Letters

"Science Is Too Important to Stay Out of Politics"

Recently we met with our congressman, Jerry L. Pettis (R-Calif.), to discuss the consequences of the squeeze in science funding. Pettis, formerly a member of the House Committee on Science and Astronautics, thought that scientists had done a poor job of communicating with Congress. His major points were:

- 1) Spokesmen for agencies such as NIH and NSF present too apologetic a case for basic science and seldom make it clear why investigative work is so vital to our nation's continued progress. Reports from these agencies were not always intelligible to laymen unfamiliar with the subject matter.
- 2) Science needs strong advocates in Congress, such as those supporting the military, farm groups, automotive, petroleum, and textile industries.
- 3) Congressmen want to cite to constituents specific scientific achievements which have been supported with tax dollars. Few congressmen understand that cutbacks in appropriations affect not only basic research, but also the training of faculty, the education of physicians, and the delivery of health care. Congress is considering emergency aid to medical education. If biomedical research is to obtain additional funds in the near future it will probably have to be tied to appropriations for health care and education.

We realize that this was only one encounter with one congressman. At the risk of being overly simplistic we suggest the following:

- 1) We should have similar meetings with the other members of the House and Senate, especially those legislators who are members of the committees on science appropriations. *Science* should keep its readers up-to-date on the membership of these committees.
 - 2) Our national scientific organiza-

tions (AAAS, ACS, FASEB, and others) should appoint committees in each state to contact their congressmen and inform them of the acute need for increased scientific appropriations. These organizations should also appoint scientists who can testify before the congressional committees and present a more unified voice for science. The groups should also have periodic meetings with administrators of HEW, the Office of Management and Budget, members of the President's Science Advisory Committee, and other presidential advisers.

- 3) We should write our legislators and members of the executive branch of government, sending them reports of our research written in language they can understand, with an interpretation of our results, emphasizing the significance and relevance of the work. Specific instances should be cited where research has been cut back, indicating important projects that would have been done if funds were available. Society newsletters should keep us better informed on bills containing scientific legislation. It might be worthwhile for our legislators to receive complementary copies of Science, Scientific American, Science News, and related publications.
- 4) Our national organizations should choose spokesmen with proven ability to interest and convince Congress and the public of the value of a healthy scientific community. We need lobbyists who can interpret science to the legislators in lively layman's terms and keep them informed on scientific questions.
- 5) We should work to elect representatives who support science. *Science* should publish legislators' voting records on bills containing science legislation.
- 6) Finally, it might be worthwhile for more able and articulate scientists to enter the administration of HEW and other agencies, or to seek elective office. A few physicists and physiologists in

Congress might have a profound influence for good on our national course.

In conclusion, "Some have said that science is too important to get mixed up in politics. The fact is that today science is too important to stay out of politics" (1).

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Forerunner of Molecular Biology

Concerning Warren Weaver's letter (6 Nov.) on the origin of the term "molecular biology," I would like to mention that in 1903 Léo Errera (8158-1905), professor of botany at the Université libre de Bruxelles, gave a course to the graduate students, the title of which was: "Cours de physiologie moléculaire." In the introduction to this course, which was published in the Recueil de l'Institut Botanique de Bruxelles, vol. VII, in 1907, it is clearly stated that "considering the extremely small size of the machinery -cells, ducts, fibers, etc., where the elementary processes of life take place, it is with the forces, often designated in physics as molecular forces, that is, forces effective over very small distances, that we will be dealing with. Therefore we can name this aspect of physiology, mo'ecular physiology" (my translation). This may be of interest to those interested in the history of molecular biology.

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FDA: Clinically Meaningful Data

In a letter (25 Sept.), Robert L. Dean of Smith Kline & French expressed concern over guidelines to be proposed by the Food and Drug Administration for clinical evaluation of drugs. His criticism was directed toward the potential for rigidity that these would assume to the exclusion of scientific judgment.

