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Assessing Protections for Biomaterials Suppliers 12 Years After the Biomaterials Access Assurance Act

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The growth of the biomaterials market, which analysts expect to reach $58.1 billion by 2014, shows that biomaterials suppliers have flourished by relying on the Biomaterials Access Assurance Act of 1998 (BAAA), 21 U.S.C. §§ 1601-1606, to forestall product liability litigation, and by resorting to additional legal defenses or extra-legal mechanisms to minimize the costs of such litigation. While more than 12 years have passed since the enactment of the BAAA, its substantive protections remain unclear. Additional legal and extra-legal means of protecting biomaterials suppliers do exist, however, and component suppliers to medical device companies should consider such means to diminish their legal risks.

The BAAA

OVERVIEW

In the scientific literature, a "biomaterial is a nonviable material used in a medical device, intended to interact with biological systems." The medical use of biomaterials dates back to 1588, when patients with cleft palate first received gold plate implants. Today, biomaterials include various ceramics, synthetic polymers, substances derived from biological processes and composites.

A series of high-profile lawsuits in the 1990s resulted in some biomaterials suppliers avoiding sales to medical device manufacturers. This created fears that a public health crisis would ensue and adversely affect innovation. In response, Congress passed the BAAA in August 1998. Although traditional common law doctrines protected biomaterials suppliers in product liability suits prior to the passage of the BAAA, Congress determined that the biomaterials field warranted special procedural protections because of its role in improving public health and its economic importance.

DEFINITIONS

The BAAA applies to biomaterials suppliers and provides them with "expeditious procedures to dispose of unwarranted suits." Whether or not a business producing biomaterials can rely on the BAAA protections largely depends on whether the BAAA classifies the business as a "supplier" or a "manufacturer." Under the BAAA, suppliers receive special procedural protections, whereas manufacturers or suppliers deemed manufacturers receive no such protections.

The BAAA defines a "biomaterials supplier" as any "entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant." The BAAA does not, however, define "biomaterial," although it does define products that may constitute biomaterials, *i.e.*, component parts and raw materials. Under the BAAA, a "component part" is defined as "a manufactured piece of an implant," and "raw material" is defined as a "substance or product that (A) has a generic use; and (B) may be used in an application other than an implant."

Implants fall under two categories. First, they include medical devices, *i.e.*, devices that are "defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) and include any device component of any combination product as that term is used in Section 503(g) of such Act (21 U.S.C. 353(g))" intended by the manufacturer of the device "(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." Second, they consist of "suture materials used in implant procedures."

Under the BAAA, manufacturers and sellers of implants receive no special protections. A business would qualify as a "manufacturer" if it meets a three-part test with respect to an implant by being

> (A) . . . engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in Section 510(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1) of the implant; and
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> (B) . . . required—
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> > (i) to register with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) 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 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section.

In general, the U.S. Food and Drug Administration (FDA) requires registration of any entity engaging in the "manufacture, preparation, propagation, compounding, or processing of a drug" or medical device, and also requires that such entities list every drug or medical device manufactured. Certain exemptions, however, apply. For instance, a "manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register" is specifically exempted.

This exemption, however, is qualified in a way that makes it unclear whether a biomaterials supplier that falls outside of the scope of the FDA's regulations can avail itself of the BAAA's protections. For instance, § 807.20(a)(5) requires that anyone who "[m]anufactures components or accessories which are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, *e.g.*, blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, *e.g.*, a manufacturer of ophthalmic lens blanks" must satisfy the registration and listing requirements for medical devices. Commentators have noted the paradoxical incentives of the BAAA: biomaterials suppliers that previously might have registered and listed their products because they did not risk anything by complying with the regulations now may avoid listing themselves for fear that erroneously doing so may preclude them from relying on the BAAA's protections.

Under the BAAA, a business would be a "seller" so long as it "sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce" and is not afforded an exclusion from the category by being a "seller or lessor of personal property"; a provider of professional health care services in any situation in which the sale or use of the implant is only incidental to the services offered and "the essence of the professional health care services provided" is offering "judgment, skill, or services"; or acts only in a "financial capacity with respect to the sale of an implant."

