## NOTE

## A CRITICAL ANALYSIS OF THE BIOMATERIALS ACCESS ASSURANCE ACT OF 1998 AS FEDERAL TORT REFORM POLICY

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#### I. INTRODUCTION

For many years, products liability law has recognized that component part and raw material suppliers are in a unique position and are thus entitled to special protections from liability for injuries caused by products in which their materials were integrated.<sup>1</sup> The common law has developed two doctrines that create a high level of protection for component parts and raw materials suppliers: the component part and the sophisticated purchaser doctrines.<sup>2</sup> Despite the difficulty in obtaining supplier liability, there are essentially three contexts in which plaintiffs will bring suit against suppliers for product defects: (1) where a small manufacturer purchases materials from a larger supplier and the manufacturer becomes insolvent; (2) where the potential liability is excessively large, to such an extent that alternative defendants will be sought to meet the demand; and (3) when there is a comparative negligence situation (i.e., where various defendants claim that the other parties were negligent).<sup>3</sup> Suppliers sued under these circumstances will face expensive litigation costs to establish that they are not liable, even though the law is clearly in their favor.

While supplier liability in general has been treated as a special situation in products liability law, suppliers of materials for implantable medical devices ("biomaterials suppliers") have now been singled out to benefit further from a novel federal enactment, the Biomaterials Access Assurance Act of 1998 (the "Biomaterials Act" or "Act").<sup>4</sup> The Biomaterials Act was a federal response to the excessive litigation expenses faced by biomaterial suppliers and the chilling effect that such expenses created for the medical device industry.<sup>5</sup> The

<sup>&</sup>lt;sup>1</sup> See M. Stuart Madden, Component Parts and Raw Materials Sellers: From the Titanic to the New Restatement, 26 N. KY. L. REV. 535, 539-40 (1999). Professor Madden lists some of the considerations unique to supplier liability, including: (1) the fact that such materials are often changed before they reach the consumer; (2) modifications by other parties may have made the parts dangerous; (3) the parts supplier cannot foresee and remedy the potential hazards of all of possible uses of its materials; and (4) the fabricator of the product is in a better position to avoid product risks. See id.

<sup>&</sup>lt;sup>2</sup> See Brett W. Roubal, Casenote, Protecting Suppliers of Safe Component Parts and Raw Materials Through the Component Part Doctrine and the Sophisticated Purchaser Doctrine: In re Temporomandubular Joint (TMJ) Implants Products Liability Litigation, 31 CREIGHTON L. REV. 617, 617 (1998).

<sup>&</sup>lt;sup>3</sup> See Jerry R. Palmer, The Restatement and the Liability of Suppliers of Raw Materials or Component Parts, 8 KAN. J.L. & PUB. POL'Y 106, 107-08 (1998).

<sup>&</sup>lt;sup>4</sup> Biomaterials Access Assurance Act of 1998, 21 U.S.C. §§ 1601-1606 (Supp. IV 1999).

<sup>&</sup>lt;sup>5</sup> See id. § 1601(8), (10), (15).

purpose of the Act was "to safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices" by clarifying the grounds for supplier liability.<sup>6</sup> The Act also "provide[s] expeditious procedures to dispose of unwarranted suits against the suppliers in such a manner as to minimize litigation costs."<sup>7</sup> The Biomaterials Act is a unique federal attempt to reform products liability law, an area of authority traditionally reserved to the States.

This note will argue that the Biomaterials Act is an appropriate and effective method of tort reform policy. This note, however, cautions that the Act should not serve as precedent for more expansive federal tort reform enactments because of the unique nature of the biomaterials supply problems. Part II of this note will provide necessary background for the analysis. It will discuss the traditional deference to state governance of tort law, the so-called "biomaterials crisis," and the rationale of the Biomaterials Act. Further, it will discuss biomaterials supplier liability case law to illustrate that existing doctrines do not adequately protect biomaterials suppliers. Finally, it will explain the details of the Act.

Part III will first critically analyze the history of supplier liability under the common law and the new Restatement (Third) of Torts: Products Liability, which codifies the common law supplier liability doctrines.<sup>8</sup> This part of the discussion concludes that the Act's liability scheme does not deviate from or change the liability scheme created by state courts over time. It will further argue that the supplier liability doctrines that are necessary under the Biomaterials Act meet the traditional tort law goals of corrective justice and economic efficiency. This part of the analysis concludes that the Biomaterials Act's procedural provisions are a necessary addition to the traditional tort law protections for biomaterials suppliers. The note will then analyze the more global issue of the social cost of biomaterials supplier litigation. It will pose the question whether a federal enactment was the best means to reduce the social cost and suggest that private measures, i.e., pre-dispute arbitration agreements, may have better controlled the social costs. Part III concludes with an examination of the constitutionality of the Biomaterials Act, arguing that Congress had the affirmative power under the Commerce Clause to enact this law and that the anti-commandeering doctrine is not violated by the Act's procedural provisions.

#### II. BACKGROUND

## A. Traditional Deference to State Governance of Tort Law.

The Biomaterials Act may be problematic as federal tort reform because tort law traditionally has been believed to be within the states' domain.<sup>9</sup> Respect

<sup>&</sup>lt;sup>6</sup> Id. § 1601(15)(A).

<sup>&</sup>lt;sup>7</sup> Id. § 1601(15)(B).

<sup>&</sup>lt;sup>8</sup> See Restatement (Third) of Torts: Prod. Liab. § 5 (1998).

