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42 U.S. Code § 247d-7e

Biomedical Advanced Research and Development Authority

(a) Definitions

In this section:

(1) BARDA

The term "BARDA" means the Biomedical Advanced Research and Development Authority.

(2) Fund

The term "Fund" means the Biodefense Medical Countermeasure Development Fund established under subsection (d).

(3) Other transactions

The term "other transactions" means transactions, other than procurement contracts, grants, and cooperative agreements.

(4) Qualified countermeasure

The term "qualified countermeasure" has the meaning given such term in section 247d–6a of this title.

(5) Qualified pandemic or epidemic product

The term "qualified pandemic or epidemic product" has the meaning given the term in section 247d–6d of this title.

(6) Advanced research and development

(A) In general

The term "advanced research and development" means, with respect to a product that is or may become a qualified countermeasure or a qualified pandemic or epidemic product, activities that predominantly—

(i) are conducted after basic research and preclinical development of the product; and

(ii) are related to manufacturing the product on a commercial scale and in a form that satisfies the regulatory requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or under section 262 of this title.

(B) Activities included

The term under subparagraph (A) includes—

(i) testing of the product to determine whether the product may be approved, cleared, or licensed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or under section 262 of this title for a use that is or may be the basis for such product becoming a qualified countermeasure or qualified pandemic or epidemic product, or to help obtain such approval, clearance, or license;

(ii) design and development of tests or models, including animal models, for such testing;

(iii) activities to facilitate manufacture of the product on a commercial scale with consistently high quality, as well as to improve and make available new technologies to increase manufacturing surge

capacity;

(iv) activities to support, maintain, and improve domestic manufacturing surge capacity and capabilities, as appropriate, including through the utilization of advanced manufacturing and platform technologies, to increase the availability of products that are or may become qualified countermeasures or qualified pandemic or epidemic products;

(v) activities to improve the shelf-life of the product or technologies for administering the product; and

(vi) such other activities as are part of the advanced stages of testing, refinement, improvement, manufacturing, or preparation of the product for such use and as are specified by the Secretary.

(7) Security countermeasure

The term "security countermeasure" has the meaning given such term in section 247d–6b of this title.

(8) Research tool

The term "research tool" means a device, technology, biological material (including a cell line or an antibody), reagent, animal model, computer system, computer software, or analytical technique that is developed to assist in the discovery, development, or manufacture of qualified countermeasures or qualified pandemic or epidemic products.

(9) Program manager

The term "program manager" means an individual appointed to carry out functions under this section and authorized to provide project oversight and management of strategic initiatives.

(10) Person

The term "person" includes an individual, partnership, corporation, association, entity, or public or private corporation, and a Federal, State, or local government agency or department.