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with the sisters who own the hospital.
The final authority on medicomoral matters is not the administrator or the board of Directors, but the local bishop.

No Retreat

The encounter then is imminent. I see no hint that the bishops are about to retreat from their position of total opposition to sterilization. Dissenting and abstaining bishops in the 1971 vote are more likely to have now joined the vast majority because, among other things, they have had the opportunity to review their medicomoral principles during chats with John Cardinal Wright on their recent trips to Rome.

The bishops have their choice of offering women an alternative which is not as certain but just as safe as tubal ligation. They could offer their gentle, guiding hand, covered with the velvet glove and insist that all Catholic women throughout the country attend Billings type ovulation-temperature classes in a massive program. There is precedence for this in their insistence that all engaged couples attend Cana instruction classes before they marry. Their other alternative is the iron fist approach, as they have been with abortion, declaring automatic excommunication for any woman and perhaps any physician who participates in sterilization.

They could also smooth the velvet glove and strike with the iron fist simultaneously.

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The Willowbrook Experiments

Eugene F. Diamond, M.D.

At a recent meeting of the American College of Physicians, there was a student protest during the bestowing of the James D. Bruce Memorial Award on Dr. Saul Krugman for his research on hepatitis at the Willowbrook School in New York. This was the latest incident in an ethical debate which has followed the revelation in 1971 that Dr. Krugman had deliberately injected retarded children at Willowbrook with an active strain of hepatitis virus as part of an experiment directed toward the development of active and passive immunization against serum hepatitis.

Willowbrook is the world's largest institution for the mentally retarded, housing some 5,200 patients in a sprawling complex of twenty-seven buildings on 400 acres of Staten Island. The current census is actually down from a peak of 6,250 and there is evidence that the current administration was striving mightily to improve conditions under the usual conditions of overcrowding and understaffing which the American citizenry has tacitly accepted as standard for the care of the mentally retarded in most states. The spotlight of a press expose was, however, focused on Willowbrook's incredibly

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In this article, Dr. Diamond considers the ethical points raised by research on the prevention of viral hepatitis at the Willowbrook school in New York — specifically experiments involving injection of childrenmates with an active strain of hepatitis. Although a number of points are considered, Dr. Diamond notes that the central issue is the "right to perform a dangerous experiment on an individual when no benefit can accrue to that individual."
deplorable conditions and allegations of “human warehouses” and “Bedlam in 1972” became daily headlines in New York and throughout the country. It was against this background of not inappropriate emotionalism that Dr. Krugman’s studies were evaluated. The issues raised, however, are cogent and of crucial importance particularly in view of the current medical and experimental climate.

A French-sponsored resolution in the U. N. General Assembly on December 20, 1971, stated that “The mentally retarded person has to the maximum degree of feasibility the same rights as other human beings”—i.e., the right to proper medical care, economic security, legal safeguards, a meaningful occupation, freedom from abuse or abridgment, and all other assistance necessary to enable him to develop to his maximum potential. A series of United States court decisions in recent years have underscored the need for a “bill of rights” for the retarded in this country. In the 1965 St. Elizabeth’s Hospital Case in Washington, D. C., it was ruled that the retarded must be “cared for and trained, not just kept in custody.” This standard was also applied in the Pennhurst Case in Pennsylvania in 1971. In an Alabama case, Federal Judge Frank Johnson held that these rights “are present ones and must not only be declared but secured at the earliest practicable time.”

Three recent class-action suits on behalf of residents of Belchertown State School in Massachusetts, Willowbrook in New York and Willow School in Alabama have had the effect of circumventing state legislatures to make better care for the retarded a direct judicial mandate.

There is, of course, absolutely no evidence that Dr. Krugman in any way condoned conditions at Willowbrook. (The allegation that he was “racist” because of the predominance of black and Latin residents at Willowbrook is likewise spurious and unfounded.) There is evidence that Dr. Krugman was motivated by humanitarian considerations especially in his original work at Willowbrook using the measles vaccine. As a result of this program, measles was completely eradicated at Willowbrook with no single case having been reported there since 1963. The work of the Krugman group on the natural history and prevention of viral hepatitis at the Willowbrook School has been impressive since 1956. Twenty-five thousand serum specimens were studied to clarify the incubation period, natural history, and effectiveness of gamma globulin prophylaxis on hepatitis. The discovery of Australia antigen by Blumberg and associates opened a new era in hepatitis research. It was shown at Willowbrook that hepatitis associated antigen (HAA) was consistently present in sera from patients with serum hepatitis. (MS-2) but was not present in sera from patients with infectious hepatitis (MS-1). Since gamma globulin prophylaxis was effective only against MS-1 hepatitis, experiments were undertaken to find a method of prophylaxis against MS-2 hepatitis which has been endemic at Willowbrook since 1949. Contrary to some prevailing views about serum hepatitis, it was shown that MS-2 hepatitis is transmissible by mouth as well as by the parenteral route.

