The tests were part of what the Washington Daily News has found to be a pattern of clinical research with humans, but possibly more important, they may depict the impotence of regulations in the field.

The trials with the drugs were conducted nearly 16 years after an international tribunal had set the norm that humans must volunteer to take part in medical experiments and months after this norm was codified by the United States, yet the Welfare Department physicians did not seek individual consent from the patients involved.

Then further down:

Welfare medical director Dr. Jack Kleh claims drug tests did not undergo the department's review policies because they were "controlled by the Food and Drug Administration and was, therefore, in the scope of responsibility of the research committee." Yet a FDA spokesman claims that they only "monitor" such tests and the burden of obtaining releases from patients is placed squarely on the drug company involved and the physicians it engages to conduct the tests. Dr. Kleh reports these two drugs were handled by Welfare Department doctors.

Now, I understand that in orphanages, children—at least occasionally—are used for human experiments. What I would like to know is how does this problem of informed consent apply to elderly patients in institutions or to children?

Dr. LEY. The consent in this category of elderly patients and children is a difficult problem. If you turn to section 130.37 of our regulations, we have a definition of consent which means that a person involved has legal capacity to give consent and so situated as to be able to exercise free power of choice and is provided with a fair explanation of pertinent information pertaining to investigation of drug, et cetera.

Obviously, this definition does not apply to the case of children or to persons who might be not in full possession of their mental faculties. This is a very serious and controversial area of discussion among medical investigators today. There are many studies that should be done in children if children are to receive the drugs which are available to the adult. Under normal circumstances, the guardian of the child has the right to provide consent for participation by the child in such studies. Similarly, in the case of a person who is incapacitated, senile, or otherwise not mentally capable of giving consent, the guardian or nearest relative would have this power to grant consent for investigational study.

Mr. GORDON. Dr. Ley, who is the guardian of, say, a retarded child in an institution?

Dr. LEY. This would depend upon the situation. If the child's parents are alive, I believe the parents would be the legal guardian. I would have to turn to counsel for further comment on it.

Mr. GOODRICH. That would vary from State to State, Mr. Gordon. In some instances, the superintendent of the institution would be the legal guardian; in other instances, the director of welfare. But in all instances, there would be someone who would be the legal guardian.

Mr. GORDON. But the point here, I think, or at least one of the points is that the relationship between a parent and his or her child would not be the same as a legal guardian to one of his wards, say a superintendent of an institution. I do not think he would have that love or feeling toward the child. The situation is quite different, I think.

In another article in the same series, a doctor claims that there is a widespread practice of using institutionalized patients and indigent persons in public hospitals to try out medical techniques which physi-