

1. Provide the PB2 technology to the CRADA Collaborator.

2. Jointly develop a series of donor viruses containing the mutant PB2 gene with or without a second non-hemagglutinin (HA), non-neuraminidase (NA) attenuating gene.

3. Jointly produce a series of reassortants bearing current H1 or H3 hemagglutinins (HAs) for evaluation in clinical trials in humans.

4. Jointly produce experimental vaccines and evaluate them in clinical trials.

The role of the Collaborator(s) will be to:

1. Participate in joint activities 2–4 above.

2. Evaluate a variety of mammalian cell lines for production of live attenuated virus vaccines in lieu of production in the allantoic cavity of eggs.

Selection criteria for choosing the CRADA Collaborator(s) will include but are not limited to the following:

1. The ability to collaborate with the NIAID on further research and development of this technology. This ability can be demonstrated through experience and expertise in this and related areas of technology.

2. The demonstration of adequate resources to perform the research, development, and commercialization of this technology (e.g., personnel, expertise, and facilities) 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, ELA/PLA and FDA approval for a new vaccine or other products based on this technology.

4. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this technology.

5. The level of financial support to CRADA Collaborator will provide for CRADA-related Government activities.

6. The willingness to cooperate with the NIAID in the timely publication of research results consistent with the protection of proprietary information and patentable inventions that may arise during the period of the CRADA.

7. Agreement to be bound by DHHS rules and regulations involving human subjects, patent rights, ethical treatment of animals, and randomized clinical trials.

8. The willingness to accept the language and legal provisions of the NIH model CRADA with only minor modifications, if any. These provisions govern the equitable distribution of patent rights to any inventions

developed under the CRADA. Generally, the rights of ownership are retained by the organization which is the employer of the inventor, with (1) The grant of an irrevocable, non-exclusive, royalty-free license for research purposes to the Government when the CRADA Collaborator's employee(s) is/are the sole inventor(s), or (2) the grant of an option to negotiate an exclusive or non-exclusive license to the CRADA Collaborator when a Government employee(s) is/are the sole inventor(s).

Dated: November 30, 1995.

Barbara M. McGarey,
Deputy Director, Office of Technology Transfer.

[FR Doc. 95–30004 Filed 12–8–95; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Amended Notice of Meeting

Notice is hereby given of the rescheduling of the meeting of the Ad Hoc Clearinghouse Subcommittee of the National Deafness and Other Communication Disorders Advisory Council, the notice of which was published in the Federal Register 60 FR 55849 on November 3, 1995. This meeting could not be convened on November 16 due to the partial shutdown of the Federal Government. It is rescheduled for December 18 from 11:00 a.m. to 1:00 p.m., as a telephone conference call originating in room 3C05, Building 31, 9000 Rockville Pike, Bethesda, Maryland. The meeting will be open to the public, limited to space available.

Dated: December 4, 1995.

Susan K. Feldman,
Committee Management Officer, NIH.

[FR Doc. 95–30001 Filed 12–8–95; 8:45 am]

BILLING CODE 4140–01–M

Consensus Development Conference on Physical Activity and Cardiovascular Health

Notice is hereby given of the NIH Consensus Development Conference on "Physical Activity and Cardiovascular Health," which will be held December 18–20, 1995, in the Natcher Conference Center of the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. The conference begins at 8:30 a.m. on December 18, at 8 a.m. on December 19, and at 9 a.m. on December 20.

Over the past 25 years, the United States has experienced steady declines in the death toll from cardiovascular

disease (CVD), primarily in coronary heart disease and stroke. Despite these declines, heart disease remains the number one and stroke the third leading cause of death. Lifestyle improvements by the American public and better control of the risk factors for heart disease and stroke have been a major factor in this decline.

Cardiovascular disease is of multifactorial etiology. Modifiable risk factors include high blood pressure, high blood cholesterol, obesity, smoking, diabetes, and physical inactivity. In contrast to the positive trends observed with the reduction of high blood pressure and high blood cholesterol, overweight and physical inactivity have been on the increase. In light of this, the accumulating evidence of the risk of cardiovascular disease associated with a sedentary lifestyle and the role of physical activity in the prevention and treatment of CVD and other CVD risk factors needs to be examined.

In 1991, 58 percent of adults reported that they exercised sporadically or not at all. Data from the 1990 Youth Risk Behavior Survey suggests that adolescents are less active than they were a decade ago. Only 37 percent of teenagers in grades 9 through 12 reported performing at least 20 minutes of vigorous exercise at least three or more times per week. About 50 percent of students reported they did not participate in physical education (PE) classes. Of those who reported participating in PE classes, 25 percent said they do not do any physical activity.

