

3. Providing support for ongoing CRADA-related research in the development of candidate therapeutic compounds:
 - (a) financial support to facilitate scientific goals;
 - (b) technical or financial support for further design of candidate therapeutic compounds; and
 - (c) financial and logistical support for clinical trials Phases I-III.
4. Providing and implementing plans to independently secure future continuing supplies of candidate therapeutic compounds to assure continued preclinical and clinical development.
5. Providing plans and supporting clinical development leading to FDA approval of candidate therapeutic compounds.
6. Producing, packaging, marketing, and distributing successful therapeutic compounds.
7. Using the proposed technology for other novel biopharmaceutical and/or veterinary applications.
8. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include but not be limited to:

1. The ability to collaborate with NCI on further research and development of this technology. This ability can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.
2. The demonstration of adequate resources to perform the research, development and commercialization of this technology (e.g. facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
3. The ability to perform clinical testing or trials, and obtain IND, NDA and FDA approval for a new drug or treatment modality.
4. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.
5. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of technology.
6. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.
7. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.
8. The agreement to be bound by the appropriate DHHS regulations relating

to human subjects, and all PHS policies relating to the use and care of laboratory animals.

9. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the equitable distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization which is the employer of the inventor, with (1) the grant of a research license to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to negotiate for an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated July 28, 1995.

Thomas D. Mays,

Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

[FR Doc. 95-19733 Filed 8-9-95; 8:45 am]

BILLING CODE 4140-01-P

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Institute of Mental Health Special Emphasis Panel:

Agenda Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: August 14, 1995.

Time: 1:30 p.m.

Place: Parklawn Building, Room 9C-18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Phyllis L. Zusman, Parklawn Building, Room 9C-18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301-443-1340.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Numbers: 93.242, Mental Health Research Grants; 93.281, Mental Research Scientist Development Award and Research Scientist Development Award for Clinicians; 93.282, Mental Health Research Service Awards for Research Training.

Dated: August 4, 1995.

Margery G. Grubb,

Senior Committee Management Specialist, NIH.

[FR Doc. 95-19732 Filed 8-9-95; 8:45 am]

BILLING CODE 4140-01-M

Prospective Grant of Exclusive License: Tumor Infiltrating Lymphocytes as a Treatment Modality for Human Cancer

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to practice the inventions embodied in U.S. Patent 5,126,132 and corresponding foreign patent applications entitled, "Tumor Infiltrating Lymphocytes as a Treatment Modality for Human Cancer" to Applied Immune Systems, Inc. of Santa Clara, California. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Conventional chemotherapy is relatively ineffective in the treatment of patients with metastatic cancer. An effective therapy of patients with malignancy is needed. New cancer therapy modalities utilizing the augmentation of a cancer patient's immune system (immunotherapy) have attracted much scientific interest. The present invention covers a method of providing immunotherapy to cancer patients using a combination of tumor infiltrating lymphocytes (TIL) and interleukin-2. Tumors that are removed from cancer patients are used for the isolation of lymphocytes (tumor infiltrating lymphocytes). Single cell suspensions are prepared which consist largely of tumor cells but with occasional lymphocytes. These lymphocytes are cultured in presence of IL-2 which expands their numbers and activates them to destroy the tumor cells. Patients with cancer are then

treated with these TIL along with interleukin-2. At the site of tumor, these TIL destroy tumor either by direct contact or by the secretion of cytokines. Several clinical studies have demonstrated the efficacy of this cancer therapy.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: Raphe Kantor, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804. Telephone: (301) 496-7735 ext. 247; Facsimile: (301) 402-0220. A signed Confidentiality Agreement will be required to receive copies of the patent applications. Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by NIH on or before October 10, 1995 will be considered. Comments and objections will not be made available for public inspection and, to the extent permitted by law, will not be subject to disclosure under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 26, 1995.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 95-19734 Filed 8-9-95; 8:45 am]

BILLING CODE 4140-01-P

Office of Inspector General

Publication of OIG Special Fraud Alerts: Home Health Fraud, and Fraud and Abuse in the Provision of Medical Supplies to Nursing Facilities

