

# THE BIOMATERIALS ACCESS ASSURANCE ACT OF 1998 AND SUPPLIER LIABILITY: WHO YOU GONNA SUE?

## ABSTRACT

*The DuPont Company spent \$26 million litigating more than 650 lawsuits over implants used to treat temporomandibular joint syndrome (TMJ) after DuPont had supplied a raw material to the medical device manufacturer. The Biomaterials Access Assurance Act of 1998 (BAAA) was enacted with the aim of preventing suppliers, such as DuPont, from becoming entangled in this type of product liability litigation. This note explores the legitimacy of BAAA and the relative impact it may have on businesses that supply raw materials or component parts to medical device manufacturers. Part II overviews provisions of BAAA, while also discussing common law doctrine that protects component part suppliers from liability and pertinent Food and Drug Administration regulations. Part III reviews the TMJ implant litigation that helped spur Congress' enactment of BAAA. Part IV examines the purported need for BAAA and examines procedural nuances of the Act. Part V concludes that, in theory, BAAA is a legitimate attempt to codify well-established common law. As a result, the BAAA may afford biomaterials suppliers a comfort level that will allow them to safely reenter the market and achieve the Act's purported goal: to prevent a shortage of raw materials, thereby preventing a shortage of life-saving medical devices.*

## I. INTRODUCTION

Opinions concerning the legitimacy of the Biomaterials Access Assurance Act of 1998<sup>1</sup> (BAAA or the Act) run the gamut. Corporations that manufacture medical devices view the Act as prudent federal legislation aimed at ensuring the future of a vital health-care industry.<sup>2</sup> Consumer protection organizations, however, view BAAA as nothing less than "legal extortion for immunity" from product liability litigation.<sup>3</sup>

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<sup>1</sup>The Biomaterials Access Assurance Act of 1998, Pub. L. No. 105-230, 112 Stat. 1519 (codified at 21 U.S.C.A. §§ 1601-1606 (West Supp. 1999)).

<sup>2</sup>See generally Aronoff Associates, *Biomaterials Availability: A Vital Health Care Industry Hangs in the Balance* (April 1997) (visited Jan. 30, 2000) <<http://www.himanet.com/publicdocs/bioavail.pdf>> (describing the alleged shortage of raw materials and component parts for medical devices). This is the report of a study that was commissioned by the Health Industry Manufacturers Association (HIMA). *Id.* at 6.

<sup>3</sup>Public Citizen, *Top Ten Reasons to Oppose the Biomaterials Access Assurance Act of 1998* (visited Oct. 6, 1998) <<http://www.citizen.org/congress/civjus/biomaterials/topten.htm>>.

BAAA sets forth "expeditious procedures to dispose of unwarranted [product liability] suits" against business entities that merely supply raw materials for use in the manufacturing of medical devices.<sup>4</sup> Thus, BAAA is aimed at preventing these suppliers from becoming entangled in product liability litigation over harm allegedly caused by the final manufactured medical device.

Generally, suppliers of raw materials and component parts have little to do with the design, production, or testing of the medical device into which the materials are ultimately incorporated.<sup>5</sup> Nonetheless, component part suppliers have been swept up in product liability litigation,<sup>6</sup> where plaintiffs have made allegations ranging from inadequacy of design to inadequacy of warning with regard to the final medical device.<sup>7</sup> The DuPont Corporation, for example, spent \$26 million litigating more than 650 lawsuits over implants used to treat temporomandibular joint syndrome (TMJ) after DuPont had supplied a raw material, namely Teflon, to the device manufacturer.<sup>8</sup>

Even though suppliers are rarely held liable in such actions, the fear of incurring the enormous cost associated with litigation has caused some suppliers to stop providing much-needed materials to medical device manufacturers.<sup>9</sup> This sequence of events has led Congress to pass BAAA in an attempt to ward off a shortage of raw materials that could, in turn, lead to a serious shortage of often life-saving medical devices.<sup>10</sup>

This note explores the legitimacy of BAAA, and the relative impact on businesses that supply raw materials or component parts to medical device manufacturers. Part II provides an overview of the provisions of BAAA, and discusses common law doctrines that protect component part suppliers from liability, and the subsequent codification of these doctrines in BAAA. Part II also describes pertinent Food and Drug Administration

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<sup>4</sup>21 U.S.C.A. § 1601(15)(B).

<sup>5</sup>See *id.* § 1601.

<sup>6</sup>See, e.g., Ronald Begley, *Even the Wins are Costly*, CHEM. WK., Aug. 2, 1995, at 23, 24 (tallying up the costs incurred by Dow Corning, DuPont, and Dow Chemical, for successfully defending themselves in product litigation over silicone breast implants (approximately \$8 million in costs), jaw implants (\$26 million in costs), and a single breast implant suit (more than \$1 million), respectively).

<sup>7</sup>See 21 U.S.C.A. § 1601(7).

<sup>8</sup>Begley, *supra* note 6, at 23.

<sup>9</sup>See 21 U.S.C.A. § 1601(8). Dow Chemical Co., for example, while continuing to supply raw material for use in medical devices that remain in the human body for only a short time, has stopped supplying raw materials for use in pacemakers leads. See Steven Toloken, *Doubt Shrouds Biomaterials Assurance Act: Resin Makers Take Wait-and-See Stance with Liability Protection Law*, PLASTICS NEWS, May 31, 1999.

<sup>10</sup>See 21 U.S.C.A. § 1601(9).

(FDA) regulations regarding the marketing of medical devices including regulations requiring medical device and drug manufacturers to register manufacturing establishments and list products with the agency. Part III of this note reviews recent TMJ implant litigation, which helped spur Congress' enactment of BAAA.

Part IV examines the purported need for BAAA and explains further procedural nuances of the Act. Part IV also discusses a possible constitutional challenge to the Act that has been posited by consumer protection organizations.<sup>11</sup>

Part V concludes that, in theory, BAAA is a legitimate attempt to codify well-established common law, but that procedural aspects of the Act may, in practice, prove troublesome. Finally, Part V discusses that the mere existence of BAAA may afford biomaterials suppliers a comfort level that will allow them to reenter the market. That comfort level may, in and of itself, achieve the Act's purported goal: to prevent a shortage of raw materials, thereby preventing a shortage of life-saving medical devices.

## II. BACKGROUND

### A. Bulk Supplier Doctrine/Sophisticated User Defense

In general, the bulk supplier doctrine provides that an entity, which supplies "nondefective" product components, is not liable for harm caused by the final product into which the component is incorporated.<sup>12</sup> The supplier may be liable either if the component itself is defective and the defect subsequently causes the harm,<sup>13</sup> or if the supplier of the component part participates in the design of the final product and the integration of the component causes the harm.<sup>14</sup>

The bulk supplier doctrine is particularly pertinent in product liability cases involving medical devices and pharmaceuticals because these products are often composed, at least in part, of materials the manufacturer has

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<sup>11</sup>See Public Citizen, *Memorandum on Biomaterials Assurance Act of 1998*, at 2 (July 14, 1998) (visited Oct. 6, 1998) <<http://www.citizen.org/congress/civjus/biomaterials/memo98.htm>>.

<sup>12</sup>See RESTATEMENT (THIRD) OF THE LAW TORTS: PRODUCTS LIABILITY § 5, cmt. a (1997).

<sup>13</sup>See, e.g., *Donahue v. Phillips Petroleum Co.*, 866 F.2d 1008, 1010 (8th Cir. 1989) (holding that it was appropriate to submit to the jury whether a manufacturer of a chemical odorizing warning agent, which may have lost its odorizing properties, was liable for injuries to consumers who were injured while attempting to light a propane-fueled water heater, where the odorizing warning agent had been incorporated into the propane fuel).