Physical activity not only independently protects against the development of cardiovascular disease but also has effects through the CVD risk factors of high blood pressure, high blood cholesterol, diabetes mellitus/insulin resistance, and overweight. The type, frequency, and intensity of the physical activity, however, remains controversial. Some experts suggest that moderate forms of physical activity can help prevent cardiovascular disease, while others suggest it must be vigorous and sustained.

Physical activity is also important in the treatment and management of patients with CVD or its risk factors, including patients who have stable angina, have suffered a myocardial infarction, or have heart failure. Physical activity is an important component of cardiac rehabilitation but questions remain regarding the type, frequency, and intensity needed for patients.

In addition, to potential benefits, questions remain regarding risks

associated with becoming physically active and whether environmental factors affect possible benefits.

Becoming physically active is a lifestyle behavior that is influenced by many variables such as socioeconomic status, cultural influences, age, and health status. There is a need to understand how such variables influence the adoption of this behavior by various population groups including children, adolescents, adults, the elderly, and minority populations. Various intervention strategies might be more or less useful for encouraging individuals to adopt and comply with a physically active lifestyle. Different environments such as schools, work sites, health care settings, and family structures need to be examined for their role in promoting physical activity. In addition, costs and availability of adequate resources can influence the adoption of a physically active lifestyle.

The conference will bring together specialists in cardiology, exercise physiology, cardiovascular and behavioral medicine, epidemiology, nutrition, family practice, physical therapy, and nursing as well as representatives from the public on Physical Fitness and Sports.

Advance information on the conference program and conference registration materials may be obtained from: Debra DeBose, Technical Resources International, Inc., 3202 Tower Oaks Blvd., Suite 200, Rockville, Maryland 20852, (301) 770-3153, ddebose@tech-res.com.

The consensus statement will be submitted for publication in professional journals and other publications. In addition, the statement will be available beginning December 20, 1995 from the NIH Consensus Program Information Service, P.O. Box 2577, Kensington, Maryland 20891, phone 1-800-NIH-OMAR (1-800-644-6627).

Dated: November 29, 1995.

Ruth L. Kirschstein,
Deputy Director, NIH.

[FR Doc. 95-30006 Filed 12-8-95; 8:45 am]

BILLING CODE 4140-01-M

Prospective Grant of Exclusive License: Antibacterial Therapy With Bacteriophage Genotypically Modified to Delay Inactivation by the Host Defense System

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

ACTION: Notice.

SUMMARY: This is notice in accordance with 15 U.S.C. 209(c)(1) and 37 CFR

404.7(a)(1)(i) that the National Institutes of Health (NIH), 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 Application 08/222,956 and corresponding foreign patent applications entitled, "Antibacterial Therapy with Bacteriophage Genotypically Modified to Delay Inactivation by the Host Defense System" to Exponential Therapies, Inc., New York, New York 10001. 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 the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Alternatively, the subject technology may be licensed as a CRADA invention under 15 U.S.C. 3701 *et seq.* if it is determined to have been made in whole or in part under CRADA 94/0023.

The patent application concerns bacteriophage therapy and discloses methods that enable bacteriophage to delay inactivation by any and all parts of the host defense system (HDS) against foreign objects that would tend to reduce the numbers of bacteriophage and/or the efficiency of those phage at killing the host bacteria present during an infection. The application discloses two method for producing genotypically modified bacteriophage: (1) Selection by serial passaging and (2) genetic engineering. The foregoing methods can be used to manufacture a variety of distinct therapeutics for antibiotic-resistant bacterial diseases.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Girish C. Barua, Ph.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7735 ext. 263; facsimile: 301/402-0220. A signed Confidentiality Agreement will be required to receive copies of the patent applications. Applications for a license in the indicated exclusive field(s) 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 February 9, 1996 will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 1, 1995.

Barbara M. McGarey,
Deputy Director, Office of Technology Transfer.

[FR Doc. 95-30003 Filed 12-8-95; 8:45 am]

BILLING CODE 4140-01-M@

Prospective Grant of Exclusive License: Activity Dependent Neurotropic Factor

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 (NIH), 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 Applications 07/688,087, 07/871,973 and 08/324,297 and corresponding foreign patent applications entitled, "Activity Dependent Neurotropic Factor" to Pfizer Inc. of New York, NY. 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.

The present patent applications cover a purified non-neuronal activity-dependent neurotropic factor (ADNF) protein that increases the growth and survival of developing spinal cord neurons and prevents neuronal cell death. It may have extensive use in treating various neurological deficiencies, such as Alzheimer's disease, Huntington's disease, diabetic neuropathy, spinal cord injury, HIV encephalopathy and stroke.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: Girish C. Barua, Ph.D.,