§ 1544. Compensation

(a) In general

Members of the Advisory Commission who are officers or employees of the United States shall not receive any additional compensation for service on the Advisory Commission. The remaining members of the Advisory Commission shall receive, for each day (including travel time) that they are engaged in the performance of the functions of the Advisory Commission, compensation at rates not to exceed the daily equivalent to the annual rate of basic pay payable for grade GS–10 of the General Schedule.

(b) Travel expenses

Each member of the Advisory Commission shall receive travel expenses, including per diem in lieu of subsistence, in accordance with sections 5702 and 5703 of title 5.

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

REFERENCES IN TEXT

Grade GS–10 of the General Schedule, referred to in subsec. (a), is set out under section 5332 of Title 5, Government Organization and Employees.

§ 1545. Terms of office

(a) In general

Subject to subsection (b) of this section, the term of office of a member of the Advisory Commission 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

§ 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.

(2) Claimant

(A) In general

The term ''claimant'' means any person who brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused directly or indirectly by an implant, including a person other than the individual into whose body, or in contact with whose blood or tissue, the implant is placed, who claims to have suffered harm as a result of the implant.

(B) Action brought on behalf of an estate

With respect to an action brought on behalf of or through the estate of a deceased individual into whose body, or in contact with whose blood or tissue the implant was placed, such term includes the decedent that is the subject of the action.

(C) Action brought on behalf of a minor or incompetent

With respect to an action brought on behalf of or through a minor or incompetent, such term includes the parent or guardian of the minor or incompetent.

(D) Exclusions

Such term does not include—