

mission shall be 3 years, except that, as designated at the time of appointment—

- (1) of the initial members appointed under section 1543(a)(1) of this title, two shall be appointed for a term of 2 years;
- (2) of the initial members appointed under section 1543(a)(2) of this title, two shall be appointed for a term of 2 years; and
- (3) of the initial members appointed under section 1543(a)(3) of this title, one shall be appointed for a term of 1 year.

(b) Vacancies

Any member appointed to fill a vacancy for an unexpired term of a member shall serve for the remainder of the unexpired term. A member of the Advisory Commission may serve after the expiration of such member's term until a successor has been appointed and taken office.

(Pub. L. 100-690, title I, §1045, as added Pub. L. 105-20, §2(a)(2), June 27, 1997, 111 Stat. 233.)

§ 1546. Meetings

(a) In general

After its initial meeting, the Advisory Commission shall meet, with the advanced approval of the Administrator, at the call of the Chairperson (or Co-chairpersons) of the Advisory Commission or a majority of its members or upon the request of the Director or Administrator of the Program.

(b) Quorum

Six members of the Advisory Commission shall constitute a quorum.

(Pub. L. 100-690, title I, §1046, as added Pub. L. 105-20, §2(a)(2), June 27, 1997, 111 Stat. 233.)

§ 1547. Staff

The Administrator shall make available to the Advisory Commission adequate staff, information, and other assistance.

(Pub. L. 100-690, title I, §1047, as added Pub. L. 105-20, §2(a)(2), June 27, 1997, 111 Stat. 233.)

§ 1548. Termination

The Advisory Commission shall terminate at the end of fiscal year 2007.

(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.)

AMENDMENTS

2001—Pub. L. 107-82 substituted “2007” for “2002”.

CHAPTER 21—BIOMATERIALS ACCESS ASSURANCE

- | | |
|-------|--|
| Sec. | |
| 1601. | Findings. |
| 1602. | Definitions. |
| 1603. | General requirements; applicability; preemption. |
| | (a) General requirements. |
| | (b) Applicability. |
| | (c) Scope of preemption. |
| | (d) Statutory construction. |
| 1604. | Liability of biomaterials suppliers. |
| | (a) In general. |

- | | |
|-------|--|
| Sec. | (b) Liability as manufacturer. |
| | (c) Liability as seller. |
| | (d) Liability for failure to meet applicable contractual requirements or specifications. |
| 1605. | Procedures for dismissal of civil actions against biomaterials suppliers. |
| | (a) Motion to dismiss. |
| | (b) Manufacturer of implant shall be named a party. |
| | (c) Proceeding on motion to dismiss. |
| | (d) Summary judgment. |
| | (e) Dismissal with prejudice. |
| | (f) Manufacturer conduct of litigation. |
| 1606. | Subsequent impleader of dismissed biomaterials supplier. |
| | (a) Impleading of dismissed defendant. |
| | (b) Standard of liability. |
| | (c) Discovery. |

§ 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;