

### § 1604. Liability of biomaterials suppliers

#### (a) In general

Except as provided in section 1606 of this title, a biomaterials supplier shall not be liable for harm to a claimant caused by an implant unless such supplier is liable—

(1) as a manufacturer of the implant, as provided in subsection (b) of this section;

(2) as a seller of the implant, as provided in subsection (c) of this section; or

(3) for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, as provided in subsection (d) of this section.

#### (b) Liability as manufacturer

##### (1) In general

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the biomaterials supplier is the manufacturer of the implant.

##### (2) Grounds for liability

The biomaterials supplier may be considered the manufacturer of the implant that allegedly caused harm to a claimant only if the biomaterials supplier—

(A)(i) registered or was required to register with the Secretary pursuant to section 360 of this title and the regulations issued under such section; and

(ii) included or was required 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;

(B) is the subject of a declaration issued by the Secretary pursuant to paragraph (3) that states that the supplier, with respect to the implant that allegedly caused harm to the claimant, was required to—

(i) register with the Secretary under section 360 of this title, and the regulations issued under such section, but failed to do so; or

(ii) 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, but failed to do so; or

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraph (A) or (B), if the court deciding a motion to dismiss in accordance with section 1605(c)(3)(B)(i) of this title finds, on the basis of affidavits submitted in accordance with section 1605 of this title, that it is necessary to impose liability on the biomaterials supplier as a manufacturer because the related manufacturer meeting the requirements of subparagraph (A) or (B) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

#### (3) Administrative procedures

##### (A) In general

The Secretary may issue a declaration described in paragraph (2)(B) on the motion of

the Secretary or on petition by any person, after providing—

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

#### (B) Docketing and final decision

Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 120 days after the petition is filed, the Secretary shall issue a final decision on the petition.

#### (C) Applicability of statute of limitations

Any applicable statute of limitations shall toll during the period from the time a claimant files a petition with the Secretary under this paragraph until such time as either (i) the Secretary issues a final decision on the petition, or (ii) the petition is withdrawn.

#### (D) Stay pending petition for declaration

If a claimant has filed a petition for a declaration with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition.

#### (e) Liability as seller

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant only if—

(1) the biomaterials supplier—

(A) held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer; or

(B) acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 1605(c)(3)(B)(ii) of this title finds, on the basis of affidavits submitted in accordance with section 1605 of this title, that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

#### (d) Liability for failure to meet applicable contractual requirements or specifications

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the claimant in an action shows, by a preponderance of the evidence, that—

(1) the biomaterials supplier supplied raw materials or component parts for use in the implant that either—

(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for the supplying of the product; or

(B) failed to meet any specifications that were—

- (i) accepted, pursuant to applicable law, by the biomaterials supplier;
- (ii) published by the biomaterials supplier;
- (iii) provided by the biomaterials supplier to the person who contracted for such product;
- (iv) contained in a master file that was submitted by the biomaterials supplier to the Secretary and that is currently maintained by the biomaterials supplier for purposes of premarket approval of medical devices; or
- (v) included in the submissions for purposes of premarket approval or review by the Secretary under section 360, 360c, 360e, or 360j of this title, and received clearance from the Secretary if such specifications were accepted, pursuant to applicable law, by the biomaterials supplier; and

(2) such failure to meet applicable contractual requirements or specifications was an actual and proximate cause of the harm to the claimant.

(Pub. L. 105-230, § 5, Aug. 13, 1998, 112 Stat. 1524.)

**§ 1605. Procedures for dismissal of civil actions against biomaterials suppliers**

**(a) Motion to dismiss**

A defendant may, at any time during which a motion to dismiss may be filed under applicable law, move to dismiss an action against it on the grounds that the defendant is a biomaterials supplier and one or more of the following:

- (1) The defendant is not liable as a manufacturer, as provided in section 1604(b) of this title.
- (2) The defendant is not liable as a seller, as provided in section 1604(c) of this title.
- (3) The defendant is not liable for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, as provided in section 1604(d) of this title.
- (4) The claimant did not name the manufacturer as a party to the action, as provided in subsection (b) of this section.

**(b) Manufacturer of implant shall be named a party**

In any civil action covered by this chapter, the claimant shall be required to name the manufacturer of the implant as a party to the action, unless—

- (1) the manufacturer is subject to service of process solely in a jurisdiction in which the biomaterials supplier is not domiciled or subject to a service of process; or
- (2) a claim against the manufacturer is barred by applicable law or rule of practice.

**(c) Proceeding on motion to dismiss**

The following rules shall apply to any proceeding on a motion to dismiss filed by a defendant under this section:

**(1) Effect of motion to dismiss on discovery**

**(A) In general**

Except as provided in subparagraph (B), if a defendant files a motion to dismiss under

subsection (a) of this section, no discovery shall be permitted in connection with the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss.

**(B) Discovery**

If a defendant files a motion to dismiss under subsection (a)(3) of this section on the grounds that it did not furnish raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, the court may permit discovery limited to issues that are directly relevant to—

- (i) the pending motion to dismiss; or
- (ii) the jurisdiction of the court.

**(2) Affidavits**

**(A) Defendant**

A defendant may submit affidavits supporting the grounds for dismissal contained in its motion to dismiss under subsection (a) of this section. If the motion is made under subsection (a)(1) of this section, the defendant may submit an affidavit demonstrating that the defendant has not included the implant on a list, if any, filed with the Secretary pursuant to section 360(j) of this title.

**(B) Claimant**

In response to a motion to dismiss, the claimant may submit affidavits demonstrating that—

- (i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 1604(b)(2)(B) of this title; or
- (ii) the defendant is a seller of the implant who is liable under section 1604(c) of this title.

**(3) Basis of ruling on motion to dismiss**

The court shall rule on a motion to dismiss filed under subsection (a) of this section solely on the basis of the pleadings and affidavits of the parties made pursuant to this subsection. The court shall grant a motion to dismiss filed under subsection (a) of this section—

(A) unless the claimant submits a valid affidavit that demonstrates that the defendant is not a biomaterials supplier;

(B) unless the court determines, to the extent raised in the pleadings and affidavits, that one or more of the following apply:

- (i) the defendant may be liable as a manufacturer, as provided in section 1604(b) of this title;
- (ii) the defendant may be liable as a seller, as provided in section 1604(c) of this title; or
- (iii) the defendant may be liable for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, as provided in section 1604(d) of this title; or

(C) if the claimant did not name the manufacturer as a party to the action, as provided in subsection (b) of this section.