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth two recently issued OIG Special Fraud Alerts concerning fraud and abuse practices in the home health industry and in the provision of medical supplies to nursing facilities. For the most part, the OIG Special Fraud Alerts address national trends in health care fraud, including potential violations of the Medicare anti-kickback statute. These two Special Fraud Alerts, issued directly to the health care provider community and now being reprinted in this issue of the **Federal Register**, specifically address fraud and abuse in the provision of (1) home health

services and (2) medical supplies to nursing facilities, including the submission of false claims and anti-kickback violations.

FOR FURTHER INFORMATION CONTACT: Joel J. Schaer, Office of Management and Policy, (202) 619-0089.

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Inspector General (OIG) issues Special Fraud Alerts based on information it obtains concerning particular fraudulent and abusive practices within the health care industry. These Special Fraud Alerts provide the OIG with a means of notifying the industry that we have become aware of certain abusive practices which we plan to pursue and prosecute, or bring civil and administrative action, as appropriate. The alerts also serve as a powerful tool to encourage industry compliance by giving providers an opportunity to examine their own practices.

The Special Fraud Alerts are intended for extensive distribution directly to the health care provider community, as well as those charged with administering the Medicare and Medicaid programs. On December 19, 1994, the OIG published in the **Federal Register** the texts of 5 previously-issued Special Fraud Alerts, and announced the intention to publish in the same manner subsequent issuances as a regular part of distribution of these Special Fraud Alerts (59 FR 65372).

The first of these new Special Fraud Alert serves to point out the prevalence of certain types of home health care fraud, including (1) cost report frauds; (2) billing for excessive services or services not rendered; (3) use of unlicensed or untrained staff; (4) falsified plans of care; (5) forged physician signatures on plans of care; and (6) kickbacks that the OIG has uncovered.

The second new Special Fraud Alert, focusing on the provision of medical supplies to nursing facilities, identifies some of the illegal practices that the OIG has recently uncovered. These include (1) the submitting of claims to Part B of Medicare for medical supplies and equipment that are not medically necessary; (2) submitting claims for items that are not provided as claimed; (3) double billings; and (4) paying or receiving kickbacks in exchange for Medicare or Medicaid referrals.

These two issuances are the first in a series of new Special Fraud Alerts being developed by the OIG over the next year to heighten both the public's and industry's awareness of fraudulent

health care practices. A reprint of both of these Special Fraud Alerts follows.

II. Special Fraud Alert: Home Health Fraud

(June 1995)

The Office of Inspector General was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse and waste in Health and Human Services programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations and inspections.

To help reduce fraud and abuse in the Medicare and Medicaid programs, the OIG actively investigates schemes to fraudulently obtain money from these programs and, when appropriate, issues Special Fraud Alerts which identify segments of the health care industry that are particularly vulnerable to abuse. This Special Fraud Alert focuses on the home health industry and identifies some of the illegal practices the OIG has uncovered.

What Is Home Health Care And Who Is Eligible To Receive It?

Medicare's home health benefit allows people with restricted mobility to remain non-institutionalized and receive needed care at home. Home health services and supplies are typically provided by nurses and aides under a physician-certified plan of care.

Medicare will pay for home health services if a beneficiary's physician certifies that he or she:

- is homebound—i.e., confined to the home except for infrequent or short absences or trips for medical care, and
- requires one or more of the following qualifying services: physical therapy, speech-language pathology, or intermittent skilled nursing.

If a homebound patient requires a qualifying service, Medicare also covers services of medical social workers and certain personal care such as bathing, feeding, and assistance with medications. However, a beneficiary who needs only this type of personal or custodial care does not qualify for the home health benefit.

Fraud and Abuse in the Home Health Industry

Home care is consuming a rapidly increasing portion of the federal health budget. This year, Medicare payments for home health will reach close to \$16 billion, up from \$3.3 billion in 1990—nearly a five fold increase. Home health care is particularly vulnerable to fraud and abuse because: