

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation

[Account Number: 4151-04]

Technical Review Panel on the Medicare Trustees Reports; Notice of June 28-29 Meeting

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of June 28-29 meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces the first meeting of the Technical Review Panel on the Medicare Trustees Reports (the Panel). This meeting is open to the public.

Pursuant to Public Law 92-463 (the Federal Advisory Committee Act), the Panel was established on August 12, 1999, by the Secretary of HHS to review the methods and assumptions underlying the annual reports of the Board of Trustees of the Hospital Insurance and Supplementary Medical Insurance Trust Funds.

DATES: The first meeting will be held on June 28, 2000 (11:00 a.m. to 5:00 p.m.) and June 29, 2000 (9:00 a.m. to 1:00 p.m.).

ADDRESSES: The meeting will be held at the Health Care Financing Administration (HCFA) Headquarters, Training Center Room C-101, 7500 Security Boulevard, Baltimore, Maryland.

FOR FURTHER INFORMATION CONTACT: Ariel Winter, Executive Director, Technical Review Panel on the Medicare Trustees Reports, Department of Health and Human Services, Room 442E, 200 Independence Avenue, SW., Washington, DC, 20201, (202) 690-6860, medpanel@osaspe.dhhs.gov. Additional information is also available on the Panel's web site: <http://aspe.hhs.gov/health/medpanel.htm>.

SUPPLEMENTARY INFORMATION: The Board of Trustees of the Medicare Trust Funds (the Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) Trust Funds) report annually on the funds' financial condition. The reports describe the trust funds' current and projected financial condition, within the next 10 years (the short term) and over the subsequent 65 years (the long term). The Medicare Board of Trustees has directed the Secretary of Health and Human Services (who is one of the Trustees) to establish a panel of technical experts to review the

assumptions and methods underlying the HI and SMI annual reports.

The panel's review will include the following four topics:

1. Medicare assumptions (e.g., utilization rates, medical price increases).
2. Projection methodology (how assumptions are used to make cost projections).
3. Long-range growth assumptions for HI and SMI.
4. Use of stochastic forecasting techniques.

The Panel will issue its findings in reports to the Secretary and the other Trustees.

The Panel will consist of seven members who are experts in the fields of economics and actuarial science. The following individuals will be sworn in as members at the first meeting: Len Nichols, Ph.D.; David Cutler, Ph.D.; Michael Chernen, Ph.D.; Dale Yamamoto, F.S.A., M.A.A.A., F.C.C.A., E.A., B.S.; James Robinson, F.S.A., M.A.A.A., Ph.D.; Alice Rosenblatt, F.S.A., M.A.A.A., M.A.; and Sam Gutterman, F.S.A., F.C.A.S., M.A.A.A., M.A. (the chair-designate). The members' terms will end August 12, 2001.

The first meeting of the Panel is scheduled for June 28, 2000 (11:00 a.m. to 5:00 p.m.), and June 29, 2000 (9:00 a.m. to 1:00 p.m.). The meeting will be held at the Health Care Financing Administration (HCFA) Headquarters, Training Center, Room C-101, 7500 Security Boulevard, Baltimore, Maryland. The meeting is open to the public, but attendance is limited to the space available. There will also be an executive session on June 28 from 9:00 a.m. to 11:00 a.m. for the swearing-in of Panel members. This session will be closed to the public.

At this meeting, the members will discuss the Panel's scope of work. HCFA's Office of the Actuary will make presentations to the Panel on how the estimates in the Medicare Trustees' Reports are developed. Specific presentation topics may include: the HI and SMI benefits and income models, measures of actuarial soundness, and health care utilization assumptions.

Individuals or organizations that wish to make 5-minute oral presentations on the agenda issues mentioned in this notice should contact the Executive Director by 12 noon on June 12, 2000. The number of oral presentations may be limited to the time available. A written copy of the presenters' oral remarks should be submitted to the Executive Director no later than 12 noon, June 19, 2000, for distribution to the Panel members.

Any interested member of the public may submit written comments to the Executive Director and Panel members for review. Comments should be received by the Executive Director by 12 noon, June 19, 2000, for distribution to the Panel members.

