

§ 1603. General requirements; applicability; preemption

(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—

(A) shall not be considered an action that is subject to this chapter; and

(B) shall be governed by applicable commercial or contract law.

(c) Scope of preemption

(1) In general

This chapter supersedes any State law regarding recovery for harm caused by an implant and any rule of procedure applicable to a civil action to recover damages for such harm only to the extent that this chapter establishes a rule of law applicable to the recovery of such damages.

(2) Applicability of other laws

Any issue that arises under this chapter and that is not governed by a rule of law applicable to the recovery of damages described in paragraph (1) shall be governed by applicable Federal or State law.

(d) Statutory construction

Nothing in this chapter may be construed—

(1) to affect any defense available to a defendant under any other provisions of Federal or State law in an action alleging harm caused by an implant; or

(2) to create a cause of action or Federal court jurisdiction pursuant to section 1331 or 1337 of title 28 that otherwise would not exist under applicable Federal or State law.

(Pub. L. 105-230, § 4, Aug. 13, 1998, 112 Stat. 1523.)

§ 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