

proval to proceed is granted. One purpose of this special care is to further insure proper informed consent of patients electing to participate in gene therapy experiments. FDA also has the authority to oversee the adequacy of informed consent in clinical experimentation involving new therapeutic products, and this might include gene insertion technologies (Esber, 1984).

One special aspect of human gene therapy, the potential for wide publicity, may merit attention in the process of securing informed consent. Widespread interest in human gene therapy among scientific, religious, and government leaders in advance of its successful application suggests that the early clinical trials will be sub-

ject to potentially intrusive publicity. It is unlikely that government oversight bodies can assure the privacy of subjects who agree to participate in gene therapy experiments, and so acknowledgment of this risk may be necessary by investigators before commencing. Investigators may also need to anticipate responding to the demand for media information by developing mechanisms for channeling interest through hospital spokesmen, preparing families to deal with the press, and careful observation of privacy safeguards. The risk of media exposure is part of the process of informed consent, because this may prove to be the salient difference between gene therapy and other experimental medical techniques.

## Issues that may arise from clinical application

If gene therapy moves through the early stages of development and reaches the stage of standard medical practice, several medical issues may emerge. None of these is different in kind from issues arising in connection with other medical technologies, but the context of the new problems would be different.

### ***Medical malpractice***

Issues related to malpractice may be raised by gene therapy if it develops into a routine medical technology. Physicians could be sued, for example, for failing to treat a genetic disorder. A patient who suffered an untoward side effect because of genetic changes induced by gene therapy might also bring suit. What would the standards of care for this technique be?

Several medicolegal issues might enter into assessments of liability and responsibility. It is not clear, for example, who would be qualified to employ the sophisticated techniques of gene therapy if it were to become standard medical practice. Should all physicians do it? Only those certified by the American Board of Medical Genetics, the National Board of Pediatrics, the Hematology and Oncology subspecialty board in internal medicine, or the American Board of Obstetrics and Gynecology? Should gene therapy take place at

all hospitals, or only in certain ones? Who would practice gene therapy, and where, may well be determined by decisions made by the court system, State and local Governments, national medical specialty boards, and other medical and legal organizations.

### ***Parental responsibilities***

Parental views on religion and medical practice, including those that might preclude even somatic cell gene therapy, might pit the beliefs of parents against standard medical practices. Many court decisions about whether to allow blood transfusions to children of parents who reject such treatments on religious grounds exemplify this kind of conflict. Some legal scholars have even contended that parents who fail to intervene on behalf of the health of their children might be forced to do so. In one recent case, a woman who objected to cesarian section on religious grounds was compelled to undergo the operation to preserve the life of the fetus (Lenon, 1983; Finamore, 1983). If gene therapy were widely available and standard medical practice, analogous conflicts might arise.

Whether medical practitioners, courts, institutional committees, or parents decide on who is treated will depend on how gene therapy and