A "biomaterials supplier," however, does receive protection as a result of its status as such a supplier under the BAAA unless it is liable as a manufacturer under 21 U.S.C. §1605(b), a seller under §1605(c), or an entity furnishing raw materials or component parts that did not meet contractual requirements or specifications, pursuant to §1605(d).

A biomaterials supplier would be considered a manufacturer—and hence unable to rely on the protections of the BAAA—in only three cases. First, liability as a manufacturer would attach if the biomaterials supplier registered or was required to register with the Secretary of Health and Human Services pursuant to §510 of the Federal Food, Drug, and Cosmetic Act (FDCA) and any issued regulations pursuant to that section, or if the supplier included or was required to include the implant on a list of devices under §510(j) of the FDCA and its implementing regulations. Second, the biomaterials supplier would be liable as a manufacturer if the Secretary declared that such supplier of the implant that allegedly harmed the claimant was required to register the implant under §510 of the FDCA and the regulations implemented pursuant to §510, yet failed to do so, or was required to list the implant with the Secretary under §510(j) of the FDCA and the regulations implemented pursuant to §510, yet failed to do so. Third, the biomaterials supplier would be liable if a court found that it was "related by common ownership or control" to a manufacturer under the two previous cases and that, on the basis of affidavits, "it is necessary to impose liability" because the manufacturer to which it is related "lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail."

Under the BAAA, a biomaterials supplier may be liable as a "seller" for the harm caused by an implant under the following three conditions:

- Such supplier held title to the implant and then acted as a seller of the implant after the manufacturer initially sold it.
- Such supplier acted as a seller under contract to coordinate the direct transfer of the implant to the claimant after the manufacturer first sold it.
- Such supplier is found to be related by common ownership or control to a seller liable under the first or second point, and a court finds it necessary for liability to be imposed on the biomaterials supplier because the seller lacks sufficient resources to allow a claimant to recover a judgment that the court feels it is likely to enter if the claimant prevails.

PROCEDURAL PROTECTIONS

Generally, under the BAAA, a biomaterials supplier may move for dismissal because it is not liable as a manufacturer, as a seller, or for supplying raw materials or components that failed to live up to their contractual requirements or specifications, or because the claimant did not name the manufacturer as a party to the action. However, failure to name the manufacturer is not necessary

in certain instances. As set forth at 21 U.S.C. §1605(b), a claimant is not required to name the manufacturer as a party if the supplier is only subject to service of process in a jurisdiction where the claimant is neither domiciled nor able to reach the manufacturer by service of process, or the claim against the manufacturer is barred.

Once the biomaterials supplier files a motion to dismiss, the claimant may only obtain discovery to the extent necessary to determine whether there is a lack of jurisdiction. If the biomaterials supplier files a motion to dismiss because it did not provide the raw materials or component parts for the implant that allegedly failed to meet the relevant contractual requirements or specifications of the medical device manufacturer, the court may allow limited discovery, but only to the extent that such discovery is directly relevant to either the motion to dismiss or the jurisdiction of the court. Generally, however, once the biomaterials supplier has filed the motion to dismiss, discovery is precluded until the court rules on the motion. Based on the pleadings and affidavits supplied by the parties asserting that the biomaterials supplier is neither a manufacturer nor a seller, the court will grant the motion for dismissal, unless the claimant offers affidavits demonstrating that the defendant was not a biomaterials supplier, or the court finds that the defendant may be liable for the harm caused by the implant as a manufacturer, seller or provider of materials that failed to meet contractual specifications or requirements. The court may treat the motion to dismiss as a motion for summary judgment, which, like any dismissal under the BAAA, will be "entered with prejudice."

Section 7 of the BAAA, however, significantly undermines the procedural protections it seems to offer to biomaterials suppliers. This section allows a manufacturer or a claimant to move a court to implead a biomaterials supplier that had been dismissed under the BAAA within 90 days in the following two situations. First, if the manufacturer makes an assertion—and the court agrees—that under applicable law (1) the dismissed supplier, through its negligence or intentionally tortious conduct, actually and proximately caused the harm to the plaintiff, and (2) the manufacturer's liability should be reduced as a result of such conduct, then the court can subsequently implead the previously dismissed supplier. Second, if the claimant moves to implead the supplier and the court finds that (1) the dismissed supplier, though its negligence or intentionally tortious conduct, actually and proximately caused the harm to the plaintiff, and (2) the claimant will probably not be able to recover the full amount of damages from the other defendants, the court can then implead the previously dismissed supplier. Under the BAAA, a biomaterials supplier that is impleaded may thus find itself in the unenviable position of having to defend itself for the first time after a jury has already determined it was at fault for the plaintiff's injuries.

