British Broadcasting Corporation Media Centre Media Village White City 201 Wood Lane London W12 7TQ
Telephone 020 8743 8000 Fax 020 8008 1864 Email ecu@bbc.co.uk

BBC

Editorial Complaints Unit

ECU/AB 0700123

Ms Jeanne Bergman
Director of Planning and Policy Research
Centre for HIV Law and Policy
65 Broadway, Suite 832
New York, NY 10006
USA

31 July 2007

Dear Ms Bergmann,

Guinea Pig Kids, BBC2, 30 November 2004 & BBC News Online

Thank you for your letter of 2 May. I understand that you have previously raised these complaints with the BBC, but that you were unhappy with the response you received. I hope I can address your concerns here. I am sorry that this has taken a little longer than we hoped but, as my colleague Andrew Bell explained to you, it has raised complex issues which have taken more time than we anticipated to resolve.

We have now had a chance to view the programme and the website article by Jamie Doran. We have also reviewed the previous correspondence between Nathan Geffen and the BBC and the correspondence arising from the earlier complaint brought by the Incarnation Children's Centre in March 2005. We have also put your complaints to the programme-makers and considered the response from them.

You may be aware that it is the role of the ECU to investigate whether there has been a serious breach of the standards set out in the BBC's Editorial Guidelines. You can find these at: www.bbc.co.uk/guidelines/editorialguidelines. In this case, I have taken the relevant guidelines to be those concerning Accuracy and Impartiality.

The guidelines on Accuracy say:

> *The BBC's commitment to accuracy is a core editorial value and fundamental to our reputation. Our output must be well sourced, based on sound evidence, thoroughly tested and presented in clear, precise language. We should be honest and open about what we don't know and avoid unfounded speculation.*

> *For the BBC accuracy is more important than speed and it is often more than a question of getting the facts right. All the relevant facts and information should be weighed to get at the truth. If an issue is controversial, relevant opinions as well as facts may need to be considered.*
>
> *We aim to achieve accuracy by:*
>
> - *the accurate gathering of material using first hand sources wherever possible.*
> - *checking and cross checking the facts...*
> - *corroborating claims and allegations made by contributors wherever possible.*

The Guidelines describe Impartiality as "due impartiality" which:

> *... requires us to be fair and open minded when examining the evidence and weighing all the material facts, as well as being objective and even handed in our approach to a subject. It does not require the representation of every argument or facet of every argument on every occasion or an equal division of time for each view...*
>
> *In practice, our commitment to impartiality means:*
>
> - *...we must ensure we avoid bias or an imbalance of views on controversial subjects...*
> - *...we must rigorously test contributors expressing contentious views during an interview whilst giving them a fair chance to set out their full response to our questions...*
> - *...we should not automatically assume that academics and journalists from other organisations are impartial and make it clear to our audience when contributors are associated with a particular viewpoint.*

This programme set out, in the programme makers' words:

> *...to question the ethics of testing anti-HIV drugs on vulnerable and poor children who had no choice in whether or not to take part in trials and no proper advocates to speak on their behalf.*

You and your co-signatories concede that there was:

> *...one administrative problem that subsequent legitimate investigations have revealed: that in a very few cases an independent advocate was not appointed for a participant, although such a step was required by the research protocols*

In the event, subsequent investigations have revealed that this *"administrative problem"* was significantly more widespread than had been alleged in the programme, both in terms of numbers and in geographical spread. It has led to a major publicly-funded investigation being conducted by the VERA Institute of Justice, which is still ongoing. An investigation by the US Department of Health and Human Services has already concluded that in New York federal guidelines covering the way that children were selected for trials, and the way that consent should be properly obtained, had been broken. In terms of this important issue, the programme arguably performed a significant public service and its journalism was vindicated.

The complaints which you have asked us to consider concern not that central thrust of the programme but issues ancillary to it. That is not to say, however, that they are without significance themselves, as some of the allegations complained of would, if true, arguably be even more serious than those allegations conceded to have merit.

