

the realignment of the functions within the Office on Women's Health (OWH), OPHS, to provide a critically needed management substructure to assist the Director in the planning, coordination, and operation of the OWH.

The changes are as follows:

Under Chapter AC, Office of Public Health and Science, Section AC.20 Functions, delete paragraph B, "Office on Women's Health (ACB)," and replace with the following:

1. Office on Women's Health (ACB)—The Office on Women's Health is headed by the Deputy Assistant Secretary for Health (Women's Health), who reports to the Assistant Secretary for Health, is Director of the Office on Women's Health, and serves as the principal advisor on scientific, ethical, and policy issues relating to women's health. The issues cut across all HHS components which provide research, service, prevention, promotion, treatment, training, education and dissemination of information relating to women's health.

2. The Immediate Office of the Director (ACB1), headed by the Deputy Assistant Secretary for Health (Women's Health) coordinates the programmatic aspects of HHS components in regard to issues relating to women's health; serves as the locus within HHS to identify changing needs, to recommend new studies, and to assess new challenges to the health of women; serves as a focal point within HHS to coordinate the continuing implementation of health objectives for the future; assures liaison with relevant HHS agencies and offices; and facilitates the expansion of services and access to health care for a women.

Plans and directs financial management activities, including budget formulation and execution; provides liaison on personnel management activities with the OPHS, and the Program Support Center, Division of Human Resources (PSC); provides administrative services in support of OWH; and serves as the focal point for the support of information resources management, telecommunications equipment and systems for the OWH. The Immediate Office will also provide scientific analyses for all initiatives.

3. The Division of Policy and Program Development (ACB2), headed by the Division Director, advises the OWH Director on the development of strategic and operational plans and provides staff support to and liaison with program staff in coordinating, integrating, and articulating these plans; advises the OWH Director on policy issues; develops the OWH's plan for evaluating the focus and impact of ongoing programs and the development of new

programs and policies; provides analytical reports of program trends and future forecasts; and is responsible for implementing the Congressional, international health, and national (regional) components for the OWH mission.

4. The Division of Program Management (ACB3), headed by the Division Director, provides technical consultation and assistance to the Centers of Excellence in Women's Health, which are responsible for providing state-of-the-art comprehensive and integrated health care services, multidisciplinary research, and public health and health care professional education targeted toward the special needs of women; and coordinates OWH requirements relating to contracts and reimbursable agreements for major office activities. The contract development, review and award process is supported and coordinated with the Program Support Center, DHHS.

5. The Division of Communications (ACB4), headed by the Division Director, provides oversight and direction to the management of the National Women's Health Information Center toll-free telephone number and web site; plans, organizes, administers, and when appropriate, implements the OWH's communication programs consistent with policy direction established by the Office of the Assistant Secretary for Public Affairs; systematically captures, assesses, and disseminates information on scientific and policy developments relating to women's health research results and current or emerging trends and issues; manages the OWH information, education and awareness activities both within the Department and externally; coordinates, assigns, develops, researches, and prepares briefing materials on women's health for DASH and other HHS offices; manages public information activities and media and press relations; plans and coordinates efforts to promote the OWH's programs and policies in the voluntary and corporate sectors; and manages exhibits, and develops visual and other graphic materials for the OWH.

Dated: April 26, 1999.

John J. Callahan,

Assistant Secretary for Management and Budget.

[FR Doc. 99-11197 Filed 5-4-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of June 1999.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: June 9, 1999; 9:00 a.m.–5:00 p.m.

Place: Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The meeting is open to the public.

Agenda: Items will include, but not be limited to: an update on Vaccines in Clinical Trials, an update on Pre-1988 Claims, a discussion on coverage of new vaccines, and reports from the Department of Justice, the National Vaccine Program Office, and routine program reports.

Public comment will be permitted before lunch and at the end of the Commission meeting on June 9, 1999. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Shelia Tibbs, Committee Management Assistant, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A-46, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443-6593. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file an advance request for a presentation, but desire to make an oral statement, may sign-up in Conference Rooms G and H on June 9, 1999. These persons will be allocated time as time permits.

Anyone requiring information regarding the Commission should contact Ms. Tibbs, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A-46, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-6593.

For further information, call Ms. Eve Morrow at (301) 594-4144.

Agenda items are subject to change as priorities dictate.

Dated: April 28, 1999.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99-11251 Filed 5-4-99; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing; "Receptor-Mediated Delivery of Third-Party Proteins and Peptides to the Cytosol of Mammalian Cells"

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

ACTION: Notice.

SUMMARY: The invention listed below is owned by or controlled by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development.

