
21 U.S. Code § 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);
- (2) as a seller of the implant, as provided in subsection (c); 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).

(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.

This document is only available to subscribers. Please log in or purchase access.

Purchase Login