

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—

(i) a provider of professional health care services in any case in which—

(I) the sale or use of an implant is incidental to such services; and

(II) the essence of the professional health care services provided is the furnishing of judgment, skill, or services;

(ii) a person acting in the capacity of a manufacturer, seller, or biomaterials supplier; or

(iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, except that—

(I) neither the exclusion provided by this clause nor any other provision of this chapter may be construed as a finding that silicone gel (or any other form of silicone) may or may not cause harm; and

(II) the existence of the exclusion under this clause may not—

(aa) be disclosed to a jury in any civil action or other proceeding; and

(bb) except as necessary to establish the applicability of this chapter, otherwise be presented in any civil action or other proceeding.

**(3) Component part****(A) In general**

The term “component part” means a manufactured piece of an implant.

**(B) Certain components**

Such term includes a manufactured piece of an implant that—

- (i) has significant non-implant applications; and
- (ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant.

**(4) Harm****(A) In general**

The term “harm” means—

- (i) any injury to or damage suffered by an individual;
- (ii) any illness, disease, or death of that individual resulting from that injury or damage; and
- (iii) any loss to that individual or any other individual resulting from that injury or damage.

**(B) Exclusion**

The term does not include any commercial loss or loss of or damage to an implant.

**(5) Implant**

The term “implant” means—

(A) a medical device that is intended by the manufacturer of the device—

- (i) to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days; or
- (ii) to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for a period of less than 30 days; and

(B) suture materials used in implant procedures.

**(6) Manufacturer**

The term “manufacturer” means any person who, with respect to an implant—

(A) is engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in section 360(a)(1) of this title) of the implant; and

(B) is required—

- (i) to register with the Secretary pursuant to section 360 of this title and the regulations issued under such section; and
- (ii) to include the implant on a list of devices filed with the Secretary pursuant to section 360(j) of this title and the regulations issued under such section.

**(7) Medical device**

The term “medical device” means a device, as defined in section 321(h) of this title, and includes any device component of any combination product as that term is used in section 353(g) of this title.

**(8) Raw material**

The term “raw material” means a substance or product that—

- (A) has a generic use; and

(B) may be used in an application other than an implant.

**(9) Secretary**

The term “Secretary” means the Secretary of Health and Human Services.

**(10) Seller****(A) In general**

The term “seller” means a person who, in the course of a business conducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce.

**(B) Exclusions**

The term does not include—

- (i) a seller or lessor of real property;
- (ii) a provider of professional health care services in any case in which—
  - (I) the sale or use of the implant is incidental to such services; and
  - (II) the essence of the professional health care services provided is the furnishing of judgment, skill, or services; or
- (iii) any person who acts in only a financial capacity with respect to the sale of an implant.

(Pub. L. 105-230, §3, Aug. 13, 1998, 112 Stat. 1520.)

## EFFECTIVE DATE

Section applicable to all civil actions covered under this chapter commenced on or after Aug. 13, 1998, including any in which the harm or harmful conduct occurred before such date, see section 8 of Pub. L. 105-230, set out as a note under section 1601 of this title.

**§ 1603. General requirements; applicability; pre-emption****(a) General requirements****(1) In general**

In any civil action covered by this chapter, a biomaterials supplier may—

- (A) raise any exclusion from liability set forth in section 1604 of this title; and
- (B) make a motion for dismissal or for summary judgment as set forth in section 1605 of this title.

**(2) Procedures**

Notwithstanding any other provision of law, a Federal or State court in which an action covered by this chapter is pending shall, in connection with a motion under section 1605 or 1606 of this title, use the procedures set forth in this chapter.

**(b) Applicability****(1) In general**

Except as provided in paragraph (2), this chapter applies to any civil action brought by a claimant, whether in a Federal or State court, on the basis of any legal theory, for harm allegedly caused, directly or indirectly, by an implant.

**(2) Exclusion**

A civil action brought by a purchaser of a medical device, purchased for use in providing professional health care services, for loss or damage to an implant or for commercial loss to the purchaser—