Individuals requiring sign language interpretation for the hearing impaired and/or other special accommodation, should contact Ariel Winter at (202) 690-6860 by June 16, 2000.

Dated: May 30, 2000.

Margaret A. Hamburg,
Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00062]

Postdoctoral Fellowship Training Program in Infectious Diseases; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for Postdoctoral Fellowship Training Programs in Infectious Diseases. CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus area of Immunization and Infectious Disease.

The purpose of this cooperative agreement is to assist recipients in the development and implementation of a two- to three-year Postdoctoral Fellowship Training Program in Infectious Diseases (PFTP) which provides a combination of clinical training and basic laboratory or epidemiologic training in infectious diseases. The goal is to improve the ability of the U.S. public health system to respond to the problem of infectious diseases by increasing the number of academic infectious disease physicians with demonstrated skills in the public health aspects of infectious diseases and to provide them with the essential, pertinent clinical and research skills.

PFTPs should be implemented as new distinct fellowship positions/tracks in recipient's existing infectious disease

postdoctoral training program. PFTPs should be aimed at physicians with training in infectious diseases who wish to pursue a career in academic infectious diseases of public health importance. The objective is to offer a combination of research and clinical training which will lead to eligibility for certification in infectious diseases by the American Board of Internal Medicine, Subspecialty Board of Infectious Diseases (the cognizant member board of the American Board of Medical Specialties). Specific areas of clinical concentration may include: Clinical rotations in infectious diseases, infectious diseases in transplant recipients, clinical microbiology, outpatient infectious diseases, pediatric infectious diseases, or infectious disease pharmacology. The recipient must be able to provide support for physicians of unusual ability and promise or proven achievement by giving them an opportunity to conduct clinical, laboratory, and epidemiologic research on significant public health problems caused by infectious diseases. Specific areas of research concentration may include: Viral and rickettsial infections, nosocomial infections, antimicrobial resistance, vector-borne infectious diseases, respiratory and food-borne bacterial diseases, parasitic diseases, sexually transmitted diseases, and acquired immunodeficiency syndrome.

In 1994, CDC initiated the Postdoctoral Fellowship Training Program in Infectious Diseases (PFTP) and made awards to two U.S. medical schools. The PFTP was renewed competitively in 1997 and continued programs at the original two schools and added a third. Under all three awards, the PFTP was integrated into the school's existing postdoctoral program as a separate PFTP track and several physicians have been enrolled.

B. Eligible Applicants

Assistance will be provided only to university affiliated schools of medicine with infectious disease programs accredited by the Accreditation Council for Graduate Medical Education (ACGME).

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$180,000 is available in FY 2000 to fund approximately three awards. It is expected that the average award will be \$60,000, ranging from

\$25,000 to \$100,000. It is expected that the awards will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

Grantee cost-sharing is required under this program. CDC will provide up to 50 percent of the total cost for items directly related to the support of fellows such as stipends (consistent with PHS policies) and professional travel. CDC funds will not be provided for supplies and equipment or for direct salaries/fringe, travel, space, *etc.*, for recipient's faculty or administrative personnel. In a training grant, recipient's indirect charges are limited to 8 percent of direct costs. CDC funds are not intended to supplant recipient's existing infectious disease fellowships, rather they are intended to support new fellowship opportunities that are consistent with the stated Purpose of this cooperative agreement program.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

a. As a distinct and separate track of recipient's existing infectious disease postdoctoral fellowship program, develop and conduct a two- to three-year PFTP that combines clinical and basic laboratory or epidemiologic research in prevention and control of infectious diseases of public health importance.

b. Design and conduct the PFTP such that, upon completion of the fellowship, fellows will become eligible for certification in infectious diseases by the American Board of Internal Medicine.

c. Provide preceptors for training.

d. Develop a fellowship candidate application, review, ranking, and selection process. Based on this process, select applicants to be awarded two- to three-year PFTP fellowships.

e. Provide administrative support to fellows during their tenure in the PFTP including the payment of stipends, professional travel, *etc.* (see Availability of Funds for cost sharing requirements).

f. Assist fellows in publishing and/or otherwise disseminating results of their research.

g. Monitor and evaluate the progress of fellows and progress toward achieving program goals. To measure the overall success of the PFTP, establish a mechanism to follow-up and report on fellows (*e.g.*, where they work, in what field, *etc.*) periodically for up to five years after they complete the PFTP.

h. If fellow's research involves the use of human subjects, assure appropriate IRB review by all cooperating institutions participating in the project.

