Editorial

Protecting Children and Society

by Leonard H. Glantz, J.D.

In his thought provoking article in this issue of MEDICOLEGAL NEWS, Edward Porcaro argues that one should never conduct non-therapeutic research on a child unless the child gives informed consent. This approach essentially outlaws all research on young children. Although he is in good company in making this argument,[1] it raises many questions, the primary one being the social cost of such a policy.

The most recently proposed rules on research involving children promulgated by the Department of Health, Education and Welfare,[2] attempt to balance the conflicting concerns of medical progress and children's rights. Institutional Review Boards [IRB] are given additional tasks, such as making sure that children are not used as subjects until there have been adequate studies performed on animals and adults. The regulations then divide biomedical research into that which involves minimal risks and that with greater than minimal risks. Minimal risk is defined as "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy children."[3] If the child "assents," and the parents give their "permission," research involving such minimal risks may be done.

Research involving greater than minimal risk and holding no prospect of direct benefit to individual subjects may also be performed if the IRB finds that the research is appropriate, the child and his or her parents agree to the child's participation, and:

1. The risk represents a minor increase over minimal risk;
2. The intervention presents "experiences" reasonably commensurate with those inherent in the child's actual or expected medical, dental, psychological, social, or educational situations; and
3. The intervention is "likely" to yield generalizable knowledge about the subject's disorder or condition which is of "vital importance" in understanding the amelioration of the disorder or condition.[4]

The Secretary of H.E.W. may permit even riskier research in certain circumstances.[5]

Individual IRBs are to determine if the children-subjects are capable of giving "assent."[6] This may be done on a group or individualized basis. However, if the IRB determines that the child is not capable of assenting to the procedure, the research may still be done. In such a case, the IRB "may" appoint an "advocate" for the child whose role is to "advise" the IRB, the parents, and the investigators of any concerns the advocate may have about the child's participation.

It is interesting to note that under these rules, no one actually "consents" to the research. Parents give "permission" and children "assent." Additionally, when the child cannot assent, the research may be done anyway, and the IRB has great latitude and little guidance in determining which children are capable of "assenting." Like any compromise solution to a difficult problem, the proposed regulations cause some discomfort to both sides.

There are many questions that need to be answered before we will be comfortable with either Mr. Porcaro's or H.E.W.'s proposals: When are children capable of understanding the facts necessary to give or withhold their consent or assent? At what point in the average child's life does the child understand the concepts of risk, harm, altruism, benefit, etc.? Our colleagues engaged in child development should be encouraged to help us resolve these questions.

Lewis, *et al.* have started this process by conducting a study in which children between the ages of six and nine were given the opportunity to refuse to consent to a trial of the Swine Flu vaccine.[7] The nature of the study was described to a classroom of children, and they were told that if they indicated that they did not wish to participate in the study that their parents would not be contacted. If they could not decide, they were advised that they could share the decision-making with their parents. Thus, only the parents of children who answered "yes" or who were uncertain received a letter explaining the study and asking for their consent. During the question and answer period with the researchers, the children verified that the study would require shots, asked about side effects, how soon and how likely they would occur, why blood samples had to be taken, whether the side effects would be so severe that they would have to miss school, whether the vaccine had been tried before, what would happen if they got the flu, and whether the investigator had taken the vaccine. Fifty-four percent of the 213 children involved answered either "yes" or that they wanted their parents to help them decide. Younger children more often declined to consent than older children. This study appears to indicate that relatively young children, in a situation where they have peer support and are not overwhelmed by either parental or researcher authority, are capable of at least asking the right questions. Interestingly, the children were more willing to cooperate than their parents were to let them participate. Of the parents who received a letter, only 15 percent permitted their child to participate: the parents were more protective of their children than the children were of themselves.

Another unanswered question is what authority do parents have over their children, and to what standard do we hold parents? This question applies not only to non-therapeutic research, but to a whole variety of activities. For example, when may a parent refuse to consent to medical treatment of a child, what types of parental inaction constitute child neglect, and may parents

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"voluntarily" institutionalize their child in a mental hospital against the child's will? Parental authority is undergoing re-examination and the lack of a clear understanding of the boundaries of parental authority makes the determination of a parent's right to consent to non-therapeutic research difficult until some consensus is reached by society.

Mr. Porcaro argues that parents are required to act in their children's "best interests," and this standard is widely voiced by both the courts and many commentators. It is, if literally interpreted, however, an unenforceable ideal, and a bit of an aberration among legal standards. It is difficult to think of another situation where the law requires a standard involving "the best." Usually the law only requires people to act "reasonably." We do not require parents to be the "best" parents, or send their children to the "best" school, or obtain the "best" medical care for their children. We usually require parents to provide reasonable or even merely adequate care.

A similar point has been made in *Beyond the Best Interests of the Child*.[8] The authors discuss the issue of child custody decisions, and the fact that courts usually utilize the "best interests of the child" standard in making custody decisions. The point the authors make is that when a sufficiently tragic set of events occurs, so that a court is put in the position of making a custody decision, acting in the "best interests" of the child becomes a true fiction. They suggest that it would be more realistic for courts to use "the least detrimental alternative" standard, since the best that can be hoped for in a custody case is that the child will be harmed as little as possible.

Further, the "best interests of the child" standard does not reflect the reality of the parent-child relationship. We let parents consent to their 16-year-old playing high school football even though that is a situation fraught with serious risks. We let parents purchase bicycles for their children, even though thousands of children are killed or seriously injured on bicycles each year. Parents can corporally punish children, send them to their rooms without dinner, or send them off to boarding or military schools for whatever reasons they wish, and we never question these parental actions until they become *unreasonable, i.e.*, the corporal punishment is *unreasonably* severe, or the deprivation of food is *unreasonably* prolonged. It seems to me that a similar standard can be used in the area of parental consent to non-therapeutic research when the child is too young to consent or assent. Indeed, this standard was set forth in a bone marrow transplant case, *Nathan v. Farinelli*,[9] where the court was asked to put its imprimatur on the decision to take bone marrow from a healthy child in order to try to save the life of a sibling. The court found that no benefit to the donor could be established, but held that as long as the parents' decision was "fair and reasonable," it should be allowed to stand. However, since there might be a "conflict of interest" — the parents must consent to the removal of bone marrow from their healthy child to save their terminally ill child — the court continued the tradition of reviewing the parents' decision.

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It seems to me that the "fair and reasonable" standard has a place in non-therapeutic research. First, the parents are not in a conflict situation if neither they nor their children receive any benefit from the research. Thus, the parents must be offered *no* reward nor threatened with any loss. This frees the parents to focus solely on protecting their child. Second, an IRB and the funding agency should make findings about the appropriateness and importance of the research, the absolute necessity for the use of children-subjects, and the other criteria set forth in the proposed regulations.[10] Included in this review would be a finding that it would be "fair and reasonable" for a parent to consent to the proposed procedure. Third, where there is any risk involved, at least one parent should be present to witness the research procedure. If it's too disturbing for them to watch, then it's too severe for it to be done on their unconsenting child. Additionally, this gives parents the ability to exercise their right to withdraw consent to the procedure at any time should they so desire.

It is important that work similar to Lewis' go on so that we can realistically assess the ability of young children to consent or refuse to participate in biomedical research. When that age was set at seven in previously proposed regulations, many people moaned. But Lewis' work suggests that setting a rebuttable presumption of an age when children can refuse to participate somewhere around seven makes sense. By setting that age rationally we not only give the child the right to say no, but we also give credibility to the child who says yes.

Neither absolute prohibition nor absolute power to decide is a satisfactory resolution. The resolution lies somewhere in between, and that's what makes the problem so tough.

References

1. *See e.g.*, Ramsey P, *The Enforcement of Morals: Non-Therapeutic Research on Children*, HASTINGS CENTER REPORT 6(4): 21-30 (August 1976).
2. 43 FEDERAL REGISTER 31786 (July 21, 1978).
3. *Ibid* at 31793 §46.403 (j).
4. *Ibid* at 31793-94 §46.407.
5. *Ibid* at 31794 §46.408.
6. *Ibid* at 31794 §46.409 (a).
7. Lewis, Lewis and Ifekwunigue, *Informed Consent by Children and Participation in an Influenza Vaccine Trial*, AMERICAN JOURNAL OF PUBLIC HEALTH 68:1079 (November 1978).
8. Goldstein, Freud and Solnit, BEYOND THE BEST INTERESTS OF THE CHILD (The Macmillan Co., New York, 1973).
9. Nathan v. Farinelli, No. 74-87 (Mass. Eq., 1974).
10. 43 FEDERAL REGISTER 31793 §46.404 (a).

COMING IN THE NEXT ISSUE OF MEDICOLEGAL NEWS

- Massachusetts Supreme Judicial Court Justice Paul J. Liacos, the author of the renowned *Saikewicz* decision, breaks precedent and publicly comments on the decision, its history, and his feelings of the decision's aftermath. The speech is referred to following the Conference Report in this issue of MEDICOLEGAL NEWS, *see* page 11.
- *The National Medical Program Development Project for Workers' Compensation: A Professional Challenge for Law and Medicine*, by Stephen S. Leavitt, M.D.
- The much expanded Medicolegal Reference Shelf, *see* the introduction to this issue's segment on page 18.

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