LETTERS

Nuclear Reactor Operators

The letter from Kenneth S. Pitzer (22 June, p. 1263) reflects a general public misunderstanding of the staffing and licensing of a nuclear power plant.

The concept of "reactor captain" and licensed reactor officers is presently used by the government. A detailed description can be found in the *Code of Federal Regulations*, Title 10, part 55, and part 55, appendix A. All nuclear power plants have two levels of licensed operators—senior reactor operators and reactor operators. These people are trained extensively in nuclear theory and plant operations. This knowledge is tested by written and practical examinations developed and given by the U.S. government. Constant review, additional training, and retesting is a way of life for the nuclear plant operators.

I commend Pitzer's opinion that this is the correct way to operate a nuclear power plant. His concept has been used for the entire history of commercial nuclear power.

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"Uninformed Consent"

Some reform may be needed in the procedure for gaining informed consent from "human subjects" asked to participate in an experiment, but the reasons advanced in "Informed consent may be hazardous to health," by Loftus and Fries (Editorial, 6 April, p. 11) obscure the fundamental issues.

The editorial begins with the noncontroversial statement that "before human subjects are enrolled in experimental studies, a variety of preliminary rituals are now required. . . . These rituals . . . came into existence because of a strong belief in the fundamental principle that human beings have the right to determine what will be done to their minds and bodies." Still, one wonders at the use of "ritual" in this connection, associated as "ritual" is with the notion of an idle exercise, empty of substantive import. It is true of course that when arresting officers inform arrestees of their rights, the officers tend to recite them like a catechism, but it would hardly be termed a ritual.

Having stated the principle, the authors go on to claim that "A considerable body of psychological evidence indicates that humans are highly suggestible. Information has been found to change people's attitudes, to change their moods and feelings, and even to make them believe they have experienced events that never in fact occurred." From this premise it is astonishingly concluded, "This alone would lead one to suspect that adverse reactions might result from information given during an informed consent discussion." The premise is remarkable for its understatement. It is common knowledge and not the science of psychology which tells us that if someone we trust informs us that our house is on fire and our children are burning, our moods will assuredly change; if someone we trust informs us falsely of such an event, our mood will also change and we may be made to believe something that never in fact occurred. The principle behind the informed consent procedure is not threatened by such facts; the subject has a prima facie right to determine what will be done with his or her mind and body in or out of an experiment, and the opportunity to make that determination is frustrated if information is withheld or deception practiced by the experimenter. How is a subject to decide rationally about participating in an experiment if information is withheld or he or she is being deceived?

We wonder at the relevance of the "dark side to the placebo effect" to the assertion that informed consent may be "harmful." If volunteer subjects are informed that they may or may not be getting a placebo and that placebos sometimes or occasionally have adverse effects, that information is required if they are to exercise their rights. They are entitled to the most complete information in deciding whether to participate or withdraw.

The editorial then proceeds to medical matters in support of the claim that informed consent is potentially harmful. It cites, for example, "hypotheses that heart attack may follow coronary spasm," which hypotheses "indicate physiological mechanisms by which explicit suggestions, and the stress that may be produced by them, may prove fatal." The authors conclude, "Thus the possible consequences of suggested symptoms range from minor annoyance to, in extreme cases, death." One expects (hopes?) that a subject with heart spasms who might die from being informed about possible further symptoms would not be asked to participate in experiments in which details of the experiment (whether given or withheld) are dangerous to his life and health. For that, after all, is what the editorial was about; the relationship between a *voluntary subject* in an experiment and the experimenter. It was not about the special peculiarities of the client-doctor relationship.

If one of us has a heart spasm we will very likely seek the services of a doctor, but not as an experimental subject. In contracting for those services we can expect that the doctor will do what he can to help reduce suffering and restore health. In consultation with a doctor, a client may even insist that there are some things he or she doesn't want to know, and the doctor may have some hard choices. But even in the doctor-client context the prima facie right to full information on matters which may affect our minds and bodies prevails. Balancing those rights against putative harms in that context is a delicate business which we need not go into since, as noted above, the editorial is about human subjects in scientific experimentation. The two contexts must be kept distinct and explicitly so even where they involve the same doctor and the same subject.