To us, a more far-reaching danger is the FDA's subtle introduction of a requirement for evidence of "clinically meaningful" effectiveness results. The ramifications of this obviously transcend the direct concern and competence of the industry and regulatory personnel involved, as well as the concern of clinical investigators and bioscientists. This letter is to alert the scientific community to this development and thus, hopefully, to provide impetus for a broad discussion of the implications of the phrase "clinically meaningful." The following examples illustrate some of the issues involved:

- 1) On a conceptual level, "clinical meaningfulness" defies definition. It has significance only at the level of the individual physician and his particular patient.
- 2) The definition of a "clinically meaningful" response, even if conceptually feasible, presents many problems -not the least of which is coping in a "satisfactory" way with the inherently multivariate criteria that must be required for even the least complicated disease or condition.
- 3) There is much yet to be learned about clinical drug trials. For example, we have observed marked differences among investigators as therapists, even in a carefully controlled clinical setting (1). Without fundamental improvement in methodology, the evidence for "clinically meaningful" effectiveness must be obtained largely at the expense of an increasing likelihood of rejecting potentially useful drugs.
- 4) Without specific definitions of "clinical meaningfulness," the results of clinical investigations, even though conducted in rigid accordance with the pertinent guideline, will be evaluated on a very individual and unpredictable basis by the FDA's medical "expert" assigned to that drug class at that particular time. In one instance, there was a candid explanation that the FDA was not prepared to define a "clinically meaningful" result for the drug class in question, nor did it know when such a definition might be forthcoming.
- The FDA is legally required to insure that there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof. . . ." We believe this statute is desirable, but in no way does it constitute a license for the

FDA to enforce its judgment about the desirability of a particular drug treatment. FDA personnel have suggested, for example, that a drug sponsor must provide evidence that a hypotensive agent actually "causes" decreased morbidity in addition to lowering a patient's elevated blood pressure per se. This philosophy ignores the literature (2-5) which documents the danger of not treating hypertension. It is both unnecessary and dangerous to subject a control group with moderate and severe hypertension to placebo therapy.

We hope the scientific community will become aware of the FDA's use of the phrase "clinically meaningful" and respond in a positive fashion to this imminent regulatory development.

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What Substitute for Cars?

H.R. Lahr (Letters, 6 Nov.) presents a good condensation of what I take to be the prevailing opinion of residents of the Los Angeles area—that the convenience of automotive transit outweighs its disadvantages. Thus, the paving of an appreciable portion of the area and substitution of an irritating yellow substance for air are acceptable.

This represents a value judgment and should not be criticized by us outsiders, but by the same token we should not be asked to help provide the best of two worlds to the Angelenos.

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Lahr typifies the attitude of many affluent suburbanites who "wouldn't use a streetcar if it ran right past my house." His sense of what is economical, however, might change if he had to pay his true share of the cost of constructing and maintaining the superhighways which enable him to reach his destination so rapidly and conveniently. Most superhighways come into being because of the pressure exerted on our elected representatives by powerful, special interest lobbies. A large portion of the tax revenue required for their construction and maintenance, however, comes from the urban community whose residents rarely want and often actively oppose such construction. Lahr's letter might have been more pertinent if it represented the viewpoint of a resident of the Watts district of Los Angeles. . . .

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Lahr is quite correct in claiming that the automobile is the best mass transportation system for Los Angeles. The two grew together and influenced each other. He is also perfectly correct in saying that we cannot sell the public something unless it is better than what it already has. Nineteenth-century streetcars, buses, and subways will not work in Los Angeles. They are not very attractive in older cities, which have not grown up to cater to the horrifying extravagance the automobile brings about in cities.

However, there are a great variety of new transportation systems being developed which promise to combine all the advantages of the automobile and public transportation without most of the disadvantages. These are socalled "dual-mode" systems. Privately owned vehicles and public-operated transit vehicles alike will be able to join high-speed guideways that use a small fraction of the width of an expressway and that will handle 5,000 to 10,000 vehicles per hour in a continuous flow. When the labor component of public transportation is reduced, the incentives are toward the use of small vehicles rather than ever-larger units, so that more personalized public transportation is possible. Even the family automobile will probably become low-powered with short range, probably using battery power. When there are guideways within 3 miles of every part of a city, and going between cities, 300-horsepower automobiles will no longer be necessary and may even be banned in cities.

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