



October 10, 1997

The Honorable Tom Harkin
United States Senate
Washington, D.C. 20510

Dear Senator Harkin:

Thank you for taking time today for a frank exchange of views on the Office of Alternative Medicine (OAM), its recent activities, and its future role at the NIH. As we agreed, I am setting down in this letter the central points I tried to make—and appending a number of relevant documents—to give you an opportunity to think further about my position on this matter. I have also asked some NIH Institute Directors, Dr. Elvira Ehrenfeld, and Dr. William Harlan to write brief accounts for you of their views of the Office, in particular to document for you the several ways in which the Institutes, the Center for Scientific Review, and the OAM have worked collegially and productively together, in contrast to the opinions offered to you by other informants. You should receive these letters shortly.

As I indicated on the phone, I have been giving considerable thought to alternative medicine, because it has become a significant public health issue and because it is symptomatic of widespread attitudes to conventional medicine. Some of my views on the problem formed the basis for the talk I gave at the Stanford Medical School Commencement Exercises this June, and I have appended a copy of that talk.

I believe we share a few basic assumptions: that alternative (or complementary or unconventional) medicine needs increased scientific attention and that (as stewards of Federal dollars) the quality of the science we bring to it must be high. I would like to summarize six perceptions about our current approach and propose ways in which we should adapt our approach in the immediate future.

1) Setting up Centers for training and pilot projects to investigate alternative practices was a reasonable idea, but it is taking a long time to develop a new cohort of investigators who can successfully apply for investigator-initiated awards and provide answers to some of the most pressing questions about the efficacy of such practices. I suggest that we instead get answers to such questions more quickly by "buying" good science. The Institutes can do this in conjunction with the OAM through cooperative agreements and research contracts to well-established clinical trials experts in the academic and commercial sectors. The questions would be formulated by the OAM, in consultation with its advisors (see below), and the projects would be overseen by the scientific staff in the appropriate Institute, after suitable review. Funding would be derived from the budget of the OAM in the first year and from the relevant Institute in subsequent years.

(A sterling example of how this can be done is offered by the recent award of a contract by the OAM, NIMH, and the Office of Dietary Supplements to Duke University to study the efficacy of St. John's wort in clinical depression, as described in appended documents.)

2) The OAM needs close and expert oversight from experienced scientist-administrators. In my view, the functions of the Office have improved measurably under the guidance of Dr. William Harlan, NIH Associate Director for Disease Prevention and Director of the Office of Disease Prevention, the Office in which the OAM resides. It was Dr. Harlan, for example, who directed the OAM to the St. John's wort and other recent projects. This or similar forms of oversight need to be continued as currently practiced or elsewhere; oversight could be provided, for example, within one of the established Institutes.

3) The OAM needs more funds than the operating costs that were requested for it this year. The additional money (in the range of \$5 million, as approved by the Senate in its Appropriations bill for FY98, with increases as deemed appropriate in subsequent years) would be used to initiate each year several targeted studies of the type described for St. John's Wort above. The money would not form a commitment base; the relevant Institutes would assume the out-year costs of initiated projects.

4) Alternative medicine needs the attention of more agencies than the NIH alone. This is so because the issues it raises extend beyond those usually addressed by the NIH to evaluation of health care practices, outcomes, and effectiveness; drug use, access, and safety; and the health of large populations. My conversations over the past few months with leaders of the CDC, AHCPR, and FDA indicate a genuine interest in the impact of alternative practices on these issues. I propose that a DHHS coordinating committee be convened with high-ranking representatives of the four agencies and of several NIH Institutes with substantial research interests in alternative medicine. The coordinating committee would meet regularly to consider activities that might be undertaken by any of the agencies or Institutes in conjunction with the OAM. The Office would, of course, continue to receive advice on many aspects of its activities from its established Council of non-government experts.

5) The ten Centers established with OAM funds at several academic health centers around the country have not yet had enough time to determine whether they can effectively train investigators, identify important research topics, and conduct productive pilot studies. When their progress is reviewed during recompetition a year from now, funds should be provided for significant increases in support for those Centers with especially promising records of accomplishment. In this way, the Centers might eventually become the sites at which decisive clinical trials of alternative practices are definitively evaluated, as originally intended when the Centers were established.

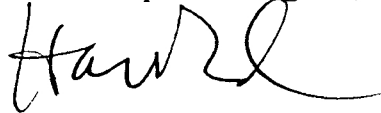
6) Alternative medical practices, however defined, need to be evaluated by the same kind of rigorous science as so-called conventional practices. Likewise, the same kinds of standards need

to be applied to evaluation of proposals for funding research on both kinds of practices. Dr. Elvira Ehrenfeld, the new Director of the Center for Scientific Review (formerly the Division of Research Grants), is skilled at assembling appropriate review groups in many contentious areas of science, and she is prepared to insure that review of applications for all kinds of research is both fair and rigorous. (The CSR will also provide a synopsis of its approach to review of applications in the alternative medicine arena.)

I recognize that you and I differ about the need for—or, indeed, the desirability of—developing a free-standing Center for Complementary and Alternative Medicine, with full authorities to review and support applications for research grants. I have appended a list of some of the reasons why I believe we should not develop such a Center.

I hope that this letter and the additional materials will convince you that my colleagues and I are taking the public health issues raised by alternative medical practices seriously and that substantial measures other than those you propose will effectively address those issues.

With best personal regards,

A handwritten signature in black ink, appearing to read "Harold Varmus", written in a cursive style.

Harold Varmus, M.D.
Director

Enclosures