<sup>14</sup>See, e.g., *Stecyk v. Bell Helicopter Textron, Inc.*, No. 94-CV-1818, 1996 U.S. Dist. LEXIS 4022, at \*37 (E.D. Pa. Apr. 1, 1996) (declining to grant summary judgment in favor of a component part manufacturer defendant because a genuine issue of material fact existed with respect to the defendant's involvement in the design of a critical portion of the final product).

procured from an outside supplier.<sup>15</sup> Under most circumstances, when an injured party tries to impose liability on the outside supplier, the bulk supplier doctrine is an available defense.<sup>16</sup>

Closely linked to the bulk supplier doctrine is the sophisticated user defense. This defense, also known as the learned intermediary defense, allows the separate or remote supplier to depend on the manufacturer of the final product to convey the required warnings to the consumer or patient.<sup>17</sup> After all, the manufacturer of the final product is in the best position to determine what specific warnings are appropriate and to communicate those warnings to the consumer.<sup>18</sup> In general, BAAA codifies these two common law defenses in the business of medical device manufacturing, which often entails separate suppliers of important raw materials and component parts.<sup>19</sup>

### B. *The Biomaterials Access Assurance Act of 1998*

Companies that supply raw materials and component parts to medical device manufacturers rarely participate in the design, production, or testing of the ultimate medical device. These companies, however, have been brought into litigation over inadequate warnings and improper design and testing of finished products.<sup>20</sup> Business entities that supply raw materials and component parts are usually not held liable in such actions, yet fear of incurring the costs of exoneration in such litigation has led certain corporations to stop providing these essential raw materials to the medical device manufacturers.<sup>21</sup>

In an attempt to ensure a continued supply of the materials needed to maintain existing life-saving medical devices, Congress exercised its Commerce Clause<sup>22</sup> powers and enacted BAAA.<sup>23</sup> Under the Commerce

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<sup>15</sup>See RICHARD J. HEAFEY & DON M. KENNEDY, *PRODUCT LIABILITY: WINNING STRATEGIES AND TECHNIQUES* ch. 10, *Special Considerations in Cases Involving Prescription Drugs or Medical Devices* § 10.05 (Law Journal Seminar-Press, division of The New York Law Publishing Company, 1996).

<sup>16</sup>*Id.*

<sup>17</sup>See M. Stuart Madden, *Liability of Suppliers of Natural Raw Materials and the Restatement (Third) of Torts: Products Liability - A First Step Toward Sound Public Policy*, 30 U. MICH. J.L. REFORM 281, 284 n.13 (1997).

<sup>18</sup>See *id.* at 285.

<sup>19</sup>See Biomaterials Access Assurance Act of 1998, H.R. REP. 105-549, pt. 1, at 9-11 (1998).

<sup>20</sup>See 21 U.S.C.A. § 1601 (West Supp. 1999).

<sup>21</sup>See *id.*; see also Begley, *supra* note 6, at 24 (noting that Monsanto abandoned work on a nearly-ready-to-market phosphate fiber, which was to be used as a substitute for asbestos, out of fear of litigation).

<sup>22</sup>U.S. CONST. art. I, § 8, cl. 3.

<sup>23</sup>See 21 U.S.C.A. § 1601(16)-(17).

Clause, Congress has the power to address a plethora of societal concerns, if they are found to have a significant impact on interstate commerce.<sup>24</sup>

The purported shortage of raw materials, which threatens to lead to shortages of the medical devices themselves, constitutes a significant interstate commerce issue.<sup>25</sup> Even though many product liability actions are brought in state courts, tort reform in any one state or group of states is unlikely to solve this problem because corporate suppliers of biomaterials are subject to litigation in virtually every state.<sup>26</sup> Thus, as a preliminary matter, action at the federal government level seems appropriate.<sup>27</sup>

Obviously, the federal government cannot step in and forbid plaintiffs from suing raw material suppliers for injuries. By codifying existing tort law defenses for suppliers of raw materials, BAAA attempts to provide these suppliers with an easy escape from litigation<sup>28</sup> prior to extensive discovery. The aim is to save the suppliers much time and money, allowing them to maintain their competitiveness within the business of supplying raw materials to medical device manufacturers.<sup>29</sup>

## 1. Findings of Congress/Key Definitions

The first section of BAAA details a seventeen-step foundation for enacting the new law.<sup>30</sup> The Act further defines key terms and descriptions

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<sup>24</sup>See Biomaterials Access Assurance Act of 1998, H.R. REP. 105-549, pt. 1, at 15 (1998).

<sup>25</sup>*Id.*

<sup>26</sup>See Biomaterials Access Assurance Act of 1998, H.R. REP. 105-549, pt. 1, at 11 (1998). DuPont was sued 651 times in 41 states over a ten-year period over the TMJ implants. *Id.* at 10 (citing Letter from Ross F. Schmucki, Senior Counsel, DuPont, to Senator Joseph I. Lieberman (July 25, 1997)).

<sup>27</sup>See *infra* notes 151-65 and accompanying text.

<sup>28</sup>See Biomaterials Access Assurance Act of 1998, H.R. REP. 105-549, pt. 1, at 9-11 (1998).

<sup>29</sup>*Id.*

<sup>30</sup>21 U.S.C.A. § 1601 (West Supp. 1999):

(1) each year millions of citizens of the United States depend on the availability of lifesaving or life-enhancing medical devices, many of which are permanently implantable within the human body; (2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices; (3) most of the medical devices are made with raw materials and component parts that — (A) move in interstate commerce; (B) are not designed or manufactured specifically for use in medical devices; and (C) come in contact with internal human tissue; (4) the raw materials and component parts also are used in a variety of nonmedical products; (5) because small quantities of the raw materials and component parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and component parts; (6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301) manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the

of business entities. Differentiation between a business entity that is deemed a "supplier," and one that is deemed a "manufacturer," is essential to the procedural aspects that drive BAAA. The Act defines a "Biomaterial Supplier" as any "entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant."<sup>31</sup> The Act defines a "manufacturer" as any person who is:

(A) . . . engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in section 510(a)(1) of

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products are properly designed and have adequate warnings or instructions; (7) notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate (A) design and testing of medical devices manufactured with materials or parts supplied by the suppliers; or (B) warnings related to the use of such medical devices; (8) even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying certain raw materials and component parts for use in medical devices for a number of reasons, including concerns about the costs of such litigation; (9) unless alternative sources of supply can be found, the unavailability of raw materials and component parts for medical devices will lead to unavailability of lifesaving and life-enhancing medical devices; (10) because other suppliers of the raw materials and component parts in foreign nations are refusing to sell raw materials or component parts for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials and component parts for medical devices are remote; (11) it is unlikely that the small market for such raw materials and component parts in the United States could support the large investment needed to develop new suppliers of such raw materials and component parts; (12) attempts to develop such new suppliers would raise the cost of medical devices; (13) courts that have considered the duties of the suppliers of the raw materials and component parts have generally found that the suppliers do not have a duty — (A) to evaluate the safety and efficacy of the use of a raw material or component part in a medical device; (B) to warn consumers concerning the safety and effectiveness of a medical device; (14) because medical devices and the raw materials and component parts used in their manufacture move in interstate commerce, a shortage of such raw materials and component parts affects interstate commerce; (15) in order to safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices, immediate action is needed — (A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and (B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs; (16) the several States and their courts are the primary architects and regulators of our tort system; Congress, however, must, in certain circumstances involving the national interest, address tort issues, and a threatened shortage of raw materials and component parts for lifesaving medical devices is one such circumstance; and (17) the protections set forth in this [Act] are needed to assure the continued supply of materials for lifesaving medical devices, although such protections do not protect negligent suppliers.

