

(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).

(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), 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) 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). If the motion is made under subsection (a)(1), 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) 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)—

(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).

(4) Treatment of motion as motion for summary judgment

The court may treat a motion to dismiss as a motion for summary judgment subject to subsection (d) in order to determine whether the pleadings and affidavits, in connection with such action, raise genuine issues of material fact concerning whether the defendant furnished raw materials or component parts of

the implant that failed to meet applicable contractual requirements or specifications as provided in section 1604(d) of this title.

(d) Summary judgment

(1) In general

(A) Basis for entry of judgment

If a motion to dismiss of a biomaterials supplier is to be treated as a motion for summary judgment under subsection (c)(4) or if a biomaterials supplier moves for summary judgment, the biomaterials supplier shall be entitled to entry of judgment without trial if the court finds there is no genuine issue of material fact for each applicable element set forth in paragraphs (1) and (2) of section 1604(d) of this title.

(B) Issues of material fact

With respect to a finding made under subparagraph (A), the court shall consider a genuine issue of material fact to exist only if the evidence submitted by the claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

(2) Discovery made prior to a ruling on a motion for summary judgment

If, under applicable rules, the court permits discovery prior to a ruling on a motion for summary judgment governed by section 1604(d) of this title, such discovery shall be limited solely to establishing whether a genuine issue of material fact exists as to the applicable elements set forth in paragraphs (1) and (2) of section 1604(d) of this title.

(3) Discovery with respect to a biomaterials supplier

A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 1604(d) of this title or the failure to establish the applicable elements of section 1604(d) of this title solely to the extent permitted by the applicable Federal or State rules for discovery against non-parties.

(e) Dismissal with prejudice

An order granting a motion to dismiss or for summary judgment pursuant to this section shall be entered with prejudice, except insofar as the moving defendant may be rejoined to the action as provided in section 1606 of this title.

(f) Manufacturer conduct of litigation

The manufacturer of an implant that is the subject of an action covered under this chapter shall be permitted to conduct litigation on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section on behalf of such supplier if the manufacturer and any other defendant in such action enter into a valid and applicable contractual agreement under which the manufacturer agrees to bear the cost of such litigation or to conduct such litigation.

(Pub. L. 105-230, § 6, Aug. 13, 1998, 112 Stat. 1526.)

§ 1606. Subsequent impleader of dismissed biomaterials supplier

(a) Impleading of dismissed defendant

A court, upon motion by a manufacturer or a claimant within 90 days after entry of a final judgment in an action by the claimant against a manufacturer, and notwithstanding any otherwise applicable statute of limitations, may implead a biomaterials supplier who has been dismissed from the action pursuant to this chapter if—

(1) the manufacturer has made an assertion, either in a motion or other pleading filed with the court or in an opening or closing statement at trial, or as part of a claim for contribution or indemnification, and the court finds based on the court's independent review of the evidence contained in the record of the action, that under applicable law—

(A) the negligence or intentionally tortious conduct of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

(B) the manufacturer's liability for damages should be reduced in whole or in part because of such negligence or intentionally tortious conduct; or

(2) the claimant has moved to implead the supplier and the court finds, based on the court's independent review of the evidence contained in the record of the action, that under applicable law—

(A) the negligence or intentionally tortious conduct of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

(B) the claimant is unlikely to be able to recover the full amount of its damages from the remaining defendants.

(b) Standard of liability

Notwithstanding any preliminary finding under subsection (a), a biomaterials supplier who has been impleaded into an action covered by this chapter, as provided for in this section—

(1) may, prior to entry of judgment on the claim against it, supplement the record of the proceeding that was developed prior to the grant of the motion for impleader under subsection (a); and

(2) may be found liable to a manufacturer or a claimant only to the extent required and permitted by any applicable State or Federal law other than this chapter.

(c) Discovery

Nothing in this section shall give a claimant or any other party the right to obtain discovery from a biomaterials supplier at any time prior to grant of a motion for impleader beyond that allowed under section 1605 of this title.

(Pub. L. 105-230, § 7, Aug. 13, 1998, 112 Stat. 1528.)

CHAPTER 22—NATIONAL DRUG CONTROL POLICY

Sec.

1701.

Definitions.

1702.

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1703.

Appointment and duties of Director and Deputy Directors.