

Letters

Damaging Criticism

As *Science* so often and appropriately notes, the role of the scientist in public policy is growing rapidly. However, scientists as a class are not uniquely qualified to assess the sociological and political aspects of their contributions, and I am not aware of anyone who has mastered this assessment procedure so well that it can serve to provide relative values on scientific or technological advances in widely different fields. Our limitations are particularly conspicuous with respect to scientific endeavors of very large magnitude, where the marshalling of nationwide public support is necessary for success.

The late John F. Kennedy was acutely aware of the importance of inspirational national goals to stimulate a coherent response from a free society. The circumstances of science, technology, and world affairs led him to choose manned exploration of the moon as a symbol of our goals, and a massive commitment in resources and time was made toward that goal, with enthusiastic public support. After the initial thrill of national participation in this bold venture had waned, the critics began to be heard from, loudly when our space ventures were in trouble, softly when success was fresh. Surprisingly enough, the most damaging criticism came from within the scientific community. Ignoring the well-known difficulty of placing values in advance on the outcome of exploration or technological progress, the scientist-critics question the value of the country's investment. In so doing, they raise doubts in the minds of the public concerning the scientific importance of the space program and the judgment of its architects.

While no public program should be free from scrutiny and criticism and none the size of the U.S. space program is free of deficiencies, it is unfortunate that criticism should be voiced in such

a way as to compromise the "magic" of enthusiastic public identification with science and discovery. In its capture of public support, in national political urgency, and in the stimulus it has given to science and technology, the moon project would be hard to match. It may be that half the funds of the space program could better be used in development of natural resources, biochemistry, social sciences, or poverty programs. It may be that instrumented exploration of space is preferable to manned exploration, or that study of the ocean is more important than study of space. But it is nonsense to believe that the optimum distribution of our national energies and talents can be defined without consideration of public identification with the goals and the progress toward them. Perhaps nothing could be so damaging to the progress of all U.S. science, and to U.S. world prestige as well, as a half-hearted public support of a shrinking, failing moon mission. But the real loss would be the disappearance of a force that has made every American a participant and sponsor of progress. Let's be clear about whether we are criticizing technical issues on which we are qualified to judge, program issues on which we are qualified to debate, or public issues which are not scientific questions.

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Animal Care:

Licensing of Experimenters

Arthur Freeman (Letters, 18 Feb., p. 776) contends that a voluntary accreditation scheme administered by the American Association for Accreditation of Laboratory Animal Care is a "better plan than legislation." Although any effort to improve animal housing is welcome, this scheme is no substitute for legislation, since it does not cope with significant aspects of

humane care that are dealt with in proposed legislation. The AAALAC scheme provides for the announced inspection of animal quarters once in 5 years. From such a rare and prearranged visit, basic physical equipment can be assessed but not day-to-day standards of care. Surely, an announced inspection will be prepared for; overcrowded and unsanitary cages and lack of food or water would probably not be observable. Cleveland Amory advised the House Interstate and Foreign Commerce Committee on 30 September 1965 that one-third of 100 laboratories he had visited unannounced were grossly inadequate in these respects. (One-third he found in moderate and one-third in good condition.) Independent testimony confirmed this view, which has remained unchallenged. Photographs taken recently during an unannounced but invited visit to a leading research institution showed dogs in cages so small they could not stand up.

Unannounced inspection appears essential to the maintenance of effective standards of animal care. Under the British system, upon which the bills of Senator Clark (S. 1071) and Representative Cleveland (H.R. 5647) are based, inspectors (all of whom are M.D.'s or veterinarians) visit marginal institutions several times a year; those with known high standards are visited infrequently; but never are visits announced. The Roybal bill does not provide for any kind of inspection.

Humane standards in the laboratory, as distinct from animal quarters, are dealt with in neither the AAALAC scheme nor the Roybal bill. Ignorance and carelessness are probably responsible for most of the inhumane acts and practices of scientists and research institutions. Animals are sometimes incinerated alive because the un-instructed investigator fails to ensure death before discarding them; anesthetized animals may be left untended and their level of consciousness may change while the experimenter goes to lunch; animals in extreme pain that serves no legitimate scientific purpose are not invariably drugged or killed. Such unnecessary and unjustified suffering could be virtually eliminated if scientists were adequately instructed, and required to maintain humane standards by individual licensing as proposed in the Clark-Cleveland bills. A licensing system of this sort has operated simply and constructively for 90 years in England, promoting both

humane standards and effective research unobstructed by either antivivisectionists or self-righteous scientists.

A medical, veterinary, or pilot's license is bestowed only on those who have shown a capacity to assume important social and professional responsibilities. Obtaining a license is a milestone in any career. A fledgling investigator learns, in England, to scrutinize his experiments from a humane as well as a scientific standpoint. He will discuss his work and the humane requirements of the law with his professor, fellow workers, and the inspector, who is a respected professional colleague, not a bureaucratic foe. Unfortunately, comparable nationwide concern with humane standards is lacking in the American research community.