*Id.*

<sup>31</sup>21 U.S.C.A. § 1602(1)(A).

the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360(a)(1)) of the implant; and (B) is required (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.<sup>32</sup>

The differentiation between manufacturer and supplier is essential because suppliers are afforded protection, while manufacturers (or suppliers who are deemed also to be manufacturers) are not protected under BAAA.<sup>33</sup>

## 2. General Liability Provisions Set Forth in BAAA

In general, BAAA sets forth that biomaterial suppliers are not liable for harm caused by a medical device, unless the supplier is also the manufacturer or the seller of the implant. Furthermore, a supplier may be held liable if it provided raw materials or component parts that were defective.<sup>34</sup>

Conversely, under the Act manufacturers are provided no special protection from liability.<sup>35</sup> A supplier will be deemed to be a manufacturer of a medical device if, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and rules promulgated thereunder, the entity "registered, or was required to register" its manufacturing facility, and listed, or was required to list, its product with FDA.<sup>36</sup>

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<sup>32</sup>*Id.* § 1602(6). *See also infra* notes 54-62 and accompanying text (discussing the implications of the fact that the "manufacturer" designation may hinge on whether the company registered its manufacturing facility and listed its products with FDA).

<sup>33</sup>21 U.S.C.A. §§ 1601-1606.

<sup>34</sup>*See generally id.* § 1604(a)(3) (stating that BAAA does not protect suppliers when the provided materials failed to meet contractual requirements or specifications, and that failure caused the harm complained of by the plaintiffs).

<sup>35</sup>*Id.*

<sup>36</sup>*See id.* § 1604(b)(2) (Grounds for Liability); *see also infra* notes 54-62 and accompanying text for a discussion of the implications of the fact that the "manufacturer" designation hinges on whether the company registered its manufacturing facility and listed its products with FDA.

### 3. Procedural Aspects of BAAA

#### a. *The Petition for a Declaration*

Perhaps the most interesting procedural aspect of BAAA concerns the petition for declaration provision. Any person may petition the Secretary of Health and Human Services<sup>37</sup> for a declaration that indicates whether the supplier/defendant is a manufacturer.<sup>38</sup> Upon receipt of such a petition, the Secretary has 120 days to issue a decision.<sup>39</sup> The statute of limitations tolls upon submission of the petition;<sup>40</sup> and the court will stay proceedings until the Secretary issues a final decision regarding the status of the subject of the litigation (i.e., whether the defendant is deemed to be a manufacturer and, hence, not protected under the Act).<sup>41</sup> Implicitly, if the Secretary deems that the defendant is not a manufacturer, the motion to dismiss will be granted unless successfully rebutted by the plaintiff.<sup>42</sup>

#### b. *Procedures for Dismissal of the Action*

Section 6, Procedures for Dismissal of Civil Actions Against Biomaterials Suppliers, contains the crux of BAAA. This section sets forth that the defendant may file a motion to dismiss, at any appropriate time, on the grounds that the defendant is a biomaterials supplier, rather than a manufacturer or seller. Also, the defendant may demonstrate that it did not furnish raw materials that fell short of any contractual requirements, or that the manufacturer of the device was not named as a party in the action.<sup>43</sup>

In addition, section six of BAAA sets forth the rules that will apply once such a motion to dismiss is filed by a defendant. Most important is the effect of the motion to dismiss on the discovery process. Once the defendant files a motion to dismiss on the grounds that it is a "biomaterials supplier"

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<sup>37</sup>Most likely, this duty will also involve the Commissioner of the Food and Drug Administration (FDA). *See, e.g.*, 21 C.F.R. § 207.20 (1999) (indicating registration and listing procedures for drug establishments). That is, the registration and listing requirements fall under the purview of the FDA. *See id.*

<sup>38</sup>*See* 21 U.S.C.A. § 1604(b)(2)(B).

<sup>39</sup>*See id.* § 1604(b)(3)(B). Before issuing a declaration that an entity was required to register and list its product with FDA, the Secretary must provide "notice to the affected persons" and "an opportunity for an informal hearing." *Id.* § 1604(b)(3)(A).

<sup>40</sup>*See id.* § 1604(b)(3)(C).

<sup>41</sup>*See id.* § 1604(b)(3)(D).

<sup>42</sup>*See* 21 U.S.C.A. §§ 1604-1605 (stating that a biomaterials supplier will not be liable unless the supplier is a manufacturer or a seller, or has furnished inadequate materials).

<sup>43</sup>*Id.* § 1605. BAAA also requires that the medical device *manufacturer* be a named party in any action covered by the Act. *See id.*

under BAAA, discovery is halted.<sup>44</sup> Yet, if the defendant files a motion to dismiss, also on the grounds that it did not furnish raw materials to the medical device manufacturer, then discovery may proceed on that issue.<sup>45</sup>

As an alternative to a costly discovery process, the plaintiff may submit affidavits stating that either the defendant is a seller of the medical device, or that the Secretary has issued a declaration that the defendant has been deemed a manufacturer.<sup>46</sup>

Under BAAA, the court shall rule on a motion to dismiss based on the pleadings and affidavits submitted by the parties, unless the plaintiff has submitted affidavits demonstrating the defendant is not a biomaterials supplier.<sup>47</sup> Furthermore, an action should survive if the court determines that the defendant may be a manufacturer, a seller, or has provided materials that did not meet specifications.<sup>48</sup>

BAAA also contains provisions whereby the manufacturer, or the plaintiff, may move to implead a previously dismissed biomaterials supplier.<sup>49</sup> The dismissed supplier may be impleaded within ninety days of a final judgment under any of these circumstances. First, the manufacturer asserts a claim for indemnification. Second, the plaintiff is unlikely to be able to recover damages from the other defendant(s), or third, the "tortious conduct of the dismissed supplier" was the cause of the harm.<sup>50</sup>

In sum, BAAA permits a business entity that has supplied raw materials or component parts to a medical device manufacturer to "head-the-plaintiff-off-at-the-pass" in a personal injury suit.<sup>51</sup> Via a motion to dismiss or a motion for summary judgment, a defendant may assert that it is a biomaterials supplier and is thus granted protection under BAAA.<sup>52</sup> Once the motion is filed, the costly process of discovery stops, and the plaintiff may instead find himself at the mercy of the Secretary of Health and Human Services for a determination of the status of the defendant-business entity.<sup>53</sup> Whether or not the entity is deemed a manufacturer hinges, at least in part, on the FDA registration and listing regulations.

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<sup>44</sup>*Id.* § 1605. The only discovery permitted at this point is discovery necessary to determine if the court has jurisdiction to hear the case. *Id.*

<sup>45</sup>*See id.* § 1605(c)(1)(B).

<sup>46</sup>*See* 21 U.S.C.A. § 1605(c)(2)(B).

<sup>47</sup>*Id.* § 1605.

<sup>48</sup>*Id.* Under BAAA, the motion to dismiss may be treated as a motion for summary judgment. *Id.* In this case, discovery may be conducted to determine if any "issue of material fact" exists as to whether the defendant is a biomaterials supplier. *See id.* § 1605(c)(4).

<sup>49</sup>*See id.* § 1606.

<sup>50</sup>21 U.S.C.A. § 1606.

<sup>51</sup>*See id.* §§ 1601-1606.

<sup>52</sup>*See id.*

<sup>53</sup>*See id.* § 1604.

### C. FDA Registration and Listing Requirements

Generally, FDA regulations require that anyone who engages in the "manufacture, preparation, propagation, compounding, or processing of a drug" or a device, register their manufacturing establishment with the FDA.<sup>54</sup> In addition to registering the manufacturing establishment, the entity should list with the FDA every drug or device product that it manufactures.<sup>55</sup>

However, manufacturers of inactive ingredients such as "excipients, colorings, flavorings, emulsifiers, lubricants, preservatives, or solvents," are exempt from the registration and listing requirements.<sup>56</sup> Also exempt are "manufacturer[s] of raw materials or components to be used in the manufacture or assembly of a [medical] device who would otherwise not be required to register."<sup>57</sup>

The protection of a corporation or other business entity as a biomaterial supplier under BAAA may hinge on whether that corporation has registered and listed its product with the FDA.<sup>58</sup> This is somewhat troublesome because the regulations are not entirely clear-cut. A comparison of the regulations' language, regarding what entities must register and what entities are exempt, is confusing. For example, a "manufacturer of raw materials or components to be used in the manufacture or assembly of a [medical] device who would otherwise not be required to register" is exempt.<sup>59</sup> Yet manufacturers of

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,]<sup>60</sup>

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<sup>54</sup>21 C.F.R. §§ 207.20(a), 807.20(a) (1999).

