March 06, 2024

Update on Biomaterials Access Assurance Act Litigation

U.S. Congress found it necessary to provide manufacturers of biomaterials—component parts or raw materials for implantable medical devices—protection from liability in litigation involving the manufacture and use of an implantable medical device under the Biomaterials Access Assurance Act (BAAA). 21 U.S.C. § 1601 et seq. The Act 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." *Id.* § 1603(b)(1). The BAAA allows biomaterials suppliers that are not the manufacturer or seller of the ultimate implantable device to be dismissed from litigation by filing a motion prior to the engagement in expensive and time-consuming discovery. *Id.* § 1605(c). Further, under § 1605(e), dismissal is with prejudice.

The following two cases are the most recent examples of the BAAA's coverage, shielding biomaterials suppliers from liability in product liability actions.

***Connell v. Lima Corp.*, No. 1:16-CV-00456-CWD, 2019 WL 403855 (D. Idaho Jan. 30, 2019)**

In this case, the plaintiff sued for alleged injuries after his femoral stem prosthesis fractured. *Connell*, 2019 WL 403855, at *3. The defendants were the manufacturer of the implant, DJO Surgical, and the component manufacturer, Lima Corporate S.p.A. Lima manufactured two of the three component parts of the implant. DJO Surgical settled with plaintiff, leaving Lima as the remaining defendant. Lima filed a motion for summary judgment, primarily arguing that because it was a component manufacturer of medical

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device component parts for DJO's hip system, all claims against it were preempted by the BAAA. *Id*. at *2. The court agreed.

The plaintiff attempted to avoid application of the BAAA by characterizing the implant manufacturer as the distributor and the component manufacturer as the manufacturer of the implant. However, the court focused on the language in the supply agreement between DJO and Lima, which identified Lima not as the implant manufacturer but as the designer and manufacturer of the component parts for total joint replacement systems. Importantly, when DJO received the two products manufactured by Lima, they were not final, implantable devices, but merely component parts. The two products underwent inspection and additional processes by DJO prior to the final implantable device's release to the market. In addition, the former defendant, the medical device manufacturer, had submitted the Section 510(k) application to FDA, listing itself as the manufacturer of the hip system. While Lima provided the implant manufacturer with information necessary for the FDA premarket approval process, it did not conduct any regulatory submissions itself. The court held that Lima was a biomaterials supplier of component parts used by DJO in its hip system, and the BAAA applied to the plaintiff's claims. *Id*. at *6.

The court also found that none of the exceptions to the BAAA applied to save the plaintiff's claims against the biomaterials supplier. The court held that there was no evidence showing that: (1) the component manufacturer was a seller of the plaintiff's hip system; or (2) the component parts provided by Lima to DJO failed to meet specifications of the supply agreement.

Finally, the court noted that the biomaterials supplier could not be considered the manufacturer of the implant because it did not register nor was it required to register with the Secretary of Health and Human Services and did not include nor was it required to include the implant on a list of devices filed with the Secretary. *Connell*, 2019 WL 403855, at *7; *see also* 21 U.S.C. §§ 1604(a)(1); 1604(b)(2)(A)(i-ii); 1604(b)(2)(B)(i-ii). Also, it found that the biomaterials supplier was not related by common ownership or control to the manufacturer of the hip system. *Connell*, 2019 WL 403855, at *7; *see also* 21 U.S.C. § 1604(b)(2)(C). The court ultimately granted the motion for summary judgment and dismissed all of the plaintiff's claims with prejudice.

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***Daley v. Smith & Nephew Inc.*, 321 F. Supp. 3d 891, 894 (E.D. Wis. 2018)**

Daley is another case in which the plaintiffs' claims against the component manufacturer were preempted under the BAAA,

insulating liability. Here, the plaintiffs were users of the hip replacement implant known as the M–COR Modular Hip System, a Section 510(k) device. They brought product liability claims against the implant manufacturer and component manufacturer to recover for alleged injuries sustained as a result of their use of the implants. Defendant DiSanto Technology Inc., manufacturer of the femoral neck component of the hip replacement implant, filed a motion to dismiss arguing that all of the plaintiffs' claims against it were preempted by the BAAA.

In opposition, the plaintiffs argued that their claims were not preempted because the Act does not apply to Section 510(k) devices. According to the plaintiffs, the BAAA's protection extends only to claims involving PMA devices because only the rigorous PMA process results in meaningful assurances of device safety. *Daley*, 321 F. Supp. 3d at 894-5. The court disagreed, holding that "[n]o such distinction can be found in the statutory text" of the Act and "Plaintiffs cannot engraft ambiguity into the statute where none exists." *Id*. at 895.

The plaintiffs also argued that DiSanto was not a biomaterials supplier because it had incorporated many of its own designs in the manufacture of the components it produced. The plaintiffs theorized that the BAAA "does not insulate component 'designers' as opposed to component 'manufacturers' who simply follow design specifications." *Id*. at 898. The court rejected the plaintiffs' theory as "inconsistent with the BAAA's statutory scheme, which carefully catalogs the players in implant production, including device manufacturers, device sellers, and component or raw materials suppliers." *Id*. The court held that even if the component manufacturer "participated in the design of its [component parts], a component designer is not a category recognized in the BAAA." *Id*. The court explained that in enacting the BAAA, Congress "sought to insulate component suppliers and place all the risk on device manufacturers for the failure of the implant, whether caused by a flaw in the entire implant or one of its component parts." *Id*. It went on to say that if the implant manufacturer is held liable for the harm the plaintiffs experienced and it believes the component manufacturer is responsible for indemnity or contribution, the implant manufacturer can seek such relief. The plaintiffs cannot have a "direct route to the [biomaterials supplier's] pocketbook." *Id*. The court granted the component manufacturer's motion and dismissed plaintiffs' claims with prejudice.

Courts across jurisdictions continue to uphold the BAAA's protections, dismissing biomaterials suppliers in product liability cases. The BAAA endures as a straightforward, clear means to

efficiently and effectively seek immunity and timely disposition of futile lawsuits.