LETTERS

The Feingold Diet

In her article "Food additives and hyperactivity" (Research News, 3 Feb., p. 516), Gina Bari Kolata infers that C. Keith Connors and his associates at the University of Pittsburgh studied the effect of the Feingold diet on a group of hyperactive children. She says Connors "has some evidence that the behavior of a small fraction of hyperactive children might improve with the diet. He finds that the behavior of most children, however, is not affected by it."

The Pittsburgh group did not conduct a study of the full Feingold diet. They did study the effects of artificial food dyes and artificial flavors on children. The Feingold diet eliminates artificial colors, artificial flavors, the additives BHA and BHT, and a number of natural salicylates (varying according to the sensitivity of the child). Feingold also recommends, in general, a diet that is high in protein and low in carbohydrates.

While members of the Feingold Association of the United States are gratified by the work of Connors and his associates, and even more so by the research of Herbert Levitan of the University of Maryland, we do not agree that a study of the effect of food dyes and flavors is synonymous with a test of the Feingold diet.

Parents of hyperactive children aren't waiting for the scientific imprimatur to be affixed to the diet 20 years from now. The Feingold Association, founded less than 3 years ago, now has about 20,000 families on the diet. They help each other through more than 100 local organizations. Our children are on the diet because it works.

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Retrolental Fibroplasia Study

A News and Comment article in *Science* (16 Dec. 1977, p. 1127) relays the opinion that the 1953–1954 Cooperative Study of Retrolental Fibroplasia is an example of a premature termination of a randomized controlled clinical trial. However, it should be made clear that the decision to end this study at the end of 1 year was made *before* the trial began and not as a result of findings during the trial.

The cooperative study was one of the first large-scale randomized clinical trials conducted in the United States. The details of the rather involved experimental design used in that study are spelled out in the published report (*1*). An unfortunate defect in the design of the trial limited the evidence concerning mortality.

The mischief caused by misconceptions concerning the clinical trial is felt in our courts of law. Conscientious physicians are being sued because they prescribed oxygen on the basis of the evidence available before the results of the cooperative study were announced (September 1954).

The resistance caused by a combination of social, political, and ethical forces, noted in the *Science* article, played a definite role in blocking further randomized clinical trials that might have answered the many unresolved questions about retrolental fibroplasia remaining at the end of the 1953–1954 trial. They are unresolved today.

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References

1. V. E. Kinsey, *AMA Arch. Ophthamol.* **56**, 481 (1956).

NIH Grant Investigations: A Reply

The 25 November 1977 issue of *Science* contains an article entitled "Research management scandals provoke queries in Washington" (News and Comment, p. 804). One section, in which situations investigated by the Division of Management Survey and Review (DMSR) of the National Institutes of Health (NIH) are discussed, is headed by a paragraph stating, "Like any police file, many DMSR reports . . . make for chilling reading." Several excerpts from the file are reported, including the following:

> Another case involved two researchers at Brandeis University who got a grant from the National Institute of General Medical Sciences. Afterwards, DMSR alleged, the researchers departed for Israel, and apparently took with them some $6000 worth of equipment bought with NIGMS funds. The DMSR recommended that the cost of the equipment and part of their salaries be repaid to the government.

It is generally known by the biological community that my wife Raquel Rotman Sussman and I are the two researchers from Brandeis that left for Israel. We

consider the statement above and the semantically equivocal juxtapositions in the article to be harmful to our reputations and perhaps even unfair journalistic license.

At the time of our departure from Brandeis in June 1973, we were midway through the third year of a 5-year grant from NIH. I served as principal investigator and my wife as coprincipal investigator. Several months before our leave-taking, we corresponded with NIH to obtain information in order to arrange for the premature termination of the grant. We also provided the university with an itemized list of equipment and supplies left in our laboratory and obtained permission to take certain major items with us. Some time after our departure, NIH auditors arrived on campus in connection with a dispute involving the fiscal practices of another department. While there, they spot-checked other accounts including our own. Questions arose concerning several expenditures which could not be accounted for satisfactorily by the individuals present. We were not contacted to provide the needed information and explanations. In the absence of these, NIH disallowed the expenditures in question and the costs were absorbed by Brandeis. The items included:

1) One month's salary and fringe benefits to my wife and myself. (She received her total salary from the grant. I received a stipend representing 2/9ths of my annual salary.) We arrived in Israel on 15 June and began work shortly afterward. Between then and October, the start of our appointments at the Hebrew University, we did considerably more than 1 month's work which eventually culminated in eight significant publications, all bearing formal acknowledgments of NIH support.

2) Approximately $6000 for assorted small items of equipment ranging from a flash evaporator ($300) to a centrifuge rotor ($895). These were brought to Israel and used in the performance of the work described above. Each of the items was vitally necessary to our work, and the time required for their replacement would have resulted in delays of 4 to 6 months. More than a year later, after learning of the disallowance by NIH, we offered to ship the items back to Brandeis at our expense. Instead, Brandeis donated them to the Hebrew University.

3) The sum of $111 for shipping plus $21.50 for a telegram. We shipped a package to Israel by Air Freight containing frozen antiserums and enzyme preparations that had been collected during the tenure of the grant. The telegram was to warn a graduate student to pick up the package at the airport.

In assessing the ethical niceties of our actions, three considerations might prove revealing.

1) Before my departure, I was urged to accept a leave of absence rather than resign my position. Had I accepted the leave I could have retained a token laboratory at Brandeis and continued to use the grant funds, thereby subverting the NIH policy on support of overseas research.

2) Although my wife is an independent investigator of recognized international stature, her annual salary at the time of our departure was $12,000. This significant underpayment reflects our joint desire to convince the most skeptical examiner of the propriety of our professional relationship.

3) In 27 years of support from the Office of Naval Research, the National Science Foundation, and NIH, we have never overspent our grants, nor has any item of expense been disallowed before or after this experience.

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Decision-Making: What Basis?

Decision-making by the source rather than the force of an argument is universally condemned in retrospect but widely embraced in practice. The history of every human discipline teems with illustrations of extreme examples.

I have been advised by a professor of mathematics at a major university, himself a joint author of a high school geometry text, that his time is too valuable to waste on a brief manuscript on the foundations of geometry which I asked him to review. He said, in effect, that the foundations of geometry were worked over in the last half of the last century "by some pretty good mathematicians." He did not say, but he implied, that that work is inviolate and no useful contribution could come from someone not recognized in the field.

Were this an isolated incident, the cost would be minuscule. That it is widespread, nigh universal, is the real tragedy.

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