<sup>55</sup>See *id.* § 207.20(a). Once the products are listed the FDA uses the National Drug Code (NDC) system to assign a listing number. The NDC number is 10 characters long. The first five characters identify the manufacturer and are known as the "labeler code." See *id.* § 207.35(b)(2). The second five characters consist of two sections that identify the drug and the package size and are known as the "product code" and the "package code." *Id.* "FDA requests but does not require that the NDC number appear on all [drug labeling]." *Id.* § 207.35(b)(3).

<sup>56</sup>See *id.* § 207.10(e).

<sup>57</sup>21 C.F.R. § 807.65(a).

<sup>58</sup>See *infra* note 62 and accompanying text.

<sup>59</sup>21 C.F.R. § 807.65(a).

<sup>60</sup>*Id.* § 807.20(a)(5).

are specifically required to register and list their products.<sup>61</sup>

Generally, if there was any doubt as to whether a business entity was required to register its establishment and list its drug products that entity had nothing to lose by complying with the regulations.<sup>62</sup> Now an erroneous decision to register and list may call into question a specific business entity's protection as a "biomaterial supplier" under BAAA.<sup>63</sup>

#### D. Regulation of the Medical Device Industry by the FDA

The legitimacy of BAAA's protection of the biomaterials supplier depends upon a medical device's manufacturer (rather than the supplier of the raw material or component part) being held responsible for ensuring the safety and effectiveness of the medical device.<sup>64</sup> Under the Federal Food, Drug and Cosmetic Act (FD&C Act),<sup>65</sup> the manufacturer of a medical device must demonstrate the product is safe and effective.<sup>66</sup> Additionally, the manufacturer of the medical device is responsible for ensuring the product is properly designed and the appropriate warnings and instructions are provided.<sup>67</sup>

In 1976, Congress amended the FD&C Act to include a broad regulatory scheme to govern the FDA's authority over medical devices.<sup>68</sup> As a result, the current regulatory scheme classifies all medical devices into one

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<sup>61</sup>*Id.*

<sup>62</sup>Inactive component manufacturers are not exempt from inspection by FDA. See FDA Guide to Inspections of Bulk Pharmaceutical Chemicals (BPCs) (visited Jan. 23, 2000) <<http://www.fda.sol/cdv/guidance/index.htm>>. In general, the FDA has the authority to inspect any establishments that manufacture drugs. See 21 U.S.C.A. § 374(a)(1). The term "drug" is defined quite broadly and includes any "articles intended for use as a component" of a drug. 21 U.S.C.A. § 321(g)(1)(D). Registration and listing requirements may trigger routine FDA inspections. FDA is required to inspect registered establishments at least once every two years. See 21 U.S.C.A. § 360(h) (1999). FDA district offices, that are responsible for conducting FDA inspections, are provided with lists of the registered establishments and their listed drugs. See FDA Compliance Program No. 7356.014 Drug Listing, Part II, at 1 (June 1995). Indeed, FDA purports that the efficient operation of its "major regulatory functions" depends upon "complete and accurate drug listing data." *Id.* at Part I, at 1. Even if a routine FDA inspection would not be conducted at an establishment that does not register and list its products, a for-cause inspection could always occur. See FDA Guide to Inspections of BPCs. In any event, it would appear that inspections of inactive component manufacturers would only be conducted by the FDA for cause. *Id.*

<sup>63</sup>See 21 U.S.C.A. §§ 1601-1606.

<sup>64</sup>See *id.* § 1601(6).

<sup>65</sup>*Id.* § 301.

<sup>66</sup>*Id.* § 1601.

<sup>67</sup>21 U.S.C.A. § 1601.

<sup>68</sup>See Ted Wilson & Marlene Tandy, *FDA's Regulation of Medical Devices*, FDLI PRIMER ON FOOD AND DRUG LAW AND REGULATION 101 (1998).

of three categories: Class I, Class II, or Class III.<sup>69</sup> Class III devices are those that present the greatest potential risk.<sup>70</sup> Examples of Class III devices include pacemakers, heart valves, and other permanently implantable devices. Class II devices present only a moderate risk.<sup>71</sup> Class I devices present the lowest risk.<sup>72</sup>

Each class dictates which regulations control a particular medical device under the FD&C Act. "General controls" apply to all three classes of medical devices, and include: (1) regulations against adulteration or misbranding; (2) regulations requiring establishment regulation and product listing;<sup>73</sup> (3) premarket notification; and (4) compliance with good manufacturing practices.<sup>74</sup> "Special controls" include: (1) the requirement for performance standards; (2) postmarket surveillance; and (3) patient registries.<sup>75</sup> Special controls and general controls only apply to Class II and Class III medical devices.<sup>76</sup>

In addition, manufacturers of Class III medical devices must submit for approval a Premarket Approval Application (PMA) to FDA, prior to marketing the device.<sup>77</sup> In order to gain FDA approval, the PMA must demonstrate that the device is safe and effective for its intended use.<sup>78</sup> This must be shown through scientific evidence, which usually includes extensive clinical studies.<sup>79</sup>

There is an advantage in placing a new medical device within the Class II category, for there is no requirement to file a full PMA for a Class II device. Rather, the manufacturer submits a "510(k)" notification to FDA.<sup>80</sup> A 510(k) application must argue that the device in question is "substantially equivalent" to another medical device that already exists on the market.<sup>81</sup> A device will be deemed to be substantially equivalent if it has the same intended use and the same technology as an existing (or

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<sup>69</sup>*Id.* at 101-02.

<sup>70</sup>*Id.* at 102.

<sup>71</sup>*Id.*

<sup>72</sup>Wilson & Tandy, *supra* note 68, at 102.

<sup>73</sup>See *supra* notes 54-62 and accompanying text.

<sup>74</sup>Wilson & Tandy, *supra* note 68, at 102.

<sup>75</sup>*Id.*

<sup>76</sup>*Id.*

<sup>77</sup>*Id.*

<sup>78</sup>See Wilson & Tandy, *supra* note 68, at 106-09.

<sup>79</sup>See generally 21 C.F.R. § 314(A) (1999) (discussing general provisions for approval to market new drugs); 21 C.F.R. § 814(a) (1999) (discussing general provisions for approval to market new medical devices).

<sup>80</sup>See Wilson & Tandy, *supra* note 68, at 102-03. The 510(k) gets its name from that section of the FD&C Act that created it. *Id.* at 103.

<sup>81</sup>*Id.* at 103.

"predicate") device, or if the device has the same intended use and simply uses a different technology, while not raising any concerns as to safety or efficacy.<sup>82</sup> Another advantage of the 510(k) process is cost savings.<sup>83</sup> Most 510(k) applications do not require clinical study data, the compilation of which consumes vast amounts of the manufacturing entity's resources.<sup>84</sup>

The FDA considers the 510(k) submission to be a mere notification to the agency, by which the characteristics of the existing (predicate) device and the new device are compared.<sup>85</sup> Thus, the FDA does not "approve" these applications per se. Rather, the agency characterizes its role in this process as "clearing" the 510(k) device for the market.<sup>86</sup>

Whether the device is Class II or III, 510(k) or PMA, it is the *manufacturer* of the final medical device that shoulders the responsibility for compliance with FDA regulations related to the safety and effectiveness of medical devices.<sup>87</sup> The BAAA-protected biomaterials supplier is not involved. The remainder of this note focuses on what happens when things go awry, and the heretofore — uninvolved separate supplier becomes entangled in product liability litigation.

