(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.)

§ 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

(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.

(c) 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;