

ditions on persons who carry out any activity pursuant to an authorization under this section. (June 25, 1938, ch. 675, §564, as added Pub. L. 108-136, div. A, title XVI, §1603(a), Nov. 24, 2003, 117 Stat. 1684; amended Pub. L. 108-276, §4(a), July 21, 2004, 118 Stat. 853.)

AMENDMENTS

2004—Pub. L. 108-276 amended section generally, substituting provisions of subssecs. (a) to (f) for similar former provisions, except for additional provisions in subsec. (b)(1) allowing Secretary to authorize use of medical products in actual or potential domestic and public health emergencies in addition to actual or potential military emergencies.

§ 360bbb-4. Technical assistance

The Secretary, in consultation with the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration a team of experts on manufacturing and regulatory activities (including compliance with current Good Manufacturing Practice) to provide both off-site and on-site technical assistance to the manufacturers of qualified countermeasures (as defined in section 247d-6a of title 42), security countermeasures (as defined in section 247d-6b of title 42), or vaccines, at the request of such a manufacturer and at the discretion of the Secretary, if the Secretary determines that a shortage or potential shortage may occur in the United States in the supply of such vaccines or countermeasures and that the provision of such assistance would be beneficial in helping alleviate or avert such shortage.

(June 25, 1938, ch. 675, §565, as added Pub. L. 109-417, title IV, §404, Dec. 19, 2006, 120 Stat. 2875.)

§ 360bbb-5. Critical Path Public-Private Partnerships

(a) Establishment

The Secretary, acting through the Commissioner of Food and Drugs, may enter into collaborative agreements, to be known as Critical Path Public-Private Partnerships, with one or more eligible entities to implement the Critical Path Initiative of the Food and Drug Administration by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the acceleration of medical product development, manufacturing, and translational therapeutics, and enhancing medical product safety.

(b) Eligible entity

In this section, the term “eligible entity” means an entity that meets each of the following:

- (1) The entity is—
 - (A) an institution of higher education (as such term is defined in section 1001 of title 20) or a consortium of such institutions; or
 - (B) an organization described in section 501(c)(3) of title 26 and exempt from tax under section 501(a) of such title.
- (2) The entity has experienced personnel and clinical and other technical expertise in the biomedical sciences, which may include grad-

uate training programs in areas relevant to priorities of the Critical Path Initiative.

(3) The entity demonstrates to the Secretary’s satisfaction that the entity is capable of—

- (A) developing and critically evaluating tools, methods, and processes—
 - (i) to increase efficiency, predictability, and productivity of medical product development; and
 - (ii) to more accurately identify the benefits and risks of new and existing medical products;

(B) establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance organizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and

(C) securing funding for the projects of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

(c) Funding

The Secretary may not enter into a collaborative agreement under subsection (a) unless the eligible entity involved provides an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Food and Drug Administration that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

(d) Annual report

Not later than 18 months after September 27, 2007, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

- (1) reviewing the operations and activities of the Partnerships in the previous year; and
- (2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

(e) Definition

In this section, the term “medical product” includes a drug, a biological product as defined in section 262 of title 42, a device, and any combination of such products.

(f) Authorization of appropriations

To carry out this section, there are authorized to be appropriated \$5,000,000 for fiscal year 2008 and such sums as may be necessary for each of fiscal years 2009 through 2012.

(June 25, 1938, ch. 675, §566, as added Pub. L. 110-85, title VI, §603, Sept. 27, 2007, 121 Stat. 898.)