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<sup>82</sup>*Id.* (citing F.D.C.A. § 513(I)(1)(A), 21 U.S.C.A. § 360c(I)(1)(a) (1999)). As one might imagine the substantial equivalence doctrine provides regulatory lawyers with fertile ground for creative arguments.

<sup>83</sup>*See id.* at 104.

<sup>84</sup>*See* Wilson & Tandy, *supra* note 68, at 104. About 10% of 510(k) applications require the inclusion of data from studies conducted on humans. *Id.* When clinical data (i.e., data gathered from human studies) does need to be submitted in order to gain clearance to market a medical device — whether it is the subject of a PMA or a 510(k) — the human studies must be conducted, and the data compiled, in accordance with the applicable FDA regulations that govern good clinical practices. *See, e.g.*, 21 C.F.R. § 812 (1999) (setting forth the requirements for the conduct under an Investigational Device Exemption (IDE) application. *Id.* Generally, the regulations that govern clinical investigations of new *medical devices* track the regulations that govern clinical investigations of new *drugs*, that require that clinical studies involving new drugs be conducted under an Investigational New Drug Application (IND). *See* 21 C.F.R. §§ 312 (Investigational New Drug Application); 50 (Protection of Human Subjects); 56 (Institutional Review Boards (IRBs)) (1999).

<sup>85</sup>*See* Wilson & Tandy, *supra* note 68, at 104.

<sup>86</sup>*See id.*

<sup>87</sup>*See* 21 U.S.C.A. § 301 (1999).

### III. TEMPOROMANDIBULAR JOINT IMPLANT SAGA AND THE COURTS

#### A. *TMJ*

Temporomandibular joint disorders (commonly referred to simply as TMJ) occur when the jaw becomes misaligned.<sup>88</sup> Common symptoms of TMJ include the inability to open the mouth, clicking or popping noises when the mouth is opened or closed, and the occasional locking of the jaw in one position.<sup>89</sup> More severe symptoms of TMJ can include headaches, hearing loss, pain in the shoulder, neck, or jaw, migraine, nausea, blurred vision, and dizziness.<sup>90</sup> In the United States alone, approximately 60 million people purportedly suffer from TMJ, with the disorder being more prevalent in women.<sup>91</sup>

In the late 1970s and early 1980s, many TMJ sufferers were treated by having a medical device, known as the "Proplast TMJ Interpositional Implant," surgically implanted into their jaws.<sup>92</sup> Unfortunately, these implants had a tendency to fragment and cause disastrous tissue damage.<sup>93</sup>

#### B. *Vitek and the TMJ Implant*

During the 1970s a former DuPont scientist, Dr. Charles Homsy, invented a substance called Proplast and formed a company, Vitek, to develop biomedical uses for the substance.<sup>94</sup> Proplast is created by combining polytetrafluoro-ethylene (PTFE), also known as Teflon, with various plastic resins.<sup>95</sup> Vitek purchased Teflon from DuPont to manufacture Proplast using this complex process.<sup>96</sup> Furthermore, Vitek used

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<sup>88</sup>See TMJ Disorders, *Why Does My Jaw Hurt?* (visited Oct. 31, 1998) <<http://www.marketingpartners.com/outten/tmj.htm>>.

<sup>89</sup>*Id.*

<sup>90</sup>*Id.*

<sup>91</sup>*Id.*

<sup>92</sup>*Apperson v. E.I. du Pont de Nemours & Co.*, 41 F.3d 1103, 1105 (7th Cir. 1994).

<sup>93</sup>*Id.* (noting that plaintiffs alleged that the implants triggered immune reactions, damaged surrounding bone, and sometimes required patients to undergo subsequent surgery to reconstruct facial bones); *Sawtell v. E.I. du Pont de Nemours & Co.*, 22 F.3d 248, 249 (10th Cir. 1994) (noting that the plaintiff alleged that she suffered bone degeneration resulting in extreme pain and five subsequent operations).

<sup>94</sup>See *LaMontagne v. E.I. du Pont de Nemours & Co.*, 41 F.3d 846, 849 (2d Cir. 1994).

<sup>95</sup>*Id.*

<sup>96</sup>*Id.*

another DuPont product, fluorinated ethylene propylene film (FEP), to both coat and protect the implant from the pressure of the joint.<sup>97</sup>

While still a DuPont employee, and prior to his founding of Vitek, Dr. Homsy tried to apply the use of Teflon to the field of medicine.<sup>98</sup> He suggested to the DuPont Plastics Department that medical applications of Teflon should be pursued, however, his ideas were flatly rejected.<sup>99</sup> Prophetically, the DuPont Plastics Department "conclud[ed] that the likely profit was small and was in any event insufficient to justify the risk of major medical liability."<sup>100</sup> After this rejection, Homsy resigned from DuPont and joined Methodist Hospital in Houston, where he continued to study human implants.<sup>101</sup>

In 1976 Homsy invented Proplast, and eventually formed Vitek, in order to pursue the manufacturing and marketing of Proplast-based human implants.<sup>102</sup> Although DuPont continued to supply Homsy with Teflon, DuPont repeatedly advised against the use of Teflon (PTFE) in human medical implants.<sup>103</sup>

The PTFE and FEP in the TMJ implant comprised only "a few cents worth" of the total price of the device, which was at a minimum, a purchase price of \$50.<sup>104</sup> Nonetheless, when numerous product liability lawsuits led Vitek to bankruptcy, plaintiffs targeted DuPont to pay for their injuries.<sup>105</sup> DuPont had to defend itself in over 650 lawsuits.<sup>106</sup> After consolidation, eight cases represented the claims of over 300 plaintiffs, that were decided by the United States Federal Circuit Courts of Appeal.<sup>107</sup> DuPont prevailed

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<sup>97</sup>Jacobs v. E.I. du Pont de Nemours & Co., 67 F.3d 1219, 1224 (6th Cir. 1995).

<sup>98</sup>See *LaMontagne*, 41 F.3d at 849.

<sup>99</sup>See *id.*

<sup>100</sup>*Id.*

<sup>101</sup>See *id.* at 849-50.

<sup>102</sup>See *LaMontagne*, 41 F.3d at 851.

<sup>103</sup>See *id.* at 849-51. For example, in 1968, DuPont's Patent Division told Homsy that the material he purchased was manufactured for use as a textile and that DuPont was not "medically competent to judge their suitability for medical applications." *Id.* Furthermore, DuPont had not conducted long-term tests required to show that the substance was safe for medical uses. See *id.* at 851. In 1967, while Homsy was working at the Methodist Hospital in Houston, DuPont sent him a letter emphasizing that Teflon was not for medical use. This letter described a British study that indicated that the use of Teflon in medical implants might be dangerous. See *id.* The letter concluded by stating that DuPont would continue to supply Homsy with Teflon "only on the understanding that you assume full responsibility for any consequences which may result directly or indirectly from its use." *Id.* at 850. A hospital representative signed the letter (as requested) and returned it to DuPont. *Id.*

<sup>104</sup>Jacobs v. E.I. du Pont de Nemours & Co., 67 F.3d 1219, 1225 (6th Cir. 1995).

<sup>105</sup>See *LaMontagne*, 41 F.3d at 849.

<sup>106</sup>See Begley, *supra* note 6, at 23.

<sup>107</sup>See *infra* notes 110-49 and accompanying text.

each time, but incurred many expenses due to the complicated litigation.<sup>108</sup> The next section examines the plaintiffs' theories of liability and DuPont's mostly successful defenses in those cases.