You complain that:

> ***The programme unfairly claimed that New York City's Administration for Children's Services, the Incarnation Children's Centre, Catholic charities, the Columbian Presbyterian hospital and the National Institutes of Health effectively conspired to force helpless children of colour into inappropriate and sinister "experiments" when in fact they made life saving drugs already approved for adults available to children living with HIV/AIDS who were in the foster care system;***

This complaint is predicated upon a view of what the programme said about the trials into which the children were being enrolled. In that context I think it is instructive to look at what was said by the programme's only scientific witness to the conduct and efficacy of the trials, Dr David Rasnick. He said:

> ***Dr David Rasnick***
> *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.*
>
> ***Commentary***
> *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...*

Commmentary
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.

Commmentary
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, their joints are going to swell up, they're going to roll around on the ground, you can't touch them...

There is a conjunction of apparent claims being made here which needs to be considered: that these drugs (invariably, it seems to be implied) cause serious debilitating side effects; that, in the case of AZT at least, it is not in any case life-saving, so the tests might be considered futile; and that the drugs are dangerous and in "virtually all" cases "lethal". I think the inference is inescapable that if all this were to be true, involvement in these trials would have exposed the children to serious risk and danger, and some certainly will have been harmed and possibly killed. Substantial quotes on this point from Dr Rasnick appear also in the website article.

The response of the programme makers to this item of complaint was that Dr Rasnick's contribution was limited to describing side effects many of which are listed on the drug packaging, side effects which refer to adults. Although they make a concession which I shall refer to in connection with a later point of complaint, they argue that:

> *His contention that AZT is not a life saver is not so controversial as it would be more accurately described as a life prolonger in adults when prescribed as part of a wider treatment plan.*

I have to say that I don't think that this is at all an obvious distinction, and it is plainly not what Dr Rasnick was saying. In fact, he is on record as saying just the opposite:

> *Up until today there is not a single credible study documenting the AZT prolongs the life of an HIV-positive person.*
> *(http://www4.dr-rath-foundation.org/THE_FOUNDATION/youcan2005dec/06.html)*

I think the inescapable meaning that the viewer would take from this part of the programme is that AZT, and the other drugs referred to, are dangerous and do not work. This meaning, however, would fly in the face of mainstream medical opinion, which is not heard. It is also a meaning that, significantly, the programme makers do not seek to defend.

Dr Rasnick's claims about the side effects of these drugs are also unqualified. Review of the literature on them shows that, while the side effects he lists may result from taking the drugs, it is not inevitable that they will. Most of them will affect only a proportion of patients who take them, and in some cases a very small proportion.

Overall, having heard Dr Rasnick's unchallenged view about these drugs, it is hard not to conclude that, if what he said was true (and the viewer was given no reason to think that it might not be), the children involved were exposed to unnecessary danger and likely to be harmed in trials that were of doubtful legitimacy. It should have been made clear that Dr Rasnick's view on the efficacy of drugs like AZT would be challenged by many, if not most experts in the field, and his descriptions of the side effects of these drugs should have been qualified.

The result of not doing so was that a very partial picture was presented of the potential risks to which children enrolled in these trials might be exposed and of the efficacy of the drugs which were being trialed, so that the experiments might appear to the viewer to be both sinister and inappropriate. The motive for enrolling the children in the trials becomes, at best, inexplicable, and at worst, possibly the sort of conspiracy hinted at in the complaint. For these reasons I am upholding this part of your complaint against both the programme and the website article.

The programme unfairly claimed that children were used to test drugs with no regard for their welfare;

The programme did argue strongly that insufficient protection was in place to ensure that the welfare of the children was adequately taken into account, but it did not, it seems to me, argue that no regard at all was taken of their welfare. The lesser claim, as I have already noted, was justified and borne out by subsequent investigation, so I am unable to uphold this part of your complaint.