ADDRESSES: Licensing information and copies of U.S. patents and patent applications referenced below may be obtained by contacting J. R. Dixon, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 (telephone 301/496-7056 ext 206; fax 301/402-0220; E-Mail: jd212g@NIH.GOV). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

SUPPLEMENTARY INFORMATION: Invention Title: "Recombinant Chimeric Proteins Deliverable Across Cellular Membranes into Cytosol of Target Cells".

Inventors: Drs. Ira H. Pastan (NCI), Trevor Prior (NCI), Waldemar Y. Debinski (NCI), Clay Siegall (NCI).

DHHS Ref. No. E-020-91/0 [= USP SN: 5,328,984 (= 07/663,455)—Filed March 4, 1991].

The following patent applications and patents are also available, to the extent necessary to practice the technology disclosed in the U.S.P. SN: 5,328,984, for licensing from the National Institutes of Health's Office of Technology Transfer:

1. 08/683,621, entitled: "Hybrid Molecules Having Translocation Region and Cell-Binding Region", inventor: John R. Murphy, Filed: July 17, 1996. [E-998-98/7]

2. 5,668,255 [= 08/102,387], entitled: "Hybrid Molecules Having Translocation Region and Cell-Binding

Region", inventor: John R. Murphy, Filed: August 4, 1993. [E-998-98/6]

3. 07/722,484, entitled: "Hybrid Molecules Having Translocation Region and Cell-Binding Region", inventor: John R. Murphy, Filed: June 26, 1991. [E-998-98/5]

4. 07/538,276, entitled: "Hybrid Molecules Having Translocation Region and Cell-Binding Region", inventor: John R. Murphy, Filed: June 14, 1990. [E-998-98/4]

5. 07/456,095, entitled: "Hybrid Molecules Having Translocation Region and Cell-Binding Region", inventor: John R. Murphy, Filed: December 22, 1998. [E-998-98/3]

6. 06/742,554, entitled: "Hybrid Protein and Fused Gene Encoding Same", inventor: John R. Murphy, Filed June 7, 1985. [E-998-98/2]

7. 06/726,808, entitled: "Hybrid Protein and Fused Gene Encoding Same", inventor: John R. Murphy, Filed: April 25, 1985. [E-998-98/1]

8. 06/618,199, entitled: "Hybrid Protein and Fused Gene Encoding Same", inventor: John R. Murphy, Filed: June 7, 1984. [E-998-98/0].

Background

Protein toxins have several distinctive properties that allow them to facilitate the delivery of third-party proteins to the cell cytosol. First, they are modular in nature and possess separate domains that function independently to perform distinct functions. By domain swapping, toxins can be converted into delivery agents. Toxins enter cells by receptor-mediated endocytosis, avoid degradation, and translocate to the cell cytosol where they are cytotoxic. By disabling the toxin's cytotoxicity domain, it is possible to replicate this delivery pathway without causing damage to the cell. Further, by altering toxin-expressing vectors to include cDNAs encoding non-toxin related proteins and peptides, it is possible to mediate delivery of third-party proteins from the cell exterior to the cytosol. Thus, functionally active proteins can be joined to the toxin translocation module and the resulting chimeric protein developed into a delivery vehicle. Further the toxins' binding domain can be replaced with receptor-binding ligands of choice. By combining domains of different origins, various therapeutic proteins can be generated. Toxin-mediated delivery to the cytosol can be used for: enzyme replacement (to complement a genetic defect), peptide delivery for the generation of cytotoxic lymphocytes, delivery of anti-viral peptides, agonist of antagonist peptides of signaling pathways, etc.

Invention

This invention provides a method of making a hybrid foreign protein that can be delivered into the cytosol of the target cells across the cellular membranes. Further, the present invention provides a suitable vector containing a nucleotide sequence that encodes a hybrid protein.

The advantages of the invention are achieved by (1) providing a recombinant molecule possessing at least a recognition element, a translocation function, and one or more recombinant sites for inserting foreign proteins or polypeptides, and (2) making a recombinant chimeric protein translocatable across cellular membranes into the cytosol of target cells, said chimeric protein having at least one segment which is a functionally active foreign protein desired to be introduced *de novo* into cytosol of target cells, a recognition element that directs the hybrid protein to the target cells, and an additional segment having at least a translocation function which internalizes the protein and delivers the foreign protein into the cytosol of the target cells. In the case of *Pseudomonas* Exotoxin ("PE"), the recombinant sites could be located in either or both of domains Ib or III, but not in domain II. These chimeric proteins can be used for cytotoxic, diagnostic, or therapeutic purposes, such as for compensating the deficiency or defect of an enzyme or a protein which may be causative of a disease or an abnormality. The above mentioned invention is available, including any available foreign intellectual property rights, for licensing on an exclusive or non-exclusive basis.

Dated: April 28, 1999.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 99-11204 Filed 5-4-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of meetings of the Fogarty International Center Advisory Board.

The meetings will be open to the public as indicated below, with attendance limited to space available.