### C. Case Analysis

#### 1. Threshold Issue: Preemption of State Tort Law

Initially, in an attempt to preempt state action, DuPont relied on the 1976 Medical Device Amendments (MDA)<sup>109</sup> to the FD&C Act.<sup>110</sup> DuPont used the following section of the MDA to support its claim:

[No] state or political subdivision of a State may establish or continue in effect with respect to any device intended for human use any requirement — (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.<sup>111</sup>

Courts have held that state tort TMJ implant claims are not preempted by the federal statute.<sup>112</sup> In particular, the courts stated the FD&C regulations were limited in scope to "regulated devices."<sup>113</sup> Under the regulations, "[s]tate or local requirements are preempted only when the FDA has established *specific counterpart regulations or there are other specific requirements applicable to a particular device* under the [A]ct."<sup>114</sup> With respect to the TMJ implant, this was *not* a regulated device.<sup>115</sup> The only

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<sup>108</sup>See *Rynders v. E.I. du Pont de Nemours & Co.*, 21 F.3d 835, 841-43 (8th Cir. 1994).

<sup>109</sup>See *supra* notes 64-87 and accompanying text.

<sup>110</sup>See *In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996); *Kealoha v. E.I. du Pont de Nemours & Co.*, 82 F.3d 894, 898 (9th Cir. 1996); *Jacobs v. E.I. du Pont de Nemours & Co.*, 67 F.3d 1219, 1233-36 (6th Cir. 1995); *Anguiano v. E.I. du Pont de Nemours & Co.*, 44 F.3d 806, 810-11 (9th Cir. 1995); *LaMontagne v. E.I. du Pont de Nemours & Co.*, 41 F.3d 846, 853-54 (2d Cir. 1994).

<sup>111</sup>*Jacobs*, 67 F.3d at 1234 (quoting *LaMontagne*, 41 F.3d at 853-54 (citing 21 U.S.C.A. § 360 (k)(a))).

<sup>112</sup>See *id.* at 1236 (reversing the grant of summary judgment by the District Court in the Sixth Circuit). See also *id.* (quoting the holding of the Second Circuit that DuPont's federal preemption claim failed in *LaMontagne*).

<sup>113</sup>*Id.* at 1234.

<sup>114</sup>*Id.* (citing 21 C.F.R. § 808.1(d) (1999)) (emphasis added in *LaMontagne*).

<sup>115</sup>DuPont has failed to demonstrate that the FDA issued regulations specific to the Proplast TMJ Implant — *the specific device which allegedly harmed the plaintiffs.* *Jacobs*, 67 F.3d at 1235 (quoting *LaMontagne v. E.I. du Pont de Nemours & Co.*, 834 F. Supp. 576, 583 (D. Conn. 1993))

FDA action that was specific to the TMJ implant was that it was designated as a Class II medical device.<sup>116</sup> Consequently, DuPont was unable to invoke the MDA to preempt state action.

In addition, DuPont invoked an FDA exemption regulation as a basis to preempt state tort action. Specifically, DuPont relied upon the regulation that exempts from registration with the FDA suppliers of "raw materials . . . to be used in the manufacture or assembly of a device."<sup>117</sup> Here, both the Second and the Sixth Circuits held that DuPont's status as a raw material supplier, under the federal regulation, was not a basis to preempt state action.<sup>118</sup>

After these preliminary defenses were rejected, the court considered the plaintiffs' theories of liability. Ultimately, it ruled in favor of DuPont on the merits.

## 2. Principal Theories of Liability

The plaintiffs in the various cases primarily stated their claims based on theories of strict liability,<sup>119</sup> negligence,<sup>120</sup> and negligence in failing to warn.<sup>121</sup>

Under the facts of these cases, the elements of negligence and strict liability basically converge.<sup>122</sup> Manufacturers of "unreasonably dangerous" products are subject to strict liability for injuries caused by those products.<sup>123</sup> A product may be considered "unreasonably dangerous" if it contains a

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(emphasis added in *Jacobs*).

<sup>116</sup>*Id.*

<sup>117</sup>*Id.* (quoting *LaMontagne*, 834 F. Supp. at 585 (citing 21 C.F.R. § 807.65 (1992))).

<sup>118</sup>*Id.* at 1236 (citing the court's analysis in *LaMontagne*, 834 F. Supp. at 585). "[E]xemption in FDA regulations stating that a raw material manufacturer need not comply with that agency's requirements cannot also be read to say that the federal law eliminates the applicability of any common law duties . . ." *Id.*

<sup>119</sup>*See, e.g.,* *Apperson v. E.I. du Pont de Nemours & Co.*, 41 F.3d 1103, 1107-08 (7th Cir. 1994) (rejecting plaintiffs' strict liability argument because Teflon is not inherently dangerous, and because DuPont's warnings to Vitek were adequate).

<sup>120</sup>*See, e.g.,* *Rynders v. E.I. du Pont de Nemours & Co.*, 21 F.3d 835, 842-43 (8th Cir. 1994) (approving jury instructions that stated DuPont was liable if it, *inter alia*, "failed to exercise reasonable care to inform Vitek of the danger associated with use of the product") (emphasis added).

<sup>121</sup>*See, e.g., In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1059 (8th Cir. 1996) (rejecting plaintiffs' argument that DuPont had a duty to warn the consumer of the end product about possible dangers caused by incorporation of the raw material).

<sup>122</sup>*See Apperson*, 41 F.3d at 1108. *See also Kealoha v. E.I. du Pont de Nemours & Co.*, 82 F.3d 894, 899 (9th Cir. 1996) (observing that there is little difference between strict liability and negligence where the duty to warn is the issue).

<sup>123</sup>*See In re TMJ*, 97 F.3d at 1055 (citing *Rynders*, 21 F.3d at 842 (citing RESTATEMENT (SECOND) OF TORTS § 402A (1965))).

manufacturing defect, a design defect, or if the manufacturer *fails to give adequate warnings* of the dangers of the products use.<sup>124</sup> Thus, plaintiffs argued, even though the raw material (PTFE or Teflon) was safe for many uses, it should be deemed defectively designed because it was dangerous in its "reasonably foreseeable use" as a human implant.<sup>125</sup> Yet the court stuck to the proposition that Teflon is safe for many uses, and therefore, DuPont had no duty to independently determine if it would be safe for a particular use in the final product of another "unrelated" manufacturer.<sup>126</sup>

### 3. Additional Theories of Liability

Another claim by the TMJ plaintiffs was breach of the implied warranties of merchantability and of fitness for a particular purpose.<sup>127</sup> The lower court eliminated the breach of implied warranty claims by entering judgment as a matter of law.<sup>128</sup> The Eighth Circuit affirmed, finding that DuPont did not make any warranties and Vitek did not rely on DuPont's judgment to assess medical value of Teflon in the TMJ implant.<sup>129</sup>

In holding that there was no implied warranty of fitness for a particular purpose, the record disclosed that DuPont advised Vitek of its negative research with respect to medical use of Teflon.<sup>130</sup> DuPont also "expressly disavowed any firsthand knowledge of Teflon's suitability for medical uses."<sup>131</sup> Furthermore, Vitek signed a disclaimer in which they agreed to assume full responsibility for the Teflon that they purchased from DuPont.<sup>132</sup> In sum, the claim breach of the warranty of fitness for a particular purpose was denied because DuPont neither made, nor implied, such warranty, and because Vitek "did not rely on DuPont's skill and knowledge."<sup>133</sup>

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<sup>124</sup>*Id.*

<sup>125</sup>*Id.*

<sup>126</sup>*See Kealoha*, 82 F.3d at 899. *See also In re TMJ*, 97 F.3d at 1058 (stating that "suppliers of inherently safe raw materials have no duty to ward end users of a finished product about dangers posed by incorporation of the raw materials into that product").

<sup>127</sup>*See Rynders*, 21 F.3d at 838.

<sup>128</sup>*Id.* at 839.

<sup>129</sup>*Id.* at 839-41.

<sup>130</sup>*See id.* at 839.