The programme falsely claimed that if parents or guardians objected to their children being used in tests they lost rights in relation to their children;

The programme cited three cases where children were taken away from families or careers, or where this was threatened:

- Garfield Momodu, who was taken into care by ACS in New York after his mother discontinued his anti-HIV medication because she felt it was making him ill;

- Two children being cared for by Jacklyn Hoerger, who were also taken back into care by ACS when she decided to withdraw their medication, again because she felt that they were worse when they were taking the medication than when they were not;

- The children of Christine Maggiore. Their mother was HIV positive but had declined to have them tested or treated for possible HIV infection. This led to an attempt by the Los Angeles Welfare Services (LAWS) to take them into care, which Ms Maggiore successfully contested in court.

The programme does not allege, in terms, that the actions taken to remove or attempt to remove these children into care were the result of their parents or guardians objecting to the children being used in trials. But having said that, it is difficult to see why, if this is not being intimated at least, these cases feature in the film at all, given that none of them involve children known to have been involved in trials, or whom the authorities are known to have wanted to place in trials. The inclusion of these cases does tend to suggest that what was happening to these children was in some way connected with the drugs trials. This suggestion is strengthened by the way that two of these stories are concluded. In the case of Garfield Momodu, his grandmother says at the end of the film:

> *I want to get him back. I want to get him back.* ***Because I don't want my child to remain in experimental basis*** (my emphasis).

In fact, no evidence was offered that he was enrolled in a drugs trial, but only that his new foster mother was giving him the medication that his grandmother (who now wanted to look after him following the death of his mother) was not prepared to give him. It is clear that this medication was not part of a drugs trial, and had been continued, for some time at least, after the offer of participation in a trial had been made to his mother and declined.

In the case of the children being looked after by Jacklyn Hoerger, the commentary concluding the story said:

> *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.*

This speculative comment again served to connect what happened to these children with the idea of experimentation, even though there are no grounds for believing that this was why the children were actually taken back into care.

Nor is it directly stated in the case of Christine Maggiore that parents who refused to put children into trials risked having them removed. However, in their response to the complaint, the programme-makers explained that:

> *...her inclusion was to show that if you had money and powerful advocacy you could withdraw children from trials for whatever motivation.*

The difficulty with this is that her children were not in a trial, and there is no evidence at all that the LAWS sought to enroll them in a trial. What the LAWS seemed to want, and what she objected to, was to take her children into care because she refused to have them tested and treated for possible HIV infection. The case tells us nothing about the situation of parents with children in a trial, or how easy it might or might not be to withdraw them. But again, the case did tend to create an association between trials and a loss of parental rights (a point implicitly conceded by the programme-makers' explanation).

So, although a close textual analysis does not support the idea that the programme suggested explicitly that children were taken, or risked being taken, from parents or carers who refused to put them into the drugs trials, there is no question in my mind that this is the impression that the viewer would have been left with. I am, therefore, upholding this part of your complaint.

This meaning also comes over very clearly in the website article which, talking of the side effects experienced by children on trials at ICC, says:

> *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.*

Jacklyn was not, as we have noted, trying to take the children out of a trial, but off their medication. The juxtaposition of these two statements gives a clear but misleading impression that parents or carers who tried to take children off trials risked losing them when this was not shown to be the case. I am therefore upholding this complaint against the website article as well.

> ***The programme falsely claimed that denying medication to children with AIDS will improve their health while appropriate treatment will kill them;***

In response to this complaint the programme-makers said:

> *The film included testimony that specific children who came off the tests got healthier in the short term at least. It didn't imply they were disease free. This answers the point about the distinction between the health effect of the drugs trials and the effect of the disease itself.*

Unfortunately, I don't think that it does. Two of the case studies which I have already referred to involved comparisons of the health of HIV positive children when they were taking medication and when they were not. In the case of Garfield Momadu, members of his family described how, when on his medication, he suffered from cold and itching, lost weight and lost his appetite. When his mother took him off the medication, we are told:

> *Almost immediately his health improved.*

Jacklyn Hoerger also took the two girls she was caring for off their medication. She explained that:

> *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.*

However, when she stopped the medication, they improved:

> ***Commentary***
> *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.*

Nowhere in these accounts, however, was there any discussion of the possible side effects of taking these drugs, even though Dr Rasnick enumerated the side effects that could occur, and commented on their possible severity. It is, of course, quite possible that the children appeared to improve because they ceased to experience debilitating and unpleasant side effects of powerful medication. This, however, would beg the question as to what effect withdrawing the medication might have upon their underlying health. Failure to acknowledge this possibility, and the language in which the change in the children was described did, I feel, create a clear impression that the children's health improved when they were not on the medication and declined when they took it. This, it seems to me, was not justified on the basis of the evidence provided, so I am upholding this part of the complaint.

The programme was misleading in that it presented a photograph of a child with a terrible skin condition as an ICC resident. The programme also implied that ICC clinical trials participants had developed this rash when there is no evidence for this

This picture was used at the point where Dr Rasnick discussed some of the side effects of one of the drugs being trialed. He said:

> *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.*

There is, however, at this point no direct reference to the New York trials or to the children enrolled in them. Dr Rasnick was discussing the side effects in general and, it seems to me, it was perfectly appropriate to use such a photograph for illustrative purposes. There was no suggestion that I can see that this is a child enrolled in the ICC trial.

The fact that some patients might expect to suffer such a reaction means that it is entirely reasonable to infer that some of the children in the trials might experience it. Thus, even if the programme did carry the suggestion that some of the children in the ICC might have experienced these side effects, I do not think that this would be an unreasonable or damaging inference. I am not upholding this part of the complaint.

The programme was misleading in that it presented a photograph of a child receiving medication through a tube as a photograph of an ICC resident and suggested that such systems for delivering medication are inhumane and unethical;

This illustration was used at a point where Dr Rasnick was directly referring to this method of delivering medication being used in the NY trials. However, I think this picture was also used in a legitimate way. It does not seem to me that its use necessarily implied that this picture was taken at one of the hospitals referred to in the programme; but even if it did, it does not seem to me that this would have been seriously misleading, suggesting as it did that this was a fairly routine method of delivering medication. And although the script gave the impression that children may have found the use of the tube distressing, I do not think it implied that its use was either unethical or inhumane. I am therefore not upholding this part of the complaint.

The assertion that the children of the HIV-positive mother Christine Maggiore, who featured prominently in the film, were healthy and indeed "never sick" because she had refused to have them tested for HIV and by extension would deny medication if they were HIV positive. In fact, Ms. Maggiore's 3 1/2 year old

> ***daughter died of AIDS in spring 2005, as documented by the LA City Coroner's report (http://www.aidstruth.org/ejs-coroner-report.pdf)***

Notwithstanding what I have already said about the role of this particular case study in the film, I do not agree that it attributed the apparently good health of Ms Maggiore's children to her refusal to have them tested for HIV. Whatever, tragically, may have happened to her daughter after the film was broadcast has no bearing on whether what was broadcast was itself justified. At the time, the children were apparently in good health and the programme-makers had no grounds for believing otherwise. I cannot uphold this part of the complaint.

> ***The implication that only economically and socially vulnerable children would participate in clinical trials. Vera Sherav, a self-described advocate for human subjects, rhetorically asks in the film, "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." In fact, the medications offered were, at that time, only available through clinical trials and were—and still are—the "current best treatment."***

The complaint seems to imply here that children who were socially or economically disadvantaged were used in trials where children from more secure backgrounds would, or could not be used.

In response to this the programme-makers said:

> *By definition trials with placebos can't be best treatment and the wide-ranging nature and combinations of tests point to the hunt for best treatment not best treatment in itself. Best treatment for any one child on the tests could just as likely be no additional drugs while the search for best treatment was conducted elsewhere. The point is that with no parents in situ and a suspect consent and advocacy regime these children were forced to be the test bed while others weren't.*

I think they have a point in that, almost by definition, with children receiving different drugs or combinations of drugs, and some on placebo, they cannot all be receiving best treatment. What was needed at this point was a voice explaining the medical importance of trials involving children, and this shortcoming has been acknowledged by the programme-makers. However, having said that, I did not take from the film that the authorities acted cynically in just selecting under privileged children for dangerous trials that they would not be able to conduct on any other child subjects. I am not upholding this part of the complaint against the programme or the website article.