Studies on active immunization were published in July, 1971. The infectivity of an MS-2 serum was established by inoculating varying amounts of the serum into 25 susceptible children. The attack rate was 100% based on the appearance of Hepatitis Associated Antigen, or 96% based on the development of abnormal SGOT levels. A second group of children was given the MS-2 serum after one or two injections of a boiled, inactivated preparation of a 1:10 dilution of MS-2 serum in distilled water. Active immunization was induced and prevention or modification of hepatitis was accomplished. All four of the children who received two injections were protected. Of the children who received a single injection, four were protected and six developed a modified hepatitis.

Justification for the experiments was that it was considered inevitable that susceptible children would be infected in the institution. It was alleged that artificial induction of hepatitis implied a “therapeutic” effect because of the immunity which is conferred. Written consent was obtained from all parents of children involved in the study. The means by which this becomes an “informed” consent are described in detail. The sequence was: 1) The project was discussed with parents in an interview with a psychiatric social worker. 2) A group session was held at the institution with the entire study group present, including the physicians, to explain the study in detail. 3) The family physician was consulted by parents. 4) Consent was obtained but could be withdrawn at any time. 5) No child without parents or who was a ward of the state was innoculated.

Similar experiments in passive immunization with a high-titer type specific Hepatitis B immune serum globulin were later conducted. This method proved to be 70% effective in protecting against disease after injection of the MS-2 serum.

Editorial comment in the Journal of the American Medical Association 16 and Yearbook of Medicine 17 was uniformly complimentary. It was not until Lancet 18 commented editorially that the ethical issues were delineated. What about the rightness of attempting to infect mentally retarded children with hepatitis for experimental purposes? Letters to the editor of Lancet by Goldby 19 and Shapiro 20 were sharply critical of the experiments. Dr. Krugman was given the opportunity to reply and did so, 21 again alluding to informed consent and the inevitability of institutional infection with MS-2.

The central ethical issue raised by these experiments is whether it is right to perform a dangerous experiment on an individual when no benefit can accrue to that individual. In this context, a child obviously requires more protection
than an adult and a mentally retarded child requires more protection than a normal child. The issue of informed consent is germane, but not determinative. The Krugman group points out that, in their opinion, their study conforms to the World Medical Association Draft Code of Ethics on Human Experimentation. While it is true that The Draft Code does approve of the measures used at Willowbrook to obtain informed consent, it does so only when the experiments conducted produce a therapeutic result for the individual child involved. If, on the other hand, the experiments are construed to be "solely for the acquisition of knowledge" then the code states: "Persons retained in mental hospitals or hospitals for mental defectives should not be used for human experiment." Surely the part of their experimentation carried out to determine the infectivity of the MS-2 serum was "solely for the acquisition of knowledge" since the development of immunity as a result of deliberate infection cannot legitimately be called a "therapeutic" effect.

Likewise the claim by Krugman, that the success of his experiments among those children who were deliberately challenged after being given heat-modified serum and hyperimmune serum globulin, proves a therapeutic effect is open to serious question. A therapeutic effect cannot be claimed retroactively or post-facto when a deliberate administration of infected serum has been carried out. It certainly cannot be claimed for those who were infected in spite of grave or passive immunization as it cannot be claimed on the basis of the inevitability of infection by an endemic organism.

The peculiar position taken editorially in the Journal of the American Medical Association deserves special mention. The position taken there apparently is that since the experiments were successful they were ipso facto ethical. Here we do not see the old moral fallacy of the end justifying the means, but a new imperative which says that success justifies the means. The inference is that the measures used would or be unethical if they failed to work. This advocacy of an utterly pragmatic standard of ethics is ancient but unmistakable trend in the public posture of the American Medical Association. It is reminiscent of the "what is good is ethical" position taken on abortion in 1970.

It would seem obvious that, for the individual child involved in the Willowbrook experiments, no solid claim of therapeutic benefit could be made in advance of the studies. The studies, therefore, at least violated a time-honored principle of primum non nocere. It is also obvious that therapeutic benefits will have resulted both to other residents of the Willowbrook School as well as society at large if an effective hepatitis vaccine becomes available. As dramatic and as salutary as the possible elimination of hepatitis may be, it is by no means clear that it was not achievable by an experiment constructed in some other way. Other vaccines have been successfully evaluated by the more painstaking and time consuming methods involved in studying large populations at risk. Even if this were the only method of finding a means for active and passive immunization against hepatitis, it still could not be justified since the end does not justify the means. Since the experiments may conform to the letter of the World Medical Association Draft Code of Ethics on Human Experimentation, the need for the updating of the Code is demonstrated.

REFERENCES:


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