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Research Impact Statements

There is little question that environmental impact statements should play an important role in technology assessment and social control. Would it not also be reasonable to ask that research impact statements be prepared by regulatory agencies? During the last few years, the Food and Drug Administration (FDA) and, more recently, the Environmental Protection Agency (EPA) have assumed—either indirectly or by actual legal mandate—in certain fields the dominant role in deciding what research could or could not be done and especially how long it would take to bring such work to a decision point. Should the effect of such actions on research also be evaluated? Research impact statements could be prepared either as internal agency documents or as part of an open dossier. My own recommendation is that these documents be used primarily within the agency at first, in order to permit it to determine for itself what information and policies could be derived from such statements. Even such limited use would impose upon the staffs of regulatory agencies a mental discipline that is sometimes lacking in the current decision-making process. Eventually, depending on the experience gained, the statements could become a regular feature, generally available and subject to refutation.

A typical research impact statement ought to include an evaluation (even if only a subjective one) of the research area that would be affected by given regulatory requirements. Major items that should be taken into consideration are the novelty of the research, the effects of the regulatory requirement on other areas, and, most important, a cost-benefit determination. For example, a given regulatory requirement might achieve a relatively minor gain in safety information at the expense of an important line of research. If so, what alternatives might provide such safety information without a substantial negative impact on research? What is the price in lost benefits that the public will pay through a considerable delay in the completion or total abandonment of a given project? The pharmaceutical field appears to be replete with such examples, and various people have claimed that the drastic reduction in the introduction of significant new drugs during the last decade is associated to a considerable extent with FDA-imposed requirements. If research impact statements had been required of the FDA during that decade, their review at this time and comparison with the actual research conducted would have been very useful in confirming or rejecting such claims.

Research impact statements would also be useful in the field of new insecticides. Before substantial field trials with new insecticides can be undertaken, the sponsor of such trials must receive from the EPA an "experimental permit." Refusal of such permits usually prevents further development and presumably is based on real or hypothetical environmental considerations. Would it not also be desirable for these considerations to be accompanied by a statement that would evaluate the potential damage (that is, failure to replace presently used, persistent insecticides) if such research were *not* done?

The impact of regulatory agencies on research is now so enormous that they should bear some of the responsibility for *prospective* research planning—especially if the effect can be felt on a national scale. The research impact statement may be a useful device in calling attention at an early stage to the need for modification or even elimination of counterproductive regulatory practices.—CARL DJERASSI, *Professor of Chemistry, Stanford University, Stanford, California 94305*