Finally, the most mischievous conceptual confusion is in the penultimate paragraph. It says ". . . the possibility of iatrongenic harm to the subject as a direct result of the consent ritual must be considered. This clear cost must be weighed against the potential benefit of giving some people an increased sense of freedom of choice about the use of their bodies." What is distressing is the failure to make the absolutely crucial distinction between rights and benefits, a distinction which is the cornerstone of our legal and moral system. When a police officer informs a suspect of his rights and how they might be exercised, he is not conferring a benefit. Borrowing the regional usage of the editorial, we find it "scarifying" that some experimenters on human subjects have less comprehension of such matters than the cop on the beat.

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Individuals vested in certain beliefs and unfamiliar with the nuances of a topic sometimes react to the subject of a discussion and not to its substance; this phenomenon is strikingly illustrated by the above letter. The respondents have characterized a statement strongly in favor of human rights as an attack upon such rights. Their response contains colorful but inaccurate rhetoric and a truly

novel theory concerning the predictability of heart attack. We welcome the opportunity to recapitulate our arguments.

We strongly uphold the right of individuals to determine for themselves what will be done to their minds and bodies. The basic right to self-determination, however, is threatened by two forces represented in the current "rituals" offered in the name of "informed consent." An informed consent ritual is an attempt to defend the underlying "right"; it is not in itself, either legally or ethically, a "right." It is justified *only* to the extent that it actually promotes self-determination. We very deliberately chose the term "ritual" to distinguish certain practices from the underlying "right" to self-determination. The ethical question with such "rituals" is whether or not they are the best possible ones to ensure that the "right" is protected.

The threats are these. First, institutional lawyers dictate the form of recommended consent forms, so that the forms become releases designed to protect the institution, not information designed to inform the individual. One has only to read a few such forms to note the legal language, the requirement for witnesses, and the obvious intent. We point out this happening, emphasize that it does not even protect the institution, and urge that the practice stop.

Second, those who have been formulating informed consent rituals have not paid sufficient attention to the injury that may be caused by the ritual itself. We point out, and our respondents agree, that harm may result from ill-considered offerings of "information." The harm may take the form of suggested symptoms, induced anxiety, panic-related accidents, or serious physiological reactions. The respondents would argue that all individuals have a right to this information, and that all must receive it. But does a right to harm people exist? The right of free speech has, in American legal and ethical thinking since Holmes, been specifically held to deny the right to cry "fire" in a crowded theatre. Thus, the action of unnecessarily evoking anxiety reactions which can lead to physical harm cannot be a "right"; it is this property of present informed consent rituals that we criticize.

The consent form is inescapably a part of the experimental procedure. If it has potential for harm, the subject must be warned against this possibility just as surely as against the other hazards of an experiment. Current consent form rituals constitute human experimentation, but

oddly enough they have not been subjected to as rigorous control as other forms of human experimentation. Who is going to watch the watchdog?

What, then, shall we tell our subject? "Full disclosure" is often naïvely equated with "full knowledge." In point of fact, more comprehension is generally achieved by transmission of smaller amounts of clearly stated information than by prodigious quantities of "fine print." "Full access" is a more reasonable approach, and is the one which we urge. For example, a consent form might in two or three sentences outline the experiment and accurately define the expected level of risk in terms of a universally understood referent. (As dangerous as . . . the drawing of blood, a tonsillectomy, an airplane trip.) The reverse of the form, or a separate booklet, a copy of which the subject would retain, could contain all additional information that might be desired.

Nothing should be withheld from those who wish to know it. Similarly, nothing should be forced down the throats of those who do not wish to know. For those individuals who choose to know all, there are numerous ways in which information about potential adverse side effects can be presented to them. Whatever way is chosen, it is wise to include a discussion of the placebo effect and its potential for adverse reactions, since this may mitigate the adverse effects. This recommendation, of course, is one of offering access to *more* information than is currently the custom.

We closed our editorial by noting that in some instances subjects might be at greater risk from their self-appointed guardians than from the experiment; it was precisely individuals such as our respondents that we had in mind. They would not allow the risks of informed consent to be considered; this, they say, is "mischievous." They reflexly defend actions alleged to be in defense of a fundamental right without considering whether such actions actually defend or threaten the right of individuals to determine what will be done to their minds or bodies. These obtuse advocates of full information unfailingly argue that "more is better"; they argue for protection of the subject even as their rituals increase that subject's peril. Human beings have a right to access to information that will affect them, but they simultaneously have the right to choose when they have had enough.

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