

Complementary and Alternative Medicine Research  
At the National Cancer Institute  
July 22, 2003

The National Cancer Institute (NCI) is committed to finding innovative, promising treatments for people with cancer. The NCI's Office of Cancer Complementary and Alternative Medicine (OCCAM) coordinates the Institute's research program in complementary and alternative medicine. Using the same rigorous scientific methods employed in conventional medicine, OCCAM has developed a process that evaluates data about patients who have been treated with alternative approaches. This process is called the Best Case Series (BCS) Program and is designed to evaluate data from cancer patients who have received alternative treatments. The Director of OCCAM uses the results of Best Case Series to assist in developing NCI's CAM research priorities and funding proposals.

In the BCS Program, alternative medicine practitioners submit medical records (clinical history, copies of pathology reports and copies of medical imaging reports) to OCCAM. OCCAM reviews this material and makes an initial evaluation. If the initial evaluation is positive, the next step is to obtain the original diagnostic (i.e. pathology) materials and the radiographic studies demonstrating the response. These materials are reviewed by NIH consultants and the findings, along with summaries of the case histories are provided to an expert panel of advisors in the Drug Development Group (DDG) of the NCI's Cancer Therapy Evaluation Program (CTEP), an internal advisory group whose members work in pre-clinical drug development, pharmacology, clinical trials development and regulatory affairs.

The DDG meets regularly to evaluate data from compounds that are under serious consideration for testing in humans. This group decides whether or not to recommend a drug for human trials. Meetings of the DDG are closed to the public to protect the confidentiality of patients and industry proprietary information.

Although the BCS process has been an important part of OCCAM since its inception in 1998, incorporating the DDG in its review process is new. The first agent submitted to the DDG from the BCS was a compound called 714-X. On Monday July 21, the DDG reviewed data presented to the BCS Program for 714-X, a compound manufactured and distributed exclusively by C.E.R.B.E. Distribution, Incorporated located in Quebec, Canada and its authorized agents. The DDG reviewed five 714-X clinical cases.

The manufacturer states that the main ingredient of 714-X is naturally derived camphor that has been chemically modified and that this compound supports the immune system when injected into the lymphatic system. 714-X is not approved by the U.S. Food and Drug Administration for use as a treatment for cancer or any other medical condition in the United States. It is legally available in Canada on compassionate grounds and must be obtained through a physician. The final outcomes of the OCCAM's 714-X Best Case Series review will be posted on the OCCAM Web site at <http://cancer.gov/cam>

A summary of the use of 714-X as a treatment for cancer is available from NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) and can be viewed on the NCI's Cancer.gov Web site at <http://www.cancer.gov/cancerinfo/pdq/cam/714-x> .  
Further information on drug development at NCI is available at <http://www.cancer.gov/newscenter/discovery>