rector at such time, in such manner, and accompanied by such information as the Director may require.

(2) Criteria

As part of an application for a grant under this section, the Director shall require an eligible entity to submit a detailed, comprehensive, multisector plan for addressing the local drug crisis or emerging drug abuse issue within the area served by the eligible entity.

(d) Use of funds

An eligible entity shall use a grant received under this section—

(1) for programs designed to implement comprehensive community-wide prevention strategies to address the local drug crisis in the area served by the eligible entity, in accordance with the plan submitted under subsection (c)(2);

(2) to obtain specialized training and technical assistance from the organization funded under section 4 of Public Law 107–82 (21 U.S.C. 1521 note); and

(3) for programs designed to implement comprehensive community-wide strategies to address emerging drug abuse issues in the community.

(e) Supplement not supplant

An eligible entity shall use Federal funds received under this section only to supplement the funds that would, in the absence of those Federal funds, be made available from other Federal and non-Federal sources for the activities described in this section, and not to supplant those funds.

(f) Evaluation

A grant under this section shall be subject to the same evaluation requirements and procedures as the evaluation requirements and procedures imposed on the recipient of a grant under the Drug-Free Communities Act of 1997, and may also include an evaluation of the effectiveness at reducing abuse of opioids or methamphetamines.

(g) Limitation on administrative expenses

Not more than 8 percent of the amounts made available to carry out this section for a fiscal year may be used to pay for administrative expenses.

(h) Delegation authority

The Director may enter into an interagency agreement with the Administrator to delegate authority for the execution of grants and for such other activities as may be necessary to carry out this section.

(i) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2017 through 2021.

(Pub. L. 114–198, title I, § 103, July 22, 2016, 130 Stat. 699.)

REFERENCES IN TEXT

The Drug-Free Communities Act of 1997, referred to in subsec. (a)(3), is Pub. L. 105–20, June 27, 1997, 111 Stat. 224, section 2(a)(2) of which enacted chapter 2 of the National Narcotics Leadership Act of 1988, which is classified to this subchapter. For complete classification of the Drug-Free Communities Act of 1997 to the Code, see Short Title of 1997 Amendment note set out under section 1501 of this title and Tables.

CODIFICATION

Section was enacted as part of the Comprehensive Addiction and Recovery Act of 2016, and not as part of the National Narcotics Leadership Act of 1988 which comprises this chapter.

PART B—ADVISORY COMMISSION

§§ 1541 to 1548. Repealed. Pub. L. 115–271, title VIII, § 8203(b)(5), Oct. 24, 2018, 132 Stat. 4112; Pub. L. 116–74, § 2(c)(1)(A)(ii)(II), Nov. 27, 2019, 133 Stat. 1157

Section 1541, Pub. L. 100–690, title I, § 1041, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 231, established Advisory Commission on Drug-Free Communities.

Section 1542, Pub. L. 100–690, title I, § 1042, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 231, related to duties of the Commission.

Section 1543, Pub. L. 100–690, title I, § 1043, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 232, related to membership of the Commission.

Section 1544, Pub. L. 100–690, title I, § 1044, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 232, related to compensation.

Section 1545, Pub. L. 100–690, title I, § 1045, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 233, related to terms of office.

Section 1546, Pub. L. 100–690, title I, § 1046, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 233, related to Commission meetings.

Section 1547, Pub. L. 100–690, title I, § 1047, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 233, related to Commission staff.

Section 1548, Pub. L. 100–690, title I, § 1048, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 234; amended Pub. L. 107–82, § 3, Dec. 14, 2001, 115 Stat. 820, terminated the Commission at the end of fiscal year 2007.

EFFECTIVE DATE OF 2019 AMENDMENT

Amendment by Pub. L. 116–74 effective as if included in the enactment of subtitle K of title VIII of Pub. L. 115–271, see section 2(c)(2) of Pub. L. 116–74, set out a note under section 1522 of this title.

CHAPTER 21—BIOMATERIALS ACCESS ASSURANCE

§ 1601. Findings

The Congress finds that—

(1) each year millions of citizens of the United States depend on the availability of lifesaving or life-enhancing medical devices, many of which are permanently implantable within the human body;

(2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

(3) most of the medical devices are made with raw materials and component parts that—

(A) move in interstate commerce;

(B) are not designed or manufactured specifically for use in medical devices; and

(C) come in contact with internal human tissue;

(4) the raw materials and component parts also are used in a variety of nonmedical products;

(5) because small quantities of the raw materials and component parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and component parts;

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions;

(7) notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate—

(A) design and testing of medical devices manufactured with materials or parts supplied by the suppliers; or

(B) warnings related to the use of such medical devices;

(8) even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying certain raw materials and component parts for use in medical devices for a number of reasons, including concerns about the costs of such litigation;

(9) unless alternate sources of supply can be found, the unavailability of raw materials and component parts for medical devices will lead to unavailability of lifesaving and life-enhancing medical devices;

(10) because other suppliers of the raw materials and component parts in foreign nations are refusing to sell raw materials or component parts for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials and component parts for medical devices are remote;

(11) it is unlikely that the small market for such raw materials and component parts in the United States could support the large investment needed to develop new suppliers of such raw materials and component parts;

(12) attempts to develop such new suppliers would raise the cost of medical devices;

(13) courts that have considered the duties of the suppliers of the raw materials and component parts have generally found that the suppliers do not have a duty—

(A) to evaluate the safety and efficacy of the use of a raw material or component part in a medical device; or

(B) to warn consumers concerning the safety and effectiveness of a medical device;

(14) because medical devices and the raw materials and component parts used in their manufacture move in interstate commerce, a shortage of such raw materials and component parts affects interstate commerce;

(15) in order to safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices, immediate action is needed—

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs;

(16) the several States and their courts are the primary architects and regulators of our tort system; Congress, however, must, in certain circumstances involving the national interest, address tort issues, and a threatened shortage of raw materials and component parts for lifesaving medical devices is one such circumstance; and

(17) the protections set forth in this chapter are needed to assure the continued supply of materials for lifesaving medical devices, although such protections do not protect negligent suppliers.

(Pub. L. 105–230, § 2, Aug. 13, 1998, 112 Stat. 1519.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in par. (6), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

EFFECTIVE DATE

Pub. L. 105–230, § 8, Aug. 13, 1998, 112 Stat. 1529, provided that: ''This Act [enacting this chapter] shall apply to all civil actions covered under this Act that are commenced on or after the date of enactment of this Act [Aug. 13, 1998], including any such action with respect to which the harm asserted in the action or the conduct that caused the harm occurred before the date of enactment of this Act.''

SHORT TITLE

Pub. L. 105–230, § 1, Aug. 13, 1998, 112 Stat. 1519, provided that: ''This Act [enacting this chapter] may be cited as the 'Biomaterials Access Assurance Act of 1998'.''

§ 1602. Definitions

As used in this chapter:

(1) Biomaterials supplier

(A) In general

The term ''biomaterials supplier'' means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

(B) Persons included

Such term includes any person who—

(i) has submitted master files to the Secretary for purposes of premarket approval of a medical device; or

(ii) licenses a biomaterials supplier to produce component parts or raw materials.