
21 U.S. Code § 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.

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