EFFECT

It is unclear what effect the BAAA has had on biomaterials suppliers. On the one hand, there is some evidence that biomaterials suppliers have avoided the medical device market because of the uncertainty of the protections afforded by the BAAA. Some biomaterials suppliers have elected to forgo the medical device market because the amount of biomaterial needed to manufacture implants is often orders of magnitudes smaller than the amounts sold into the overall market. Others have avoided the medical device market for fear that they might be brought into a lawsuit as a result of the manufacturer of the medical device's declaration of bankruptcy, suffer adverse publicity resulting from severe injuries caused by the implant or become subject to the jurisdiction of the FDA.

Yet it appears that many biomaterial manufacturers have entered the medical device market and have profited enormously by doing so. In fact, the total biomaterials market today is reported to have passed $28 billion as new applications of such materials have driven increased demand. Analysts anticipate that the total global market for such materials will amount to $58.1 billion by 2014 and have noted the effect that aging populations have in driving growth in this market. They predict that the cardiovascular biomaterial market will eclipse the orthopedic biomaterials market, which was the largest segment of the market in 2008 at $9.8 billion, to reach $20.7 billion by 2014. The U.S. market, the largest market for such materials, is projected to be worth $22.8 billion by 2014, with a compound annual growth rate of 13.6 percent from 2009 to 2014.

CRITICISMS

Critics have challenged both the necessity and the efficacy of the BAAA. Biomaterials suppliers have criticized the BAAA for not providing them with enough protection against unmeritorious claims. These suppliers have rarely resorted to the BAAA's protections, most likely because of the procedural anomaly of the BAAA that allows claimants to implead suppliers after a finding of fault. Other critics have suggested that the BAAA's preemption of state tort law may represent an unconstitutional intrusion into an area traditionally governed by state law and have claimed that a system that precludes product liability litigation insufficiently incentivizes the creation of safe products.

The preemption aspect of BAAA, however, most likely will survive constitutional challenges. In *Riegel v. Medtronic*, 128 S.Ct. 999 (2008), the most significant recent preemption case applicable to medical devices, the petitioner, who was allegedly injured when a Medtronic catheter burst in an angioplasty procedure, claimed that state product liability law was the type of "general requirement" related to "products in addition to devices" that the FDA's regulation "saved" from preemption. The Supreme Court of the United States disagreed, finding that the petitioner's claims were based on state law "requirement[s]" with respect to the catheter that were "different from, or in addition to," the federal ones and related to the safety and effectiveness of the catheter and thus expressly preempted. Ultimately, the Supreme Court held that the preemption clause of the Medical Device Amendments Act of 1976, which requires that manufacturers of devices obtain the FDA's pre-market approval before distributing devices that present material health risks, precludes common-law claims that challenge the safety or effectiveness of a medical device for which the FDA had granted pre-market approval. Although the law under *Riegel v. Medtronic* may be displaced by congressional enactment, the express preemption language of the BAAA will likely save it from preemption challenges.

BAAA and the *Whaley* Decision

Whaley v. Morgan Advanced Ceramics Ltd., 2008 WL 901523 (D. Colo.2008), remains the only significant reported decision on the BAAA. In *Whaley*, a medical products liability case, the defendant, Morgan Advanced Ceramics, filed a motion to dismiss pursuant to 21 U.S.C. § 1605(a) of the BAAA. Whaley, the plaintiff, had undergone a hip replacement surgery to install a system that included a femoral hip head component made by Morgan. Morgan supplied a ceramic sphere composed of zirconia powder, a material with several uses outside of the medical device industry, to Joint Medical Products, Inc., which had defined the product specifications and conducted pre-market notification for its S-ROM Total Hip System. Morgan also supplied information required for the pre-market notification regarding its hip heads, but it neither conducted the submissions nor submitted the S-ROM Total Hip System pursuant to 21 U.S.C. §360(j) of the FDCA.

The court, looking at the pleadings, affidavits, findings of fact, arguments of the parties, and the BAAA, made several findings. First, it found that Morgan was a biomaterials supplier under §1601(A) of the BAAA. Next, it found that its femoral head was a component part of the S-ROM Total Hip System implant within the meaning of §1602(3)(A). Third, it found that Morgan did not meet the definition of a manufacturer within the meaning of §1602(6)(B). Finally, it found that Morgan was not a seller within the meaning of §1602(10).

Since Morgan was neither a manufacturer nor a seller of the implant and did not furnish raw materials or components that failed to meet Joint Medical Product's requirements or specifications, the court found Morgan not liable for any harm caused by the implant. Significantly, the court held that "dismissal must be with prejudice under 21 U.S.C. §1605(e), notwithstanding the anomalous potential statutory remedy of post-judgment impleader under 21 U.S.C. §1606(a)." While *Whaley* is a case of first impression, the decision suggests that courts may broadly interpret the BAAA's protections for suppliers of biomaterials.

Shields Available to Biomaterial Manufacturers in the Absence of the BAAA

LEGAL DEFENSES

The two major defenses available to biomaterials suppliers, both of which the BAAA codifies, are the "component part" and "sophisticated purchaser" doctrines. The component part doctrine shields manufacturers that sell general purpose parts to assemblers of finished products, provided that the parts were not themselves defective. The dispositive issue that courts will address is why the component part proved unsuitable for use in the finished product. If the failure resulted from a flaw in the component part, courts will find that the component part is itself defective, resulting in the assembled product being defective. Consequently, a court may properly hold the component part manufacturer strictly liable for the harm resulting from design or manufacturing defects of the components. But if the harm resulted from the unreasonably dangerous condition of the finished product because the manufacturer of the finished product used an unsuitable component part that was not appropriate for the use for which the manufacturer employed the component, then a court may hold the manufacturer of the finished product strictly liable for the harm caused by the product.

The sophisticated purchaser doctrine, which is also known as the "bulk supplier" rule, shields component manufacturers from failure to warn claims by allowing them to rely on the expectation that sophisticated manufacturers will relay any consumer warnings with respect to product designs to the end users of the assembled product. Courts have found that the doctrine "simply

permits the court to find that [a bulk] supplier discharged its duty by reasonably relying upon the intermediary to convey appropriate warnings to the ultimate users."

EXTRA-LEGAL PROTECTIONS

Biomaterials suppliers have also relied on extra-legal means of protecting themselves from product liability claims. Contractual indemnification provisions can shift the cost of defending liability claims from biomaterials suppliers to manufacturers by requiring them both to assume any liability resulting from the use of their device and defend the supplier, including paying the suppliers' costs for any litigation that such suppliers are subject to as a result of product liability claims. A biomaterials supplier would also need to have sufficient confidence that the manufacturer of the implant is capitalized well enough to avoid bankruptcy, since insolvency could leave the supplier outside the BAAA's protections and render the bargained-for indemnification provisions moot.

Biomaterials suppliers may also consider entering into profit-sharing arrangements with manufacturers to obtain greater potential financial rewards to compensate for perceived risks in supplying biomaterials. Significant risks attend to such an approach, however, since a court could determine that the parties exhibited common ownership and control because of their joint interest in the implant. Biomaterials suppliers could also avail themselves of insurance to avoid catastrophic legal claims.

Commentators have made several recommendations for biomaterials suppliers, some of which seem counterintuitive, to protect themselves from product liability suits. First, biomaterials suppliers should make sure that the materials that they intend to supply meet their own specifications and that they can demonstrate that the products that they supply objectively meet the criteria that they have developed. Second, biomaterials suppliers should avoid communicating with manufacturers regarding product design and avoid advocating particular uses or specifications for their products to avoid seeming to substantially participate in the production of the end devices. Third, biomaterials suppliers should provide disclaimers and contractually oblige manufacturers to provide them with waivers and indemnification rights. Fourth, such suppliers should disclose known risks to manufacturers to entitle the supplier to rely on the sophisticated purchaser doctrine. By performing additional testing on the product, however, biomaterials suppliers may paradoxically find themselves assuming greater legal risk, since a court could find a duty on the suppliers' part to perform additional testing, provide more extensive disclosure or even withdraw products to avoid liability for the negligent performance of an undertaking.

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