<sup>131</sup>*Rynders*, 21 F.3d at 839.

<sup>132</sup>"[DuPont] will provide you with material that you are ordering and such 'Teflon' as you order in the future only on the understanding that you assume full responsibility for any consequences which may result directly or indirectly from its use." *Id.* at 840.

<sup>133</sup>*Id.*

To hold that there was no implied warranty of merchantability, for general public safety, the court increased its scrutiny.<sup>134</sup> Under applicable state law, the implied warranty of merchantability "requires that goods be 'fit for the ordinary purposes for which such goods are used.'"<sup>135</sup> In the record, DuPont supported many safe industrial uses for its Teflon.<sup>136</sup> DuPont also advised Vitek of Teflon's ordinary use for industrial purposes.<sup>137</sup> Because the plaintiffs proffered no evidence that DuPont provided an inferior grade of Teflon, and because the use of Teflon in human implants was deemed as extraordinary, the court held that DuPont did not breach the implied warranty of merchantability.<sup>138</sup>

Another plaintiff theory focused on Vitek's use of DuPont's Teflon trademark.<sup>139</sup> The *Kealoha* plaintiffs argued that DuPont should be held liable because it allowed Vitek to use its trademark to market implants.<sup>140</sup> According to the plaintiff, use of the trademark "[c]reated a likelihood of confusion over the identity of the manufacturer of the implant."<sup>141</sup> The Ninth Circuit concluded that the lower court was correct in finding that there was no improper use of the trademark and that even if there had been improper use the same result would follow.<sup>142</sup> Failure to adequately "police" the use of a trademark does not create de facto tort liability for the trademark owner.<sup>143</sup>

Courts may impose liability if a trademark is voluntarily licensed, or if the trademark holder "had significant involvement in the design, manufacture, or distribution" of the seller's product.<sup>144</sup> In *Kealoha*, the court indicated that there was no evidence that DuPont was involved in the development of the implant.<sup>145</sup>

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<sup>134</sup>Although implied warranties of fitness for a particular purpose may be excluded by general language . . . "[t]he warranty of merchantability . . . is so commonly taken for granted that its exclusion from the contract is a matter threatening surprise and therefore requiring special precaution." *Id.* at 841 (quoting U.C.C. §§ 2-316 cmt. 4, 2-314, cmt. 11 (1990)).

<sup>135</sup>*Rynders*, 21 F.3d at 841 (quoting S.D. CODIFIED LAWS ANN. § 57A-2-314(2)(c) (Michie 1990)).

<sup>136</sup>*Id.*

<sup>137</sup>*Id.*

<sup>138</sup>"To hold otherwise would confuse the distinction between the warranties of merchantability and of fitness for a particular purpose." *Id.*

<sup>139</sup>*Kealoha*, 82 F.3d at 902.

<sup>140</sup>*Id.*

<sup>141</sup>*Id.*

<sup>142</sup>*Id.* at 903.

<sup>143</sup>*Kealoha*, 82 F.3d at 902.

<sup>144</sup>*See id.* at 903.

<sup>145</sup>*See id.*

#### 4. Common Law Bulk Supplier/Sophisticated User Defense Applied

DuPont escaped liability for the unfortunate consequences of Teflon use in the TMJ implant through the bulk supplier doctrine and the sophisticated user defense.<sup>146</sup> The Sixth and Eighth Circuit Courts of Appeal essentially found that DuPont, as the manufacturer of a component part or raw material or as a "bulk supplier," had no duty to warn the ultimate consumer of the dangers that Teflon posed in the implant.<sup>147</sup> The court also found that DuPont had satisfied all duties to warn that *did* exist by passing along negative information about the medical applications of Teflon to Vitek, a "sophisticated user."<sup>148</sup>

Although ultimately found not liable in each case, DuPont expended a great deal of time and expense to reach these favorable results.<sup>149</sup> Given this scenario, the purpose of BAAA seems reasonable and its enactment timely.<sup>150</sup> The next part of this note, however, explores an opposite view: the concerns of consumer groups that contend that biomaterial suppliers are being unfairly protected.

#### IV. EVALUATION OF THE LEGITIMACY OF BAAA'S PURPOSE

Given the ultimate success of raw material suppliers, like DuPont, BAAA may be viewed as a legitimate means to forestall involving bulk suppliers of medical device components in product liability suits. Under the new federal law it seems that the same result would have been reached minus the expensive discovery process. If the expense of discovery can be obviated by BAAA, then perhaps there may be no shortage of raw materials for medical devices. Furthermore, if BAAA can help innocent suppliers

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<sup>146</sup>See *In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (holding that suppliers of safe raw materials have no duty to warn the ultimate consumer); *Jacobs*, 67 F.3d at 1236 (using slightly different terminology: "component parts" doctrine).

<sup>147</sup>See, e.g., *In re TMJ*, 97 F.3d at 1058 (holding that, as a matter of law, suppliers of safe raw materials have no duty to warn the ultimate consumers of potential dangers under the "raw materials/component part supplier doctrine"); *Jacobs v. E.I. du Pont de Nemours & Co.*, 67 F.3d 1219, 1236 (6th Cir. 1995) (noting that under Ohio law a manufacturer of a "component part" does not have a duty to warn "end users of the finished product of the potentially dangerous nature of its parts in that product").

<sup>148</sup>See, e.g., *Jacobs*, 67 F.3d at 1238 (holding that even if DuPont had a duty to warn it was met under the "bulk supplier/sophisticated intermediary rule" when DuPont passed negative information about medical applications of Teflon along to Homsy and Vitek).

<sup>149</sup>See Begley, *supra* note 6, at 23.

<sup>150</sup>See generally BAAA, 21 U.S.C.A. §§ 1601-1606 (1999) (clarifying permissible basis of liability for suppliers and providing procedures to quash unnecessary litigation).

avoid the discovery phase of litigation, consumers may enjoy the benefit of lower prices for these usually expensive medical devices.

Nevertheless, consumer groups, specifically Public Citizen, object to BAAA. Indeed, Public Citizen posits a more sinister account for it claims that the alleged shortage of medical device component parts does not even exist.<sup>151</sup>

### A. *Attack of BAAA by Consumer Protection Group: Public Citizen*

#### 1. Does BAAA Indirectly Protect the Manufacturer As Well?

Public Citizen is a consumer protection group who vehemently opposed the enactment of BAAA.<sup>152</sup> Perhaps its strongest argument is that the new law may protect an otherwise liable medical device manufacturer.<sup>153</sup> Specifically, Public Citizen notes that without the benefits of discovery as to the supplier BAAA may help shield the manufacturer from negative information that could implicate the manufacturer.<sup>154</sup>

Public Citizen argues that if early in a case both the medical device manufacturer and the separate supplier are targeted (i.e., are named as defendants), each of them has an incentive to provide information that will exculpate itself and inculpate the other.<sup>155</sup> "By giving suppliers immunity at the outset, this type of critical information to the claimant's case against the manufacturer will be lost."<sup>156</sup> Given this fundamental unfairness courts may be reluctant to follow the procedures set forth in BAAA.

#### 2. Is There Really a Shortage of Medical Device Raw Materials?

Public Citizen also makes a more sinister accusation. It claims that there is no evidence of a shortage of biomaterials for medical devices; thus, it asserts that the very purpose and justification for the new law does not exist.<sup>157</sup> On the contrary, according to Public Citizen, there are still many

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<sup>151</sup>See *infra* notes 156-59 and accompanying text.

<sup>152</sup>See Public Citizen, *supra* note 11.

<sup>153</sup>See generally *id.* (asserting that critical information against a device manufacturer would be lost).

<sup>154</sup>See *id.* at 2.

<sup>155</sup>See *id.*

<sup>156</sup>Public Citizen, *supra* note 11, at 2.

