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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):

DECLARATION REGARDING ADMINISTRATION OF SMALLPOX COUNTERMEASURES

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 (P.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.

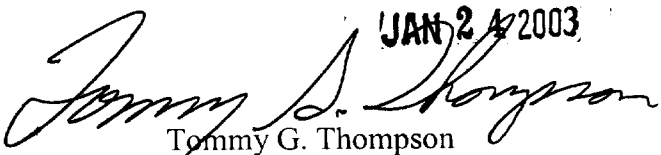
V. EFFECTIVE DATES: The declaration is effective January 24, 2003 until and including January 23, 2004. The effective period may be extended or shortened by subsequent amendment to this declaration.

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: JAN 2 4 2003



Tommy G. Thompson
Secretary