

increase because of their minimal market presence, lack of scale economies and lack of consumer brand loyalty. The proposed merger is likely to lead to unilateral anticompetitive effects in the OTC pediculicide market by eliminating the actual, direct, and substantial competition between Pfizer and Warner and allowing the combined firm to raise prices.

The proposed Consent Order remedies the merger's anticompetitive effects by requiring that Pfizer divest its entire RID brand of pediculicide and all assets associated with this product line to Bayer.

Drugs for the Treatment of Alzheimer's Disease

Pfizer and Warner market the only two products sold in the United States for the treatment of Alzheimer's disease, Aricept and Cognex, respectively. Aricept dominates the market with more than 98 percent market share, while Cognex accounts for the remainder of the market. While the FDA has recently approved one new product, Novartis AG's Exelon, for the treatment of Alzheimer's disease, Novartis has yet to market its product. Even taking into account Novartis's entry into the market, the market will still be highly concentrated. There are significant barriers to entry into this market. New entry into the manufacture and sale of drugs for the treatment of Alzheimer's disease is difficult, expensive and time-consuming because of the lengthy development periods, the need for FDA approval, and the substantial sunk costs required to research, develop, manufacture and sell these drugs. As a result, entry likely to deter or counteract the likely anticompetitive effects of the proposed merger is unlikely.

The merger would result in Pfizer's having a monopoly in the market for drugs for the treatment of Alzheimer's disease, with that monopoly position lessening only slightly when Exelon is launched in the United States. Accordingly, the merger would increase Pfizer's dominant position in the market, allowing it to increase prices and potentially eliminate Cognex, the smaller competitor, from the market. The proposed Consent Order remedies the merger's anticompetitive effects by requiring Warner to divest Cognex to First Horizon Pharmaceutical Corporation.

EGFr-tk Inhibitors for the Treatment of Cancer

Pfizer and Warner are developing Epidermal Growth Factor receptor tyrosine kinase ("EGFr-tk") inhibitors for the treatment of solid cancerous

tumors. Solid tumor cancer targets include head and neck, non-small-cell lung, breast, ovarian, pancreatic and colorectal cancers. Currently, over 1.2 million Americans are diagnosed with solid tumor cancers each year. It is anticipated that EGFr-tk inhibitors will be used in conjunction with surgery, radiation and chemotherapy to treat cancer patients.

EGFr-tk inhibitors target the EGFr oncogene that regulates cancer cell growth. The EGFr has been identified as being over-expressed (too prevalent) in as many as 700,000 of the 1.2 million Americans diagnosed with a solid tumor cancer each year. Patients with an over-expression of EGFr are believed to have a worse prognosis than other cancer patients. Accordingly, scientists have developed drugs that attempt to inhibit the EGFr activity of cell division signal transduction that results in cancer cell proliferation.

The most advanced EGFr-tk inhibitors include those being developed by Pfizer and Warner. Pfizer and Warner are two of only a few companies in clinical development of EGFr-tk inhibitors for solid tumor cancers. There are significant barriers to entry into the market. In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture and sell EGFr-tk inhibitors.

The proposed merger is likely to create anticompetitive effects in the EGFr-tk inhibitor market by potentially eliminating one of the few research and development efforts in this area. As a result of the merger, the combined entity could unilaterally delay, terminate or otherwise fail to develop one of the two competing EGFr-tk drugs, resulting in less product innovation, fewer choices, and higher prices for consumers.

To resolve these concerns, the proposed Consent order requires Pfizer to return its EGFr-tk inhibitor, CP-358,774, to its development partner, OSI. OSI holds a contractual right to obtain CP-358,774 should Pfizer terminate development efforts. Thus, while other companies have expressed interest in acquiring the rights to CP-358,774, none may do so without the prior approval of OSI.

The proposed Consent Order maintains competition in the research and development of EGFr-tk inhibitors for the treatment of cancer by requiring that Pfizer fulfill its obligations under the May 23, 2000 agreement between Pfizer and OSI to (1) transfer and surrender its rights to CP-358,774 to OSI; (2) grant OSI a royalty-free, irrevocable worldwide license, including the right to sublicense, to all

of its rights in, and to, the patents currently owned jointly by OSI and Pfizer relating to EGFr-tk inhibitors; (3) complete, a Pfizer's cost, ongoing clinical trials of CP-358,774; (4) provide OSI with a manufacturing and supply agreement for the continued supply of CP-358,774, pending transfer of manufacturing technology to a new manufacturer; (5) assume liability for all completed clinical trials; and (6) transfer all know-how and technology relating to CP-358,774 to OSI. The Consent Order also provides for an Interim Trustee to be appointed to oversee Pfizer's obligations under the Order and to ensure the continued development and viability of CP-358,774.

