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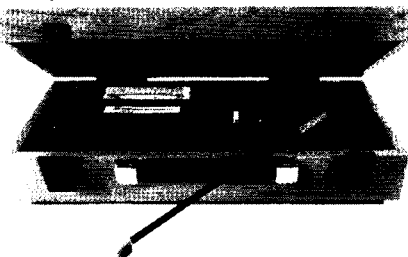
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I agree with Tullis that current regulatory practices for chemical carcinogens are neither rational nor effective, but I cannot agree with him, or with Lappé *et al.*, that our experience justifies qualitative or quantitative reliance on animal testing for regulatory decisions in this area.

That one or a few tests give apparently accurate approximations of risk to human beings is no justification for concluding that all tests are equally valid; many thousands of such tests do not provide even the appearance of approximation and are unpredictably discordant and ambiguous.

In restating that maximum tolerated doses are necessary to show an effect with weak carcinogens, Lappé *et al.* fail to recognize that this is only a statistical imposition, oblivious of real biologic difficulties ranging from overloading of metabolic and physiologic conditions to assumptions about dose response functions that are not scientifically verified or even verifiable.

If Lappé *et al.*, as regulators, wish to use animal tests for determining carcinogen threshold limit values as in their TCE example, they have the legal power to do so, but their decisions ought to be considered as being determined by a judgment of prudence and not as defensible by scientific data. Technical grade TCE has been shown to increase liver tumor incidence in mice but not in rats. If the tests were predictors of human target tissues, as these authors assert, hepatomas should be frequent in exposed workers. Any increase of these rare tumors would be readily noticed, but I am unaware of such findings.

The point they seem to have missed in my article is that, because animal tests are unreliable predictors of human risk and cannot consistently predict either safety or hazard, only two alternatives are left; one is irrational fear and the operational paralysis it ultimately implies, the other is a measure of prudence. Despite what anyone says about reliance on animal data, at the roots of regulatory decisions one invariably finds a balance of prudence and perceived need. Regulators adjust their pronouncements according to how extreme a regulation can be before it incurs a public revolt or a court challenge or causes an unsupportable economic burden. Saccharin is a signal case, where the public decided that the risks are hypothetical and the benefits tangible. As a consequence, a flood of protest has forced Congress to suspend the Delaney amendment for this substance.

It is often professed that scientific data support regulatory decisions, but usually

they are not the real basis for regulation. This is demonstrably true even when precise measures of human risk are available through epidemiologic data.

Many have advanced the astonishing apology that no better information is available than animal data. In a similar vein, Lappé *et al.* argue that failure to respond to animal data may have grave consequences. Because animal data cannot tell whether it is harmful to regulate or not, or how harmful it might be, surely this is not a scientific statement but rather a political one, and one that can be properly resolved only by a comprehensive cost-benefit analysis of the options available, these being not to regulate at all or to do so at various levels of intensity. Animal data may contribute only tangentially to such a decision. To say that this process, and the regulatory courts that I and others have suggested, would be subject to pressures is to state the obvious. The point is that in a participatory democracy a citizen's court is likely to experience many conflicting influences that may moderate each other, as opposed to the unidirectional bias of agencies that depend on regulation as a reason for existence and survival.

GIO BATTÀ GORI

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Privileged Communication

Stephen M. Schwartz (Letters, 7 Nov. 1980, p. 590) refers to the risk of plagiarism or pirating of ideas presented in grant applications. He also suggests that major scientific journals could take an editorial stand against use of the access privilege by scientists.

Such a stand has already been taken by the Committee of Editors of Biochemical Journals of the International Union of Biochemistry, of which *Science* is a corresponding member. Point 1 of its Code of Ethics, adopted in 1969, reads as follows: "All manuscripts received in the editorial office should be considered privileged communications, and be so identified." A privileged communication may be defined as a confidential document not to be shown or described to anyone except to solicit assistance in reaching an editorial conclusion provided that this privileged status is made clear to the referee.

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