals and lay activists, the AHRP fights for children's rights in biomedical experiments, and for real informed consent from adults. The range of issues is shockingly wide, from the danger of anthrax vaccines to pesticide experiments on humans.

The ICC scandal was first aired in spring 2004 by independent journalist Liam Scheff, and given high priority by AHRP. After ignoring the story for some time, government agencies finally started looking into whether guidelines for including foster children in clinical trials were violated. Predictably, the barking dogs of the AIDS establishment have rushed out to howl in defense of ICC's drug trials. Liam Scheff and Vera Sharav are being painted as bad guys who are attacking good-guy policies—ones that supposedly save children's lives by providing AIDS drugs that they wouldn't get otherwise.

But as I write this, Scheff published a new round of allegations in the New York Press. He has new interviews with caregivers and older children patients from ICC. They vividly describe forced treatments with AZT and other drugs, including the extreme coercion used on children if they refused to take meds that made them sick. Interviewees named names in allegations of treatment-related deaths. About the same time, the Los Angeles Times published a report on widespread ethics violations at the National Institutes of Health itself, the agency that holds final authority over pediatric AIDS trials.

Today, as in ancient Greece, it's shockers like this that inspire a people to demand real ethics. If Scheff's allegations are verified by a criminal investigation, we'll have to wonder about the doctors, staff, pharma executives, government officials, and others who looked at this ICC scene unmoved and let it continue for years. We'll have to ask, "What were they thinking?"

Further reading:

New York Press story by Liam Scheff: [www.nypress.com/18/30/news&columns/liamscheff.cfm](http://www.nypress.com/18/30/news&columns/liamscheff.cfm)

Alliance for Human Research Protection: [www.ahrp.org](http://www.ahrp.org).

Author of fiction bestsellers and provocative commentary, Patricia Nell Warren has her writings archived at [www.patricianellwarren.com](http://www.patricianellwarren.com). Reach her by e-mail at [patriciawarren@aol.com](mailto:patriciawarren@aol.com).

Copyright © 2005 by Patricia Nell Warren. All rights reserved.

August 2005