The purpose of this analysis is to facilitate public comment on the proposed Consent Order, and it is not intended to constitute an official interpretation of the proposed Consent Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Nominations of Candidates To Serve on the National Vaccine Advisory Committee, Department of Health and Human Services

The Public Health Service (PHS) is soliciting nominations for possible membership on the National Vaccine Advisory Committee (NVAC). This committee studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States; recommends research priorities and other measures the Director of the National Vaccine Program should take to enhance the safety and efficacy of vaccines; advises the Director of the Program in the implementation of sections 2102, 2103, and 2104, of the PHS Act; and identifies annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 2102, 2103, and 2104, of the PHS Act.

Nominations are being sought for individuals engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of

State or local health agencies, or public health organizations. Federal employees will not be considered for membership. Members may be invited to serve a four-year term.

Close attention will be given to minority and female representation; therefore nominations from these groups are encouraged.

The following information is requested: name, affiliation, address, telephone number, and a current curriculum vitae. Nominations should be sent, in writing, and postmarked by August 30, 2000, to: Gloria Sagar, Committee Management Specialist, NVAC, National Vaccine Program Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, m/s D-66, Atlanta, Georgia 30333. Telephone and facsimile submission cannot be accepted.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 19, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00065]

American Indian/Alaska Native Support Centers for Tobacco Programs; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of funds for fiscal year 2000 for cooperative agreements with American Indian/Alaska Native (AI/AN) tribes, tribal organizations, including urban, and eligible inter-tribal consortia. The purpose of the funds is to develop or improve tobacco-related resource networks and outreach to AI/AN tribes. This will enable tribal communities to address and impact the high rates of tobacco use in this population. Assistance to tribes may consist of training and technical assistance, networking and partnership building,

and promoting collaboration with other tribes, national organizations (e.g., American Cancer Society, American Lung Association), States and the Federal government.

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 quality of life. This announcement is related to the focus area of Tobacco Use. For the conference copy of "Healthy People 2010" visit the internet site: <<http://www.health.gov/healthypeople>>.

B. Eligible Applicants

Eligible applicants are AI/AN tribes, tribal organizations, including urban and eligible inter-tribal consortia. An individual AI/AN tribe or urban center is eligible to apply if its tribal population is at least 60,000 or if it represents other regional AI/AN tribes or urban populations with a combined population of at least 60,000. Tribal organizations and inter-tribal consortia are eligible if they represent tribes within a region with a combined population of at least 60,000 and if they are incorporated for the primary purpose of improving AI/AN health and represent such interests for the tribes or urban Indian communities located in its region. AI/AN tribes or urban communities represented may be located in one state or in multiple states. An urban organization is defined as a non-profit corporate body situated in an urban center eligible for services under Title V of the Indian Health Care Improvement Act, PL 94-437, as amended. Applicants should submit with application an executive summary of not more than one page and a completed and signed Eligibility Certification Form (see addendum 3 in the application package). The Eligibility Certification Form is a checklist, which will define your eligibility.

Competition is limited to those identified under "Eligible Applicants" because of the problems posed by tobacco use as evidenced by high prevalence, tobacco-related morbidity and mortality and the unique challenges faced by this population for tobacco control and prevention (see addendum 2 in the application package).

Pre-Application Telephone Conference

Applicants are invited by CDC to participate in a pre-application technical assistance telephone conference June 30, 2000 promptly at 2:00 p.m. (Eastern time) to discuss: programmatic issues regarding this program; how to apply; and questions

regarding the content of the program announcement. This telephone conference is expected to last one hour. The conference name is Tobacco RFA. The telephone bridge number for Federal participants is 404-639-3277 for non-Federal participants call 1-800-311-3437. Participants will need to enter the following conference code when prompted to be connected #345150. All questions and comments will be recorded and published on the Internet at <http://www.cdc.gov/funding> as an attachment to this program announcement.

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 \$1,000,000 is available in FY 2000 to fund five to six awards. It is expected that the average annual award will be \$170,000, ranging from \$125,000 to \$200,000. This award amount includes expenses for indirect costs. It is expected that the awards will begin September 30, 2000 and will be made for a 12-month budget period within a project period of up to five years.

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.

Funding Preference

Funding preference will be given to the geographical areas defined by the Indian Health Service which demonstrate need based on high prevalence, high tobacco-related morbidity and mortality; which lack tobacco control initiatives and culturally appropriate resources; and which show early initiation of commercial tobacco use among young people. CDC will fund up to six awards, only one award will be made within a geographical area.

D. Program Requirements

In conducting activities to achieve the goals and objectives 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) Establish a technical support center and assist tribes with tobacco control needs such as data collection,