<sup>157</sup>See Public Citizen, *The "Biomaterials Shortage": Where's the Evidence?* (visited Oct. 6, 1998) <[http://www.citizen.org/congress/civjus/biomaterials/biomaterials\\_shortage.html](http://www.citizen.org/congress/civjus/biomaterials/biomaterials_shortage.html)>.

manufacturers listed for every human implant that the medical device industry has recently labeled "threatened."<sup>158</sup>

On this particular criticism, Public Citizen's reasoning may be myopic. After all, the medical device industry (through the Health Industry Manufacturers Association (HIMA)) asserts that the current shortage of raw materials will lead to a *future* shortage of the medical devices themselves.<sup>159</sup> Accordingly, HIMA argues that Congress has acted promptly and appropriately to prevent a future shortage.<sup>160</sup> Furthermore, Public Citizen has based its criticism on evidence found by reviewing all of the registered medical device manufacturers.<sup>161</sup> Public Citizen's argument is flawed because the purported shortage is predicted for the future; thus, one would not expect to see its effects in the present.

Finally, Public Citizen has posited that another possible line of attack on BAAA may come in the form of a constitutional challenge. In particular, Public Citizen asserts that BAAA violates the concepts of Federalism.<sup>162</sup> This may be Public Citizen's weaker argument. The Supreme Court, it is true, has ended a long moratorium invalidating federal legislation on grounds that it exceeded Congress' broad power under the Commerce Clause.<sup>163</sup> The Supreme Court has struck down the Brady Act's temporary imposition on the States to perform background checks on potential gun purchasers as unconstitutional because it violated our system of dual sovereignty.<sup>164</sup> But, while this movement may lend some hope to Public Citizen's argument, the Court has also identified implicit and explicit constitutional provisions that permit federal imposition on state courts.<sup>165</sup>

Authority to permit Congress to impose federal law on state courts is *implicit*, according to Justice Scalia, in the "Madisonian Compromise," which set up one Supreme Court and made the creation of lower courts discretionary. Moreover, the authority is *explicit* in the Supremacy Clause, which indicates that the federal law is the law of the land and that state

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<sup>158</sup>See *id.* (referring to 1997 Medical Device Register, published by Medical Economics).

<sup>159</sup>See *supra* note 2.

<sup>160</sup>See *supra* note 2.

<sup>161</sup>See *supra* notes 156-57.

<sup>162</sup>See Public Citizen, *supra* note 11.

<sup>163</sup>See David O. Stewart, *Back to the Commerce Clause: The Supreme Court Has Yet to Reveal the True Significance of Lopez*, 81-Jul A.B.A. 46, 46 (1995) (citing *United States v. Lopez*, 514 U.S. 549 (1995) (ruling that Congress had exceeded its powers under the Commerce Clause in enacting the Gun-Free School Zones Act of 1990)). See also, e.g., *United States v. Morrison*, 120 S. Ct. 1740 (U.S. 2000) (ruling the Violence Against Women Act was outside the scope of the Commerce Clause).

<sup>164</sup>See *Printz v. United States*, 521 U.S. 898, 898-99 (1997).

<sup>165</sup>*Id.* at 907.

judges are so bound.<sup>166</sup> Thus, an attack on BAAA on Constitutional grounds seems weak at best.

### B. Procedural Pitfalls of BAAA — Will the New Law Work?

There are at least two procedural problems with the provisions of BAAA. Both of the problems relate to the provision that the Secretary of Health and Human Services may issue a declaration concerning the status of the defendant (i.e., is the defendant a protected "supplier," or an unprotected "manufacturer").<sup>167</sup>

First, according to the language of the new law the biomaterial supplier is liable, just like a manufacturer, if it "registered" or "should have registered" under the FDA regulations.<sup>168</sup> This provision of the new law does not appear to consider that a biomaterials supplier may have registered and listed even if it was not actually required to do so. As previously discussed, the regulations are ripe with ambiguity, and historically, if there was any doubt as to whether it was necessary to do so, a supplier had nothing to lose if it registered its establishments and listed its products.<sup>169</sup>

The second procedural problem is also related to the issuance of a declaration by the Secretary of Health and Human Services, namely that which declares the status of the defendant (i.e., supplier or manufacturer).<sup>170</sup> There are examples where the Department of Health and Human Services (specifically the FDA) was unable to comply with response-to-petition statutory deadlines.<sup>171</sup> Furthermore, when a government entity fails to meet a statutory deadline the recourse is often *more* litigation, the very thing that BAAA is trying to limit or at least streamline.<sup>172</sup>

Thus, BAAA has at least two procedural shortcomings that need to be addressed. First, the courts will have to make it clear that a biomaterials

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<sup>166</sup>See *id.* (citing U.S. CONST. art. III § 1, art. IV, cl. 2).

<sup>167</sup>See *supra* note 37 and accompanying text.

<sup>168</sup>21 U.S.C.A. § 1604(b)(2)(A)(I) (1999). See also *supra* notes 54-62 and accompanying text.

<sup>169</sup>See *supra* notes 54-63 and accompanying text.

<sup>170</sup>See *supra* notes 37-38 and accompanying text.

<sup>171</sup>See, e.g., *In re Barr Lab., Inc.*, 930 F.2d 72, 73 (D.C. Cir. 1991) (denying drug manufacturer's petition for a writ of mandamus to compel FDA to act promptly and approve or disapprove abbreviated new drug applications, where FDA's "sluggish pace" had violated a statutory deadline).

<sup>172</sup>For example, when the FDA failed to respond to a citizen petition submitted by the Washington Legal Foundation regarding its contention that certain FDA guidelines and policies violated the First Amendment, the only recourse for the Washington Legal Foundation was to engage in litigation with FDA. See generally *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.C. Cir. 1998) (finding that manufacturer's sponsorship of medical education seminars classified as commercial speech).

supplier who registered with FDA, but did not have to do so under the proper interpretation of the purpose of the regulations, is still protected. Second, the courts will need to step in if the Secretary of Health and Human Services (or her designee) fails to meet the statutory 120-day deadline.

## V. CONCLUSION

In summary, BAAA appears to fulfill a legitimate role. Its objective is to deter litigation against businesses that supply the medical device industry. Under the aegis of the Commerce Clause, Congress intends to shelter from liability innocent manufacturers of essential raw materials or component parts needed to manufacture or develop life-saving medical devices. The Act is likely to survive a Constitutional challenge. Purportedly, the protections of the Act will avoid a shortage of medical devices or, at the very least, a sharp increase in the cost to consumers. It should be recognized, however, that the new law has left open potential procedural problems.

Indeed, the success or failure of the Act, and its effect on the medical device market, remains to be seen. There are signs that the existence of BAAA is beginning to serve its purpose. If the medical device market has potential prospective value, some companies may enter or remain in the market because BAAA serves as a product liability safety net.<sup>173</sup> For example, Vitrex USA, Inc. will enter the medical implant market "because the legislation gives it additional liability protection."<sup>174</sup> Whereas, Thermedics, Inc. stayed in the medical device market all along.<sup>175</sup>

Some major medical device raw material suppliers that left the market due to concerns over product liability, however, are unimpressed with the protection of the BAAA on paper and await a "test case" in the courts.<sup>176</sup> DuPont and Dow Chemical Co., for example, have not changed position as a result of BAAA. They "remain on the sidelines" and prefer to see the new law tested in court before they consider reentry into the market.<sup>177</sup> Dow maintains that the law does not go far enough to provide protection and because of uncertainty over how the new law will work in practice feels the risk of liability is still too great.<sup>178</sup>

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<sup>173</sup>Toloken, *supra* note 9.

<sup>174</sup>*Id.*

<sup>175</sup>*Id.*

<sup>176</sup>*See id.*

<sup>177</sup>Toloken, *supra* note 9.

<sup>178</sup>*Id.*

**In the near future courts will undoubtedly face formidable challenges as they confront these uncertainties under BAAA.**

*Anne Marie Murphy*

