DoD offices responsible for implementing the waiver, DoD's Office of the Inspector General, and the FDA, consistent with its regulatory role, will conduct an ongoing review and monitoring to assess adherence to the standards and criteria under 21 CFR 50.23(d) and this order. The responsible DoD offices shall also adhere to any periodic reporting requirements specified by the President at the time of the waiver approval. The Secretary shall submit the findings to the President and provide a copy to the Commissioner.

(b) The Secretary shall, as soon as practicable, make the congressional notifications required by 10 U.S.C. 1107(f)(2)(B).

(c) The Secretary shall, as soon as practicable and consistent with classification requirements, issue a public notice in the Federal Register describing each waiver of informed consent determination and a summary of the most updated scientific information on the products used, as well as other information the President determines is appropriate.

(d) The waiver will expire at the end of 1 year (or an alternative time period not to exceed 1 year, specified by the President at the time of approval), or when the Secretary informs the President that the particular military operation creating the need for the use of the investigational drug has ended, whichever is earlier. The President may revoke the waiver based on changed circumstances or for any other reason. If the Secretary seeks to renew a waiver prior to its expiration, the Secretary must submit to the President an updated request, specifically identifying any new information available relevant to the standards and criteria under 21 CFR 50.23(d). To request to renew a waiver, the Secretary must satisfy the criteria for a waiver as described in section 3 of this order.

(e) The Secretary shall notify the President and the Commissioner if the threat countered by the investigational drug changes significantly or if significant new information on the investigational drug is received.

SEC. 5. *Training for Military Personnel.* (a) The DoD shall provide ongoing training and health risk communication on the requirements of using an investigational drug in support of a military operation to all military personnel, including those in leadership positions, during chemical and biological warfare defense training and other training, as appropriate. This ongoing training and health risk communication shall include general information about 10 U.S.C. 1107 and 21 CFR 50.23(d).

(b) If the President grants a waiver under 10 U.S.C. 1107(f), the DoD shall provide training to all military personnel conducting the waiver protocol and health risk communication to all military personnel receiving the specific investigational drug to be administered prior to its use.

(c) The Secretary shall submit the training and health risk communication plans as part of the investigational new drug protocol submission to the FDA and the reviewing IRB. Training and health risk communication shall include at a minimum:

(1) The basis for any determination by the President that informed consent is not or may not be feasible;

(2) The means for tracking use and adverse effects of the investigational drug;

(3) The benefits and risks of using the investigational drug; and

(4) A statement that the investigational drug is not approved (or not approved for the intended use).

(d) The DoD shall keep operational commanders informed of the overall requirements of successful protocol execution and their role, with the support of medical personnel, in ensuring successful execution of the protocol.

SEC. 6. *Scope.* (a) This order applies to the consideration and Presidential approval of a waiver of informed consent under 10 U.S.C. 1107 and does not apply to other FDA regulations.

(b) This order is intended only to improve the internal management of the Federal Government. Nothing contained in this order shall create any right or benefit, substantive or procedural, enforceable by any party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

WILLIAM J. CLINTON.

§ 1107a. Emergency use products

(a) WAIVER BY THE PRESIDENT.—(1) In the case of the administration of a product authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security.

(2) The waiver authority provided in paragraph (1) shall not be construed to apply to any case other than a case in which an individual is required to be informed of an option to accept or refuse administration of a particular product by reason of a determination by the Secretary of Health and Human Services that emergency use of such product is authorized under section 564 of the Federal Food, Drug, and Cosmetic Act.

(b) PROVISION OF INFORMATION.—If the President, under subsection (a), waives the condition described in section 564(e)(1)(A)(ii)(III) of the Federal Food, Drug, and Cosmetic Act, and if the Secretary of Defense, in consultation with the Secretary of Health and Human Services, makes a determination that it is not feasible based on time limitations for the information described in section 564(e)(1)(A)(ii)(I) or (II) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after such administration. The authority provided for in this subsection may not be delegated. Information concerning the administration of the product shall be recorded in the medical record of the member.

(c) APPLICABILITY OF OTHER PROVISIONS.—In the case of an authorization by the Secretary of Health and Human Services under section 564(a)(1) of the Federal Food, Drug, and Cosmetic Act based on a determination by the Secretary of Defense under section 564(b)(1)(B) of such Act, subsections (a) through (f) of section 1107 shall not apply to the use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

(Added Pub. L. 108–136, div. A, title XVI, § 1603(b)(1), Nov. 24, 2003, 117 Stat. 1689; amended Pub. L. 108–375, div. A, title VII, § 726(b), Oct. 28, 2004, 118 Stat. 1992; Pub. L. 109–364, div. A, title X, § 1071(a)(5), (g)(7), Oct. 17, 2006, 120 Stat. 2398, 2402.)

REFERENCES IN TEXT

Section 564 of the Federal Food, Drug, and Cosmetic Act, referred to in text, is classified to section 360bbb–3 of Title 21, Food and Drugs.

AMENDMENTS

2006—Subsec. (a). Pub. L. 109–364, §1071(g)(7), made technical correction to directory language of Pub. L. 108–375, §726(b)(1). See 2004 Amendment note below.

