Correspondence

More on Patient Consent

To the Editor:—In a recent publication in ANESTHESIOLOGY on "Measurement of Anti-Arrhythmic Potency of Drugs in Man: Effects of Dehydrobenzperidol," Long, Dripps and Price (ANESTHESIOLOGY 28: 318–323, 1967) have said,

> 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:* . . .

This statement comes from distinguished and senior members of a renowned university and requires attention. Theirs is such a revolutionary approach to the complex problem faced by all clinical investigators that I have taken some months since publication to mull it over, and, having come to some conclusions about it, request an opportunity to reply.

In the first place, since there is no indication to the contrary, one can only assume that the Editor and the Editorial Board, or at least a majority of those on the Editorial Board, approved of the authors' statement. (One can hardly assume that as revolutionary a statement as the one under discussion could have been published by the Editor supported by a minority of his Board, unless this were plainly stated.) This in itself is rather remarkable, for in sounding out a number of experienced investigators, I have not found a single one who agreed with the authors.

Second. The statement in question is not in accord with the law: See the Kefauver-Harris amendments to the Federal Food, Drug and Cosmetics Act of 1962, and the rulings of the National Institutes of Health, which have the effect of law. Notwithstanding, the authors say, "Instead [of informed consent] *we have accepted the role of guarantor of the patient's rights and safety.*"

Third. Granted that "fully informed consent" is a chimera, an impossibility, in many instances—probably it is in the majority of complicated studies—a point I have emphasized for years; I have also emphasized over these same years that informed consent is a *goal toward which we must strive* for ethical, sociological, and legal reasons. This is not an empty gesture, for in our striving for valid consent, the subject is alerted to the fact that he is to be a participant in an experiment. (In more than 500 well documented clinical examples this has not been the case.) This point would probably not have as much relevance in the case of volunteers as in patients subjected to experimentation not for their direct benefit; however, the honest striving for an informed consent even with volunteers would undoubtedly best bring to the volunteers' attention the hazards involved, insofar as these are known.

Fourth. I would not agree, and I believe I share this view with many others, that the deliberate evocation of ventricular extrasystoles is a safe thing to do. There is much evidence that when ventricular extrasystoles appear, ventricular fibrillation is in some cases not far behind. It is not always possible to restore a heart with ventricular fibrillation. The procedure carried out is, therefore, not without serious danger.

Fifth. In more than 35 years of experimentation in man, one of the clearest lessons to emerge from this experience is that patients will usually agree to participate in experimentation, if their doctor approaches them agreeably and asks them to do so, so long as

only discomfort and inconvenience are involved, and provided these do not last very long. On the other hand, patients will never, repeat never, willingly agree to risk their health or their lives for the sake of Science alone, except in *rare* instances, such as in a man seeking martyrdom or as in the case of a Walter Reed, whose lonely exploit is still celebrated 66 years later. In the ordinary case when *post hoc* it is evident that the health or life of several subjects have been jeopardized, it is plain that they did not all understand what they had agreed to.

Sixth. Coming late into a discussion of these matters gives me what might be considered an unfair advantage in the present debate. But I am certain that what these investigators are after is the truth, and so am I; therefore, whether comments are made late or early is irrelevant: if they are sound they will stand; if they are not they will not survive. In this connection Dr. Fink (ANESTHESIOLOGY 28: 1109, 1967) has said,

> . . . 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.

I am puzzled by Dr. Dripp's statement to Dr. Fink that "The *majority* [italics mine] acquiesced to the proposed study." Did some *not* acquiesce? Presumably, they were not included in the experiment; but this is not clear.

Seventh. It is clear from reading the context and from personal knowledge of these responsible investigators that their intent is an honest facing up to what they conclude is an impossible requirement; but they have adopted a defeatist attitude. They in fact promise something they cannot guarantee, and if the subject believes this "guarantee" he is deceived, certainly not an intentional result, but nevertheless the result of their policy.

Eighth. An adoption of the paternalistic view recommended really leaves decision-making to the investigator, and what should be a joint enterprise between subject and investigator becomes a monopoly of the investigator unhampered by personal discussion with the subject as to his wishes and interests. The sky could be the limit—not in the case of these responsible, careful investigators—but with less careful and less scrupulous investigators, if the policy stated here were to be generally adopted. I think it should not be adopted.

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To the Editor:—Dr. Beecher misunderstands our interpretation of the word "guarantor." We use it in one of the forms given in Webster's *New International Dictionary,* "to give security," to promise the best care of which we are capable. This does not seem revolutionary and I am sure that his concern stems from the perhaps unfortunate selection of the word itself.

We think of the term as applying to our responsibility to the unconscious patient who obviously cannot himself stop a given study.

I wish I could contribute to the problem of the use of man as a subject. But at least I do not want to be thought of as illegal or irresponsible. For the record, therefore, may it be stated that:

(1) we do no studies on a patient without obtaining the patient's signed and witnessed consent;

(2) we try to make this an *informed* consent, for we too know that many patients will give consent readily when they trust or like their physicians;

(3) we believe it difficult to inform the patient completely, but try to do our best;

(4) we promise nothing other than the best care of which we are capable;

(5) we regard clinical investigation as a major responsibility, demanding the utmost in integrity.

I do not wish to discuss in this letter the question of the safety of the protocol, except to state that if good evidence existed that ventricular fibrillation were a possibility we would not have done this work on humans at all.