Both Visscher (11 Feb., p. 636) and Rohweder (18 Feb., p. 778) intimate that federal legislation such as the Clark-Cleveland bills "would delay or prevent scientific discovery" and cause "an incalculable number of our friends . . . [to] die sooner because discoveries come later." Similar extravagant remarks could with as much, and as little, truth be made about delays in processing federal grants or, indeed, about scientists' summer vacations.

Laboratory animals are vehicles of our purpose as we are vehicles of God's; it behooves a civilized nation to treat them with mercy.

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Medical Experimentation on Humans

The recent discussion by Elinor Langer (11 Feb., p. 663) brings into focus many of the unresolved problems connected with experimentation on human beings. Without referring directly to the questions involved in the New York case she describes, I should like to raise a point, the disregard of which could seriously impede the accumulation of useful medical data.

It is essential to differentiate between two types of human experimentation in terms of the risk-versus-benefit ratio from the standpoint of the patient. These two categories may be termed "observational" and "manipulative." In the first, the procedure applied to the patient, be it diagnostic or therapeutic,

is one which would probably have been applied to that patient in a nonexperimental situation, the only difference being that observational techniques are added which monitor data resulting from the procedure. It is implied, of course, that the observational techniques do not in themselves pose any significant risk to the patient. The diagnostic or therapeutic procedure is assumed to be either a standard one, or a nonstandard one which promises to be of benefit to the patient. Certainly precedent for this is as old as medicine itself, and the ethical and legal questions would appear to be well covered by the established codes of ethics governing the patient-physician relationship. Each patient is a unique problem and in this sense an experiment; and, indeed, it would seem unethical not to gather as many data as possible from the situation. Fortunately, most human experimentation at this time is of this type, and the untapped wealth of information to be derived from the application of scientific observational and data-processing methods to the practice of medicine is enormous. The ethical questions here, then, seem to be clear and well tried.

In the second category, that of manipulative experimentation, the questions are not clear, precedents are lacking, and extensive discussion from the ethical, medical, and legal standpoints is essential. Manipulative human experimentation is defined as the application to a patient of a risk-posing procedure which cannot conceivably benefit him. It needs to be clearly stated that it is this type of experimentation that is of primary interest to the various groups purporting to represent the public in these questions. If we neglect this, we run the risk that the rigorous controls necessary in the manipulative type of experimentation may be applied helter-skelter to everything termed "human experimentation."

Since there is much information to be gained from the observational type of human experimentation, it is questionable whether any manipulative experimentation should be condoned until the ethical and legal issues are resolved.

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Having read the News and Comment headed "Human experimentation: New York verdict affirms patient's rights," I believe I understand the situation well enough to attempt to help lay com-

mittees develop a series of forms for obtaining patients' informed consent. I am working now on forms (see note) for our standard operations. After these have been accepted universally, it should be possible to develop standard forms for less and less standardized procedures as we learn new methods of treating diseases and congenital deformities which afflict human beings but which with our present limited knowledge cannot be effectively treated.

In fact, however, we may never need consents for performing any procedures, small or large, that are not already well established. When the two dozen or so bills in Congress against experimentation in living animals go through, and when we are prevented from attempting seemingly innocuous studies of cancer behavior in humans, as reported in the article, we may mark 1966 as the year in which all medical progress ceased. Thereafter and for the rest of time, we would need only 200 or so standard informed-consent forms to cover only the 200 or so presently standardized operations.

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Note

Proposed informed-consent form for hernia patient:

I,, being about to be subjected to a surgical operation said to be for repair of what my doctor thinks is a hernia (rupture or loss of belly stuff—intestines—out of the belly through a hole in the muscles), do hereby give said doctor permission to cut into me and do duly swear that I am giving my informed consent, based upon the following information:

Operative procedure is as follows: The doctor first cuts through the skin by a four-inch gash in the lower abdomen. He then slashes through the other things—fascia (a tough layer over the muscles) and layers of muscle—until he sees the cord (tube that brings the sperm from testicle to outside) with all its arteries and veins. The doctor then tears the hernia (thin sac of bowels and things) from the cord and ties off the sac with a string. He then pushes the testicle back into the scrotum and sews everything together, trying not to sew up the big arteries and veins that nourish the leg.

Possible complications are as follows:

- 1) Large artery may be cut and I may bleed to death.
- 2) Large vein may be cut and I may bleed to death.
- 3) Tube from testicle may be cut. I will then be sterile on that side.
- 4) Artery or veins to testicles may be cut—same result.
- 5) Opening around cord in muscles may be made too tight.
- 6) Clot may develop in these veins which will loosen when I get out of bed and hit my lungs, killing me.
- 7) Clot may develop in one or both legs which may cripple me, lead to loss of one or both legs, go to my lungs, or make my veins no good for life.
- 8) I may develop a horrible infection that may kill me.
- 9) The hernia may come back again after it has been operated on.
- 10) I may die from general anesthesia.
- 11) I may be paralyzed if spinal anesthesia is used.
- 12) If ether is used, it could explode inside me.
- 13) I may slip in hospital bathroom.