Pub. L. 109–364, §1071(a)(5), redesignated subpars. (A) and (B) as pars. (1) and (2), respectively, and, in par. (2), substituted ''paragraph (1)'' for ''subparagraph (A)''.

2004—Subsec. (a). Pub. L. 108–375, §726(b)(1), as amended by Pub. L. 109–364, §1071(g)(7), inserted ''(A)'' after ''PRESIDENT.—''.

Subsec. (a)(A). Pub. L. 108–375, §726(b)(2), struck out ''is not feasible, is contrary to the best interests of the members affected, or'' after ''such requirement''.

Subsec. (a)(B). Pub. L. 108–375, §726(b)(3), added subpar. (B).

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–364, div. A, title X, §1071(g), Oct. 17, 2006, 120 Stat. 2402, provided that the amendment made by section 1071(g)(7) is effective as of Oct. 28, 2004, and as if included in Pub. L. 108–375 as enacted.

TERMINATION DATE

Pub. L. 108–136, div. A, title XVI, §1603(d), Nov. 24, 2003, 117 Stat. 1690, which provided that section 1603 of Pub. L. 108–136 (enacting this section and section 360bbb–3 of Title 21, Food and Drugs, and amending section 331 of Title 21) would not be in effect (and the law was to read as if that section had never been enacted) as of the date on which, following enactment of the Project Bioshield Act of 2003, the President submits to Congress a notification that the Project Bioshield Act of 2003 provides an effective emergency use authority with respect to members of the Armed Forces, was repealed by Pub. L. 108–276, §4(b), July 21, 2004, 118 Stat. 859. [The Project Bioshield Act of 2003 was not enacted.]

§ 1108. Health care coverage through Federal Employees Health Benefits program: demonstration project

(a) FEHBP OPTION DEMONSTRATION.—The Secretary of Defense, after consulting with the other administering Secretaries, shall enter into an agreement with the Office of Personnel Management to conduct a demonstration project (in this section referred to as the ''demonstration project'') under which eligible beneficiaries described in subsection (b) and residing within one of the areas covered by the demonstration project may enroll in health benefits plans offered through the Federal Employees Health Benefits program under chapter 89 of title 5. The number of eligible beneficiaries and family members of such beneficiaries under subsection (b)(2) who may be enrolled in health benefits plans during the enrollment period under subsection (d)(2) may not exceed 66,000.

(b) ELIGIBLE BENEFICIARIES; COVERAGE.—(1) An eligible beneficiary under this subsection is—

(A) a member or former member of the uniformed services described in section 1074(b) of this title who is entitled to hospital insurance benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.);

(B) an individual who is an unremarried former spouse of a member or former member described in section 1072(2)(F) or 1072(2)(G));

(C) an individual who is—

(i) a dependent of a deceased member or former member described in section 1076(b) or 1076(a)(2)(B) of this title or of a member who died while on active duty for a period of more than 30 days; and

(ii) a member of family as defined in section 8901(5) of title 5; or

(D) an individual who is—

(i) a dependent of a living member or former member described in section 1076(b)(1) of this title who is entitled to hospital insurance benefits under part A of title XVIII of the Social Security Act, regardless of the member's or former member's eligibility for such hospital insurance benefits; and

(ii) a member of family as defined in section 8901(5) of title 5.

(2) Eligible beneficiaries may enroll in a Federal Employees Health Benefit plan under chapter 89 of title 5 under this section for self-only coverage or for self and family coverage which includes any dependent of the member or former member who is a family member for purposes of such chapter.

(3) A person eligible for coverage under this subsection shall not be required to satisfy any eligibility criteria specified in chapter 89 of title 5 (except as provided in paragraph (1)(C) or (1)(D)) as a condition for enrollment in health benefits plans offered through the Federal Employees Health Benefits program under the demonstration project.

(4) For purposes of determining whether an individual is a member of family under paragraph (5) of section 8901 of title 5 for purposes of paragraph (1)(C) or (1)(D), a member or former member described in section 1076(b) or 1076(a)(2)(B) of this title shall be deemed to be an employee under such section.

(5) An eligible beneficiary who is eligible to enroll in the Federal Employees Health Benefits program as an employee under chapter 89 of title 5 is not eligible to enroll in a Federal Employees Health Benefits plan under this section.

(c) AREA OF DEMONSTRATION PROJECT.—The Secretary of Defense and the Director of the Office of Personnel Management shall jointly identify and select the geographic areas in which the demonstration project will be conducted. The Secretary and the Director shall establish at least six, but not more than ten, such demonstration areas. In establishing the areas, the Secretary and Director shall include—

(1) an area that includes the catchment area of one or more military medical treatment facilities;

(2) an area that is not located in the catchment area of a military medical treatment facility;

(3) an area in which there is a Medicare Subvention Demonstration project area under section 1896[1] of title XVIII of the Social Security Act (42 U.S.C. 1395ggg); and

(4) not more than one area for each TRICARE region.

(d) DURATION OF DEMONSTRATION PROJECT.—(1) The Secretary of Defense shall conduct the demonstration project during three contract years under the Federal Employees Health Benefits program.

[1] See References in Text note below.