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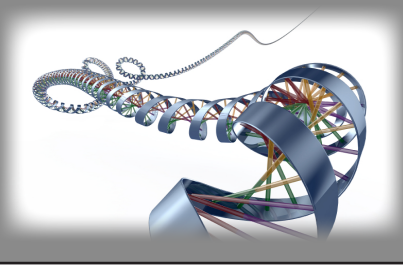

Bradley Arant Boult Cummings LLP

Biomaterial Suppliers in the Crosshairs

In the recent United States Supreme Court decision *Riegel v. Medtronic*, the Court found preemption of claims against manufacturers of Class III medical devices that have been approved through the FDA Pre-Market Approval ("PMA") process. The finding of preemption means that manufacturers of Class III medical devices are more likely to win early dismissal of personal injury lawsuits alleging problems with a device design or warning. This decision could leave individuals who believe they have been injured by a PMA Class III medical device approved via the PMA process - and the lawyers who represent them - with no ability to recover damages from the manufacturer of the device. As attempts are made to find alternative targets of liability, suppliers of biomaterials used in medical devices and suppliers of components of those devices may find themselves in the cross-hairs. The Biomaterial Access Assurance Act of 1998 (the "Act"), however, can provide a defense to claims made against these suppliers.

The Act bars suits against biomaterial suppliers except for certain limited exceptions discussed below. It was passed in 1998 as a response to court decisions holding suppliers of bulk biomaterials liable for injuries allegedly caused by the finished implants in which the biomaterials had been incorporated. As a result of those court holdings, many biomaterials suppliers had banned sales to U.S. device manufacturers. Congress determined that the Act was necessary to ensure that the public had continued access to life-saving medical devices. Congress approved the protections the Act afforded to biomaterial suppliers because medical device manufacturers were required to prove to the FDA that their devices – including the implants - were safe and effective.

To be protected by the Act, the biomaterial or component at issue must have been used in a device intended to be implanted longer than 30 days. Under the Act, biomaterials suppliers are entities that directly or indirectly supply a component part or raw material for use in the manufacture of an implant. "Component parts" are any manufactured piece of an implant, and "raw materials" means any substance or product that has a generic use and may be used in an application other than an implant. A supplier of component parts or materials can move for dismissal of claims brought in a lawsuit at any time in the litigation. Discovery against the supplier is limited solely to the issue of whether the supplier should be dismissed under the Act. Despite these limitations, a biomaterial supplier may still be subject to liability if a claimant can present evidence to meet certain exceptions under the Act.

A biomaterial supplier may be liable if it can be categorized as a "manufacturer" under the Act. Liability as a "manufacturer" can be established (1) if the supplier is registered or is required to register as a medical device manufacturer under the Food, Drug and Cosmetic Act; (2) if the Secretary of Health and Human Services declares that the supplier should have registered as a medical device manufacturer; or (3) if it is related by common ownership or control to a medical device manufacturer, and the court finds that it is necessary to impose liability on the supplier because the related manufacturer lacks sufficient financial resources to satisfy any judgment likely to be entered should the claimant prevail. Claimants can petition the FDA for a declaration that a biomaterial supplier should have registered with the FDA as a medical device manufacturer and failed to do so.

A biomaterials supplier also can be liable under the Act as the "seller" of the implant through a showing that (1) it held title to the implant and sold it to another after the initial sale by the manufacturer; (2) it acted under contract to sell the implant directly to the claimant; or (3) if it is related by common ownership or control to a medical device manufacturer and the court finds that it is necessary to impose liability on the supplier because the related manufacturer lacks sufficient financial resources to satisfy any judgment likely to be entered.

The Act also provides that a supplier may be liable for failing to meet contractual requirements or specifications relating to the raw materials but only under certain circumstances. For example, the Act provides that a supplier may be liable if it supplies the wrong product to the manufacturer. A supplier is also subject to

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liability if the raw materials or component parts fail to meet specifications agreed to, published, or provided by the entity that contracted for the supplying of the product. Liability may also be established against a supplier under this exception if the raw materials or component parts failed to meet specifications in a master file submitted by the supplier to the Secretary of Health and Human Services and that is currently maintained by the supplier for purposes of premarket approval. In addition to meeting one of these requirements, the failure to meet contractual requirements or specifications must have been an actual and proximate cause of the harm.

In addition to these exceptions, a biomaterials supplier who has been dismissed from the action may be brought back into the case if the manufacturer makes an assertion in the case that the negligence or intentional conduct of the dismissed supplier was the cause of claimant's harm and that the manufacturer's liability for damages should be reduced as a result of this conduct. Likewise, a claimant may seek to reassert claims against a biomaterial supplier if the evidence shows that the negligence or intentional conduct of the dismissed supplier was an actual and proximate harm to the claimant and that the claimant is unlikely to recover the full amount of its damages from the remaining defendants.

The Act provides a valuable defense to lawsuits brought against suppliers of biomaterials and component parts for medical devices. The Act allows for dismissal of the supplier with very limited discovery. While exceptions to early dismissal do exist, the defenses available under the Act may become particularly useful to biomaterial suppliers as plaintiffs seek alternative means to establish liability in a post-*Riegel* world.

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