

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Regarding Administration of Smallpox Countermeasures

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Notice.

SUMMARY: The Secretary of the Department of Health and Human Services is issuing this notice pursuant to section 224(p)(2)(A) of the Public Health Service Act to make a declaration regarding administration of smallpox countermeasures. The Secretary provides policy determinations regarding administration of countermeasures, and declares that a potential bioterrorist incident makes it advisable to administer, on a voluntary basis, covered countermeasures specified in the declaration for prevention or treatment of smallpox or control or treatment of adverse events related to smallpox vaccination to categories of individuals named in the declaration who may be involved in a wide range of activities associated with the administration of countermeasures against smallpox. Effective dates of the declaration, and relevant definitions are also provided.

DATES: This Notice and the attached declaration are effective as of January 24, 2003.

FOR FURTHER INFORMATION CONTACT: Jerome S. Hauer, Acting Assistant Secretary for Public Health Emergency Preparedness, (202) 205-2882.

SUPPLEMENTARY INFORMATION: The Secretary issues the following declaration pursuant to section 224(p)(2)(A) of the Public Health Service Act, 42 U.S.C. 233(p)(2)(A):

I. Policy Determinations

(1) The attacks of September and October 2001 have heightened concern that terrorists may have access to the smallpox virus and attempt to use it against the American public and U.S. Government facilities abroad.

(2) In light of these concerns, and in order to advance the public health and national security, the President announced the smallpox vaccination program on December 13, 2002.

(3) Given the potential for a bioterrorist incident, administration of smallpox countermeasures is advisable within the terms of this declaration.

(4) Smallpox vaccine is currently recommended domestically only for smallpox response teams, health care

workers, and emergency response workers.

(5) The U.S. Government is making smallpox countermeasures available to personnel associated with certain U.S. facilities abroad and administration of these countermeasures to such personnel is advisable within the terms of this declaration.

(6) Liability protections for manufacturers and distributors of smallpox countermeasures and the hospitals, health care facilities, and health care workers who will receive them and treat potentially infected smallpox cases are integral to ensuring maximum participation in the vaccination program.

(7) Section 304 of the Homeland Security Act (Pub. L. 107-296) is intended to alleviate liability concerns and therefore ensure that vaccine is available if necessary to protect the public health.

(8) Administration of a countermeasure such as smallpox vaccine is necessarily more involved than the act of placing a drop of vaccine on a two-pronged needle and inoculating a person's arm. Determining who is contraindicated; monitoring, management, and care of the countermeasure site; evaluation of countermeasure "takes;" and contact transmission of vaccinia, among other things, all arise out of and are directly related to and part of the administration of the countermeasure. All such acts also potentially give rise to legal liability that, without sufficient protections, may significantly discourage participation in the smallpox vaccination program.

(9) Under current domestic planning, many health care entities will designate individuals to receive countermeasures at a hospital or vaccination clinic determined by the state. To achieve a successful vaccination program and because it is impractical to have countermeasures administered at every health care entity involved in the program, it is critical that health care entities participate in this manner and that their personnel be protected while acting within their scope of employment.

(10) It is important to the successful implementation of the vaccination program that those workers employed by health care entities under whose auspices a countermeasure is administered be protected by section 304 while acting within the scope of their employment.

(11) Health care entities use numerous staffing arrangements to carry out daily functions. Individuals designated to receive covered countermeasures and

subsequently treat potential smallpox cases may fall into any of these arrangements. Liability protection for these individuals, to the extent described below, is necessary to encourage participation in the smallpox vaccination program.

(12) Based upon scientific data from animal model studies examining Cidofivir's effectiveness in treating lethal pox virus infections that are similar to smallpox, Cidofivir may be useful in treating smallpox in humans.

II. Declaration

I, Tommy G. Thompson, Secretary of the Department of Health and Human Services, have concluded, in accordance with authority vested in me under section 224(p)(2)(A) of the Public Health Service Act, that a potential bioterrorist incident makes it advisable to administer, on a voluntary basis, covered countermeasures specified in this declaration for prevention or treatment of smallpox or control or treatment of adverse events related to smallpox vaccination, to categories of individuals named in this declaration. The countermeasures set forth below shall be considered to be administered pursuant to this declaration when used for prevention or treatment of smallpox, or to control or treat the adverse effects of smallpox vaccination.

This declaration may be amended as circumstances require.

III. Covered Countermeasures

Countermeasures to be administered pursuant to this declaration are:

- (1) Vaccinia (Smallpox) Vaccines, including the Dryvax vaccine;
- (2) Cidofivir and derivatives thereof;
- (3) Vaccinia Immune Globulin (VIG).

