

the doctors' dilemma

"No single individual should be asked to play the role of both scientist and doctor."

This, from a physician, is less a plea for protection of the patient from irresponsible experimentation than an expression of concern for the almost insufferable burden a physician must bear when applying unproven techniques in a desperate attempt to save a life.

What brings this to mind, of course, is the recent series of experimental heart transplants, in the wake of increasing success and promise for other human organ transplants.

If the experiments had been on drugs rather than on surgical techniques, the burden of the dual role faced by Drs. Norman E. Shumway, Christiaan Barnard and Adrian Kantrowitz, in the most recent series, would not have to have been borne. In the United States, at least, the administration of experimental drugs to human subjects is rigidly circumscribed with regulation; in the life or death situation faced by the transplant recipients, the administration of a drug as untried as are the surgical transplant techniques would have been illegal.

Surgical experimentation, however, is not illegal. It falls into the gray area uncovered by law. It is governed instead by the conscience of the practitioner, the informed consent of the patient, the vigilance of the medical community and a series of codes developed in the wake of the horrors of Nazi experimentation bared at the Nuremberg trials.

These, necessarily, vary as widely in their ability to protect patients as they do in their ability to guide clinical investigators and protect them from lawsuits.

"A clinical investigator," says Georgetown University's Dr. George E. Schreiner, "walks where others fear to tread . . . and must take full responsibility for his professional decisions."

But it is a responsibility that should be shared.

The society that benefits from research, as well as the research community that encourages it must accept responsibility for what happens when doctors step, as they sometimes must, beyond the state of their art.

The laws that regulate the development of drugs are an obvious model. But they are designed to regulate a private industry, and seem inappropriate to the creative practice of medicine that is the best clinical experimentation.

Supervision of a researcher by his peers, guided by codes, is also proposed as adequate. But as recently as last February, Surgeon General Dr. William H. Stewart had to order that all institutions receiving research grants from the Public Health Service for clinical research must set up such panels.

More human experimentation seems inevitable in the foreseeable future.

Not only surgeons, but psychologists, pharmacologists and the developers of artificial organs, parts and aids are coming more and more to recognize that extrapolation to man of the results of animal research is less than satisfactory. Some things can be learned only from humans.

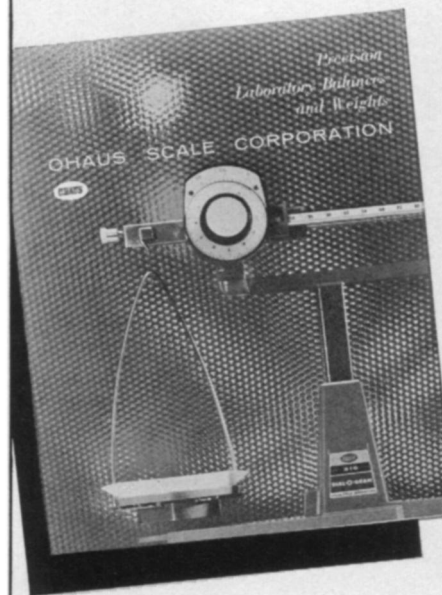
That decisions in this area should continue to be the responsibility of the courageous—or reckless—investigator, his institution's administrators and his willing—or uninformed—subject is unthinkable.

A public—or governmental, if you will—formulary committee has been proposed to determine the acceptability or comparability of drugs released to the public. This would supplement the voluntary formulary committees already operating in many hospitals.

Is it now necessary that the burden of responsibility clinical investigators and research institutions currently take upon themselves should be shared by the society they serve, through a similar supplementary technique? And is it possible to establish such public review while, at the same time, protecting research from a stultifying level of regulation?

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