Your complaint describes at some length contact between Jamie Doran and ICC, which, it seems to me, resolves itself into a complaint that Jamie Doran, and hence the programme, had a biased agenda. I am summarizing this part of your complaint as follows:

The programme was biased towards the views of "AIDS denialists".

As I have already said, the main thrust of this film was the way that these drug trials were conducted with insufficient regard for the interests and rights of the children who were being enrolled. Having said that, there is no doubt that the allegations were rendered even more serious by the unchallenged background suggestion that the trials were both futile and dangerous. This impression was created by the use of expert testimony and specific case studies where this view was spelled out, without any countervailing view being offered. These views thus took on the appearance of uncontested truth.

The two interviewees who put this case most forcefully were Dr David Rasnick and Christine Maggiore. Dr Rasnick, as I have already noted, made sweeping claims about the efficacy of these drugs and the likelihood of serious side effects that would be challenged by more mainstream medical opinion. Ms Maggiore endorsed this viewpoint, albeit from a lay perspective, when she said:

> *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.*

Both Dr Rasnick and Christine Maggiore are publicly associated with a school of thought that believes that anti-retroviral drugs are not effective against HIV and that, in any case, HIV infection does not lead to AIDS. This school, which you call "AIDS deniers" and they call "AIDS dissidents", opposes mainstream medical opinion and is a minority view. Dr Rasnick was a member of the panel of experts convened by South African President Thabo Mbeki and was a signatory to a minority statement which asserted that:

> *1. AIDS is not contagious although many of the opportunistic manifestations are,*
> *2. AIDS is not sexually transmitted,*
> *3. AIDS is not caused by HIV,*
> *4. The admittedly toxic anti-HIV drugs are killing people,*
> *5. The drug induced toxic effects are causing AIDS-defining conditions that cannot be distinguished from AIDS.*

Dr Rasnick is also senior researcher at the Dr Rath Health Foundation in South Africa, which endorses these views and promotes multivitamins to offset the effects of AIDS.

Christine Maggiore, who has campaigned against mainstream HIV/AIDS health policy for more than a decade, also disputes the causal link between HIV and AIDS, arguing that AIDS is caused by lifestyle choices such as promiscuity and drug use, and that anti-retroviral drugs have caused many of the deaths attributed to AIDS.

The programme-makers told me that Jamie Doran was aware of Dr Rasnick's background but that:

> *...he was justified in using him as he restricted him to describing side effects many of which are listed on the drug packaging. Side effects which refer of course to adults. However there is no doubt his language is coloured and the way in which he is introduced is inadequate.*

I have already pointed out that, even in listing the side effects of drugs, Dr Rasnick is controversially sweeping, and would be challenged by more mainstream opinion. But I think this concession by the programme makers (which is the one I referred to earlier) does recognize that there were shortcomings in the way that Dr Rasnick was used. The failure to inform the viewer about his particular point of view and how it related to the existing state of medical knowledge and opinion was a serious mistake. It led to significant bias being introduced into the film, in particular in fostering an impression that the tests were not just being carried out in an insufficiently regulated fashion, but were also futile and dangerous. No indication was given that these claims would be strenuously challenged by more mainstream expert voices. And while Ms Maggiore was not an expert witness in this respect, her contribution only served to amplify and reinforce this impression. For that reason I am upholding this part of the complaint.

A summary of my findings together with a note of the action taken as a result of this decision will be published in due course on the complaints page of the BBC website at bbc.co.uk. I will notify you when this has happened, and in the meantime I hope you will accept my apologies, on behalf of the BBC, for the deficiencies we found in the programme and the associated website material.

Yours sincerely

Fraser Steel

Fraser Steel
Head of Editorial Complaints