2. CDC Activities

a. The laboratory or epidemiologic research training may occur at CDC facilities. Provide preceptors and facilities for research training that occurs at CDC facilities.

b. If CDC researchers participate in fellow's research that involves the use of human subjects, assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Application Content

Use the information in this section and the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 10 single-spaced pages, printed on one side, with one inch margins (including headers and footers), and un-reduced font.

Typing and Mailing

All pages must be clearly numbered and a complete index to the application and its appendices must be included. All pages of the application and appendices must be easily run through an automatic document feed copier, thus do not bind, staple, or paperclip any pages of any copy of the application and do not include any bound documents (*e.g.*, pamphlets or other publications) in the appendices. Do not include cardboard, plastic, or other page separators between sections.

Specific Instructions

The application narrative must not exceed 10 pages (excluding abstract, budget, and appendices). Unless indicated otherwise, all information requested below must appear in the narrative. Materials or information that

should be part of the narrative will not be accepted if placed in the appendices. The application narrative must contain the following sections in the order presented below:

1. Abstract

Provide a brief (less than two pages) summary of the proposed PFTP.

2. Background and Need

Demonstrate an understanding of the background and need for the PFTP. Discuss how your proposed PFTP track differs from existing tracks/opportunities in your fellowship program and how your proposed PFTP track meets the Purpose of this cooperative agreement program.

3. Capacity and Personnel

a. Describe applicant's goals, objectives, and efforts to promote the field of academic infectious diseases. Describe relevant degree programs and sponsored regular national meetings, seminars, and/or workshops devoted to pertinent issues in academic infectious diseases with relevance to public health.

b. Demonstrate applicant's experience in academic infectious diseases education and training in general, including experience in maintaining programs that lead to eligibility for certification in infectious diseases by the American Board of Internal Medicine. Describe applicant's existing postdoctoral fellowship training programs for physicians in infectious diseases.

c. Describe applicant's resources, facilities, and professional personnel that will be involved in conducting the project. Include (in an appendix) curriculum vitae for all professional personnel involved with the project. Describe plans for administration of the project and identify administrative resources/personnel that will be assigned to the project. Provide (in an appendix) letters of support from all key participating non-applicant organizations, individuals, *etc.*, which clearly indicate their commitment to participate as described in the operational plan.

d. If proposing that fellows conduct their laboratory or epidemiologic training at CDC facilities, include a letter of support (in an appendix) from the appropriate CDC scientist (co-signed by their Division/Program Principal Management Officer) that clearly indicates their commitment to participate as described in your application Operational Plan including agreement to 1) serve as preceptor for the research training and 2) provide

space, facilities, supplies, *etc.*, for fellows.

4. Operational Plan

Present a detailed and time-phased plan for establishing and conducting the PFTP. Describe procedures to accomplish all of the required recipient activities. Describe how the clinical and research activities will be coordinated within the PFTP. Present a plan for monitoring and evaluating the progress of fellows and the progress toward achieving program goals. Describe how the plan will ensure that all fellows become eligible for certification in infectious diseases by the American Board of Internal Medicine by the end of fellowship tenure. Describe procedures and plans for assuring any fellow's research that involves the use of human subjects will receive appropriate IRB review by all cooperating institutions participating in the project.

5. Budget

Provide a line-item budget and accompanying detailed, line-by-line justification that demonstrates the request is consistent with the purpose and objectives of this program. Clearly indicate by line-item both (a) the full cost and (b) the amount requested from CDC (see Availability of Funds section for further information regarding cost-sharing).

