Letters

Biology Worldwide

The award of the Nobel prize in physiology and medicine to the French microbiologists A. Lwoff, J. Monod, and F. Jacob is highly deserved for their numerous important contributions to microbiology, biochemistry, and genetics. In addition I wish to pay tribute to them for their hospitality to and stimulation and teaching of foreign scientists. American workers have flocked to their laboratories for almost 20 years. American microbiology, biochemistry, and genetics owe an enormous debt in this generation to this French group, even as American chemistry and physics were indebted in earlier generations to numerous European schools.

For this reason, the regulation of the National Institutes of Health which prevents the assignment of training grants to foreign applicants is shortsighted. The world needs sophisticated biologists to help solve problems of health, food supply, population control. An American policy which fails to assist in the worldwide development of biology will be unable to solve its major long-range problems. I urge American biologists who recognize their debt to and dependence on biologists of all countries to take the award of the Nobel prize to Lwoff, Monod, and Jacob as an occasion to protest this weakness in the NIH regulations.

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FDA Committee Decision Explained

I read with considerable concern the article by Elinor Langer (News and Comment, 13 Aug., p. 731) on relations between the Fountain committee of the House of Representatives and the Food and Drug Administration. Langer discusses the view of FDA officials and "many" scientists that free discussion by a committee of scientific consultants could be inhibited by the prospect that complete transcripts will be made public. This view may have merit, but I have no objections to the dissemination of anything I have said in committee, and I have written to the FDA requesting the release of the tapes in question to the Fountain committee.

The article illustrates how an incomplete story can result in a distortion of the facts. Central to the article was its discussion of an *ad hoc* committee called to evaluate the possible teratogenicity of meclizine and cyclizine. The committee met twice in approximately a year. It first recommended prohibiting the sale of the drug without a doctor's prescription and later reversed this decision in favor of requiring a warning on the label. Since Langer makes no attempt to report the committee's reasons for the reversal, the implication of the article is that in the interval between the two meetings, the committee, the administration of FDA, or both were bought. As a member of the committee who argued for removing the drug from over-the-counter status on both occasions, I resent this implication. I am sure that its author could have had access to all the facts had she interviewed FDA's medical director.

Among essential facts missing from the report are these: The decision of the first committee was based on preliminary data from the Perinatal Collaborative Study which suggested a relationship between the drug and human anomalies. The decision of the second committee was based on more complete data from an additional year of evaluation of the same study which indicated no relationship. Furthermore, new data from a California study not available to the first committee likewise failed to indicate a relationship between the drug and human anomalies. At both meetings the data were quite clear that the compound is a teratogenic agent in rats. The second committee was called upon to answer the fundamental question, How much weight should be put on animal studies when there is a large experience with a drug in man and not one shred of real evidence to incriminate it in man? This is a knotty problem. A day's argument in committee failed to resolve it. Those of us who are responsible for the care of patients see small inconsistency in extrapolating from animal data alone to restrictive regulations for any but life-saving drugs. This logic reflects the training, experience, and bias of the physician. I still think any suspect drug should be regulated; otherwise, why bother with animal studies? On the other hand, a good committee represents scientists from many disciplines, and this one included a wide distribution of scientists, authorities in disciplines bearing directly on the question but removed from clinical responsibilities and biases. These people looked at the evidence in man and it was negative. In this setting of free argument and exchange among scientists of different disciplines, the consensus reached was a logical outcome. On the basis of only those facts that are given in Langer's article, the recommendation seems incomprehensible.

The problems faced by the FDA in protecting our population from drug-induced disease are formidable. Tremendous progress has been made by the administration in the past few years, and members of the scientific community have begun to address themselves to these problems on agency committees. It is disappointing to find reporting in the pages of *Science* which is destructive of these efforts and which settles for only part of a story when the whole story is available.

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Photocopying: How Much?

It seems to me very improbable that photocopying has had the influence on subscriptions to scientific journals suggested by Lodwick (Letters, 15 Oct., p. 290). In my experience and that of my colleagues in agricultural research, copying of scientific articles is limited essentially to two categories of material: older literature that is out of print or otherwise unobtainable except by loan from a technical library; and articles in the current literature published as isolated papers in a given field —mycology, for example—in periodicals otherwise devoted to other and completely extraneous matters. A my-