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 Repealed.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

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.

CODIFICATION

Pub. L. 115–271, § 8203(b)(5), which directed the repeal of subchapter II (21 U.S.C. 1541 et seq.) of ''chapter 2 of subtitle A of title I of the National Narcotics Leadership Act of 1988'', was executed by repealing part B of this subchapter, which was subchapter II of chapter 2 of the National Narcotics Leadership Act of 1988, to reflect the probable intent of Congress. The National Narcotics Leadership Act of 1988 is itself subtitle A of title I of Pub. L. 100–690.

CHAPTER 21—BIOMATERIALS ACCESS ASSURANCE

Sec.

§ 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