F. Submission and Deadline

Letter of Intent (LOI)

In order to assist CDC in planning the evaluation of applications submitted under this Program Announcement, all parties intending to submit an application are requested to submit an LOI to inform CDC of their intention to do so as soon as possible but not later than 30 days prior to the application due date. The LOI should include (1) Name and address of institution, (2) name, address, and telephone number of contact person, and if proposing that research component be conducted at CDC facilities, (3) name and telephone number of CDC scientist agreeing to participate. Notification can be provided by facsimile, postal mail, or Email to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are available at the following Internet address: www.cdc.gov/ . . . Forms, or in the application kit. On or before Friday, June 30, 2000, submit the application to the Grants Management

Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for orderly processing. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Background and Need (15 Points)

Extent to which applicant demonstrates an understanding of the background and need for the PFTP. Extent to which they clearly demonstrate that their proposed PFTP fellowship positions add to and do not supplant existing positions in their fellowship program. Extent to which they demonstrate and how the proposed PFTP track meets the Purpose of this cooperative agreement program.

2. Capacity (50 Points)

a. Institutional (25 points): The extent to which the applicant demonstrates that they have been and are devoted to promoting the field of academic infectious diseases. The extent to which the applicant has promoted the field of academic infectious diseases by conducting regular national meetings and workshops devoted to current topics. The extent to which the applicant documents experience in education and training in academic infectious diseases, including documentation of relevant degree programs offered and evidence of experience in successfully preparing students for certification in infectious diseases by the American Board of Internal Medicine. The extent to which the applicant demonstrates significant institutional experience in managing postdoctoral fellowship training programs for physicians in the area of infectious diseases. The extent to which applicant documents they have a successful existing postdoctoral

fellowship program in infectious diseases.

b. Staff and administrative (25 points): The extent to which applicant describes adequate resources and facilities (clinical, academic, and administrative) for conducting the PFTP. The extent to which applicant documents that their professional personnel involved in the PFTP are qualified and have past experience and achievements related to that proposed as evidenced by curriculum vitae, publications, *etc.* If proposing that fellow's research be conducted at CDC facilities, the extent to which applicant includes a Letter of Support as described in Application Content section 3.b., above (*i.e.*, that is signed by the appropriate CDC officials and that clearly indicates their commitment to participate as proposed in the application).

3. Operational Plan (30 Points)

The extent to which the proposed operational plan is clear, detailed, time-phased, and meets the purpose and goals of this cooperative agreement program. The extent to which the proposed operational plan addresses all required Recipient Activities. If specific fellow(s) research projects are proposed that involve the use of human subjects, the degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The proposed justification when representation is limited or absent.

c. A statement as to whether the design of the study is adequate to measure differences when warranted.

d. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

4. Evaluation Plan (5 Points)

The quality of the proposed plan to monitor, evaluate and track individual fellows; and overall plan to evaluate activities and objectives.

5. Budget (Not Scored)

The extent to which the proposed budget is reasonable, clearly justified, and consistent with the intended use of cooperative agreement funds.

6. If research involving the use of human subjects is proposed, does the application adequately address the requirements of Title 45 CFR Part 46 for

the protection of human subjects?

Yes ___ No ___

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of—

1. Annual progress reports (included with each noncompeting continuation application);

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR-1 Human Subjects Requirements

AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-3 Animal Subjects Requirements

AR-7 Executive Order 12372 Review

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 301 [42 U.S.C. 241] and 317(k)(2) [42 U.S.C. 247b(k)(2)] of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance Number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave you name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Andrea Wooddall, Grants Management Specialist, Grants Management Branch,

Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number: (770) 488-2749, Email address: ayw3@cdc.gov.

For program technical assistance, contact: Greg J. Jones, M.P.A., Office of the Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop C-12, 1600 Clifton Road, N.E., Atlanta, GA 30333, Phone: (404) 639-4180, Facsimile: (404) 639-3106, Email: GJJones@cdc.gov.

Dated: June 1, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-14267 Filed 6-6-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00C-1321]

Wesley Jessen Corp.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Wesley Jessen Corp. has filed a petition proposing that the color additive regulations be amended to provide for the safe use of mica in contact lenses.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3089.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 0C0271) has been filed by Wesley Jessen Corp., 333 East Howard Ave., Des Plaines, IL 60018. The petition proposes to amend the color additive regulations in 21 CFR part 73 subpart D—Medical Devices to provide for the safe use of mica in contact lenses.

The agency has determined under 21 CFR 25.32(l) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment