Correspondence

Patient Consent

To the Editor: The statement concerning patient consent attached to the paper "Measurement of Anti-Arrhythmic Potency of Drugs in Man: Effects of Dehydrobenzperidol" (ANESTHESIOLOGY 28: 318, 1967) presents a remarkable new interpretation of an investigator's responsibilities. It departs so sharply from the traditional view that I beg leave to quote the statement in its entirety:

"The problem of obtaining valid consent always exists in an experiment performed on human beings. Despite the fact that all of our subjects were interviewed before the study and the procedure explained, we believe that an informed consent cannot be obtained for a study of this type, because of the impossibility of transmitting to a patient both the relevant information and the *background* needed to analyze and evaluate such information. Instead, *we have accepted the role of guarantor of the patient's rights and safety:* (1) only physical status I is acceptable; (2) inhaled cyclopropane concentration must not range beyond 20–30 per cent; (3) respiratory acidosis must be prevented; (4) starting dose and rate of administration of epinephrine must be the minimal one, 3.6 μg./minute in these experiments; (5) the infusion is terminated when an arrhythmia appears."

In my opinion, the problem of obtaining a patient's valid consent for experiments on his or her person is not solved by an investigator who side-steps the problem and, instead, assumes "the role of guarantor of the patient's rights." To begin with, there is an obvious inconsistency between the claim to guarantee the patient's rights and the failure to honor the foremost of those rights, the right to exercise informed consent or dissent. A guarantee of this sort is nugatory. Further, the role itself implies infallibility, as if the investigator can always guess correctly whether the patient would consent to the procedure if she fully understood the nature of the experiment.

Neither is it possible for an investigator to guarantee the patient's safety. A physician cannot guarantee the outcome of an experiment he performs on a patient; he can reduce the risks or render them negligible, but he cannot eliminate them. Indeed, this is one of the reasons for the common rule that at the start of a new study the experimenter himself goes first, followed by his colleagues. But the question at issue is not really whether the experiment is safe, the question is, does the patient want to have it done?

Investigators, however conscientious, do not have the right to infringe the prerogative of the subject to exercise informed consent. The patient, it is universally held, is entitled to make his or her own decision and, if an informed decision demands rather a lot of information, the investigator is in duty bound to take the trouble to impart it.

I have deliberately refrained from commenting on other ethical aspects of the experiiments performed by Long, Dripps and Price. I contend that what is at issue is not the opinion of the investigator or reader about the merits of an experiment. What is at stake is the ordinary patient's right to her own considered decision concerning projected experiments on her person, and to the information necessary to make such a decision. If the information cannot be given, the experiment should not be carried out.

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To the Editor: Thank you for the opportunity to reply to Dr. Fink.

The ethics of "human experimentation" is receiving much attention. We have been involved in this for almost three decades and think that we have developed a responsible, but practical approach.