IV. Individuals Covered by this Declaration

Individuals to whom it is advisable to administer the covered countermeasures specified above are:

(1) Health care workers who may be called upon to monitor or treat any persons who are either (a) covered by this declaration or (b) are deemed to be individuals to whom a covered countermeasure was administered by a qualified person, whether domestically or abroad, pursuant to section 224(p)(2)(C) of the Public Health Service Act;

(2) Any person who is a member of a smallpox response team or teams identified by state[s] or local government entities or the United States Department of Health and Human Services;

(3) Public safety personnel, including, but not limited to, law enforcement

officers, firefighters, security, and emergency medical personnel who may be called upon to assist smallpox response teams specified in paragraph IV(2) above; and

(4) Personnel associated with certain U.S. Government facilities abroad.

V. Effective Dates

The declaration is effective January 24, 2003 until and including January 23, 2004. The effective period may be extended or shortened by subsequent amendment to this declaration.

VI. Definitions

For the purposes of this declaration, including any claim brought against the United States pursuant to section 224 of the Public Health Service Act ("PHS"), as amended by section 304 of the Homeland Security Act, the following definitions will be used:

(1) "Administration of a covered countermeasure" as used in section 224(p)(1) of the PHS Act includes, but is not limited to, the physical administration of a covered countermeasure; education and screening of covered countermeasure recipients; monitoring, management, and care of the covered countermeasure site; evaluation of covered countermeasure "takes;" and contact transmission of vaccinia.

(2) "Health care entity under whose auspices such countermeasure was administered" as used in section 224(p)(7)(B)(ii) of the PHS Act, includes but is not limited to, hospitals, clinics, state and local health departments, health care entities, and contractors of any of those entities that (a) Administer covered countermeasures; (b) designate officials, agents, or employees to receive or administer covered countermeasures; or (c) are identified by state or local government entities or the United States Department of Health and Human Services to participate in the vaccination program, whether that participation is in the United States or abroad.

(3) "Official, agent, or employee" as used in section 224(p)(7)(B)(iv) of the PHS Act and with respect to health care entities under whose auspices covered countermeasures are administered, includes health care workers who share any employment or other staffing relationship with the health care entity.

Dated: January 24, 2003.

Tommy G. Thompson,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

George E. Eagan, University of Albany, State of New York: Based on the report of an investigation conducted by the University of Albany, State of New York (UA-SUNY) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Mr. Eagan, former laboratory technician at UA-SUNY, engaged in scientific misconduct by falsification and fabrication of data supported by a subcontract to UA-SUNY on National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant R01 GM46312-11, "Structural Biochemistry of DNA Base Excision Repair."

Specifically, PHS found that Mr. Eagan engaged in scientific misconduct by falsifying and fabricating the data for two experiments, conducted on February 12 and 13, 2002, designed to test the survival of strains of bacteria exposed to different base analog mutagens. Mr. Eagan's experiments were significant because they would have contributed to the overall objective of the grant to understand the structural and biochemical interaction of enzymes involved in base-excision repair with various substrates, including the base analogs studied by Mr. Eagan.

Mr. Eagan has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of five (5) years, beginning on January 13, 2003:

(1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government referred to as "covered transactions" as defined in 45 CFR part 76 (Debarment Regulations); and

(2) To exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Mr. Eagan had admitted to falsification of data in an earlier case.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443-5330.

Chris B. Pascal,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Nominations of Topics for Evidence-based Practice Centers (EPCs)

AGENCY: The Agency for Healthcare Research and Quality (AHRQ).

ACTION: Nominations of topics for evidence reports and technology assessments.

SUMMARY: AHRQ invites nominations of topics for evidence reports and technology assessments relating to the prevention, diagnosis, treatment and management of common diseases and clinical conditions, as well as topics relating to organization and financing of health care. AHRQ's previous requests for topic nominations were published in the **Federal Register** on December 23, 1996, November 28, 1997, May 4, 1999, November 13, 2000, and February 14, 2002.

DATES: Topic nominations should be submitted by March 31, 2003 in order to be considered for the next group of evidence reports and technology assessments to be funded in Fiscal Year 2003. In addition to timely responses to this request for nominations, AHRQ also accepts topic nominations on an ongoing basis. AHRQ is not able to reply to individual responses, but will consider all nominations during the selection process. Topics selected will be announced from time to time in the **Federal Register** and through AHRQ press releases.

ADDRESSES: Topic nominations should be submitted to Jacqueline Besteman, J.D., M.A., Director, Evidence-based Practice Centers (EPC) Program, Center for Practice and Technology Assessment, AHRQ, 6010 Executive Boulevard, Suite 300, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Jacqueline Besteman, J.D., M.A., Center for Practice and Technology Assessment, AHRQ, 6010 Executive Blvd., Suite 300, Rockville, MD 20852; Phone: (301) 594-4017; Fax: (301) 594-