



OCT 6 1997

NOTE TO THE SECRETARY:

Subject: Organizational Options for Support of Complementary and Alternative
Medicine Research

Following up our discussion last week, attached are three organizational options related to complementary and alternative medicine.

I favor Option 1, a Center for Complementary and Alternative Medicine within an NIH Institute, as the option that will best support an enhanced research program in the area of complementary and alternative medicine. I have also attached a statement setting forth arguments against creating a freestanding center.

According to advice I have received from staff of the Office of General Counsel, any of these three options would require revision of existing legislation (Section 404E of the PHS Act).

We will talk more about this issue soon.


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Attachments

Organizational Options for
Complementary and Alternative Medicine

1. A center, organizationally placed within an NIH institute, modeled after the existing National Center on Sleep Disorders Research and the National Center for Medical Rehabilitation Research
2. A center for Complementary and Alternative Medicine (CAM) reporting to the Assistant Secretary for Health
3. Enhancement of the existing Office of Alternative Medicine within the Office of the Director, NIH

Option 1: Establish a Center for Complementary and Alternative Medicine
within an NIH Institute

- Establish a Center for Complementary and Alternative Medicine (CCAM) within an institute of the National Institutes of Health. This entity would be modeled after the National Center on Sleep Disorders Research (located within the National Heart, Lung, and Blood Institute) and the National Center for Medical Rehabilitation Research (located within National Institute of Child Health and Human Development).
- The mission of CCAM would encompass all of the current responsibilities of the NIH Office of Alternative Medicine (OAM) and the Office of Dietary Supplements (ODS) [authorized by P.L. 103-417], and would also provide coordination for related efforts taking place throughout NIH.
- To make as much research progress as possible, complementary and alternative medicine research should be integrated into mainstream medical research across a number of disease areas (institutes); a center within an existing NIH institute makes such integration more likely. The institutes currently spend approximately \$44 million for CAM research.
- Additional research activities, for example, evaluating CAM modalities, would be carried out primarily through research contracts and cooperative agreements involving appropriate ICDs, effective approaches now used at the NIH for managing clinical trials. Some possibilities might include evaluating St. John's Wort for depression, currently being pursued by NIMH; melatonin for jet lag and sleep disorders; and DHEA for male aging. In this way, it would be possible to select a few candidate therapies out of the thousands of complementary and alternative modalities on which to conduct well-designed studies to establish convincingly whether these products have beneficial effects.
- Oversight would be provided by a program advisory council (the existing OAM advisory council) along with a trans-NIH/PHS advisory committee representing senior scientists from the NIH and CDC, FDA and AHCPR. This advisory structure would assist in establishing funding priorities, coordinating research activities and providing oversight to the Center.
- The responsibilities and resources of the current OAM (\$12 million and 14 FTEs in FY '97) and current ODS (\$1 million and 3 FTEs) would be transferred to the Center. Other NIH institute-supported CAM research would continue to be supported by the respective institutes.
- The responsibilities of the CCAM would include developing a comprehensive plan for the conduct and support of research on complementary and alternative medicine.
- A new center within an institute would not require a new administrative hierarchy and associated costs, thereby optimizing scarce resources for research.

Option 2: A Focus on Complementary and Alternative Medicine Reporting to the
Assistant Secretary for Health

- Establish a focus for complementary and alternative medicine (CAM) under the Assistant Secretary for Health. The issues of complementary and alternative medicine are broad and relate to the responsibilities of CDC, FDA, NIH and AHCPR. The new center would broaden the activity beyond NIH interests and expertise to include those of CDC, FDA, and AHCPR.
- Its mission would be broader than the current mission of the NIH Office of Alternative Medicine (OAM), yet would include all of the elements that the OAM has: evaluation of alternative treatment modalities; research training; and an information clearinghouse.
- Research activities, for example, evaluating CAM modalities, would be carried out primarily through research contracts and cooperative agreements, effective approaches now used at the NIH for managing clinical trials. Some possibilities might include evaluating St. John's Wort for depression; melatonin for jet lag and sleep disorders; and DHEA for male aging. In this way, it would be possible to select a few candidate therapies out of the thousands of complementary and alternative modalities on which to conduct well-designed studies to establish convincingly whether these products have beneficial effects.
- Once the director of the new entity decides on a particular focus for research to be done under contract or cooperative agreement, the project would be assigned to the appropriate agency to carry out.
- Oversight could be provided by an outside advisory committee, which would be the successor to the current advisory council for the NIH OAM, as well as by the Assistant Secretary for Health and senior representatives from the CDC, FDA, NIH and AHCPR. In addition, the NIH would establish a trans-institute committee composed of senior officials from the relevant institutes to help coordinate research activities and provide advice to the new office.
- The responsibilities and resources of the current NIH OAM would be transferred to the new entity [\$12m and 14FTEs]. Additional funding would be derived from the participating agencies in accord with recommendations by the Assistant Secretary for Health. Current NIH institute-supported CAM research would continue to be supported by the respective institutes.
- The principal advantage of this type of organizational structure is that it would recognize that complementary and alternative medicine interests extend beyond NIH. The disadvantage is that it would create an operational office at the HHS Assistant Secretarial level, with a need to delegate responsibilities to several PHS agencies.

Option 3: Enhance the Existing Office of Alternative Medicine (OAM)
within the Office of the Director, NIH

- The existing OAM would be retitled the Center for Complementary and Alternative Medicine (CCAM).
- The existing advisory mechanism, the OAM Advisory Council, would be supplemented by an NIH/PHS advisory committee representing senior scientists from the ICDs and CDC, FDA, and AHCPR. This committee would assist in establishing funding priorities, coordinating research activities and providing oversight to the center.
- The responsibilities of the CCAM would include developing a comprehensive research plan for the conduct and support of complementary and alternative medicine research.
- Research activities, for example, evaluating CAM modalities, would be carried out primarily through research contracts and cooperative agreements, effective approaches now used at the NIH for managing clinical trials. Some possibilities might include evaluating St. John's Wort for depression; melatonin for jet lag and sleep disorders; and DHEA for male aging. In this way, it would be possible to select a few candidate therapies out of the thousands of complementary and alternative modalities on which to conduct well-designed studies to establish convincingly whether these products have beneficial effects.
- The CAM research would continue to be managed through the relevant institute in cooperation with the CCAM.