<sup>&</sup>lt;sup>9</sup> See H.R. REP. No. 105-549, pt. 1, at 23 (1998) (Dissenting Views on H.R. 872). States are fully capable of enacting product liability reforms when they feel it necessary to balance the competing needs of business and consumers within their borders. Indeed over the last twenty years all states have enacted some form or another of product liability or tort law protection to benefit defendants.

for state tort law generally is premised upon notions of federalism and the Tenth Amendment.<sup>10</sup> There is a general presumption that the states have the power to create and enforce tort law policies and, consequently, the federal government should not overstep the states' authority.<sup>11</sup> This note will argue that federalism and Tenth Amendment considerations do not outweigh the Biomaterials Act. Additionally, it will argue that the reform necessary to protect patients from a lack of necessary medical devices is developed most effectively by the federal government.

#### B. The "Biomaterials Crisis" and the Rationale of the Biomaterials Act.

In order to understand why the Biomaterials Act is appropriate as federal tort reform policy, one must understand the crisis faced by the biomaterials supply industry. The key result of the biomaterials crisis is increased costs for medically necessary implants. The Biomaterials Act was enacted to further protect suppliers of component parts and raw materials used in implantable medical devices.<sup>12</sup> According to one report cited in the Act's legislative history, "75 percent of the suppliers of biomaterials required for implantable medical devices have banned sales to U.S. device manufacturers .... One hundred percent of these suppliers have cited liability exposure as a key factor in discontinuing sales of their products to medical device manufacturers."13 Another report stated that DuPont spent eight million dollars annually for five vears to defend products liability actions for its role in supplying Teflon for jaw implants.<sup>14</sup> Biomaterials suppliers are leaving the market because the profits they make are insufficient to justify risking the excessive litigation costs that may result if patients are injured by devices in which their materials are Based on these considerations, Congress concluded that integrated.15

<sup>12</sup> See supra notes 5 and 6 and accompanying text.

<sup>13</sup> H.R. REP. NO. 105-549, pt. 2, at 11 (1998) (citing Aronoff Associates, Market Study: Biomaterials for Permanent Medical Implants (March 1994)).

<sup>14</sup> See Medical Devices: Liability Fears Keep Suppliers From Selling to American Manufacturing Firms, Study Says, PROD. LIAB. DAILY (BNA) (Apr. 21, 1997) [hereinafter Medical Devices], available in WESTLAW, BNA-PLD File; see also Kealoha v. E.I. DuPont de Nemours & Co., 844 F. Supp. 590, 592 n.5 (1994) ("Each implant contained only a few cents worth of DuPont [Teflon]; the final implant was sold for in excess of \$50.").

<sup>15</sup> See Medical Devices, supra note 14; see also 144 CONG. REC. H6741 (1998) (statement of Rep. Moran) ("Dupont decided in 1994 to halt the supply of three materials used in medical implants because the sale of small amounts of these marginally profitable materials exposed Dupont to very expensive product liability lawsuits, even if Dupont

Id.

<sup>&</sup>lt;sup>10</sup> See Cynthia C. Lebow, Is H.R. 956 Really "Common Sense"?: A Symposium on Federal Tort Reform Legislation: Federalism and Federal Product Liability Reform: A Warning Not Heeded, 64 TENN. L. REV. 665, 688-90 (1997) (discussing the "anti-commandeering theory" espoused in New York v. U.S., 505 United States 144 (1992), the analysis of which was premised on the doctrine of federalism and on the powers retained by the States via the Tenth Amendment).

<sup>&</sup>lt;sup>11</sup> See id. at 688 ("There can be little doubt that the potential for the award of state common law damages . . . lies at the core of the 'historic primacy of state regulation of matters of health and safety." (quoting Medtronic v. Lohr, 518 U.S. 470, 485 (1996)).

biomaterials suppliers must be protected from excessive litigation expenses in order to guarantee the future supply of lifesaving and life-enhancing medical devices. This was done by creating a liability system to clarify biomaterial supplier liability and providing expedited dismissal procedures for unwarranted suits against biomaterials suppliers.<sup>16</sup>

It is important to note that the Biomaterials Act received widespread support from patients, the consumers affected by this legislation.<sup>17</sup> The parties adversely affected by this enactment and another recent federal tort refom enactment, the General Aviation Revitalization Act of 1994,18 have generally accepted them.<sup>19</sup> They were so widely accepted because "[b]oth pieces of legislation involve 'easily identifiable problems-light aircraft were not being manufactured, and medical devices were not being made-and a readily identifiable solution. In both situations, people who would be affected by the law supported limits on liability....<sup>20</sup> Since the affected constituencies support the burden placed upon them by the federal government, one may argue that the Biomaterials Act is an appropriate use of federal power. This is especially true because the federal government is best suited to create a uniform solution for this problem.<sup>21</sup> Furthermore, protecting the continued supply of biomaterials for medical implants is essential because the lives and well-being of millions of Americans are at stake due to the biomaterials shortage.22

## C. Case Law Implicating Biomaterial Supplier Liability Indicates that the Existing Doctrines Inadequately Protect Biomaterial Suppliers

A brief examination of biomaterial supplier liability case law is useful. It illustrates that existing doctrines are inadequate to protect biomaterials

won.").

<sup>&</sup>lt;sup>16</sup> See Biomaterials Access Assurance Act of 1998, 21 U.S.C. §§ 1601(15), 1604-1607 (Supp. IV 1999).

<sup>&</sup>lt;sup>17</sup> See, e.g., 144 CONG. REC. H6740 (1998) (statement of Rep. Bilbray) ("Titus, the young man who depends on shunts to be able to stay alive . . . was basically concerned that because of liability and problems of liability, the biomaterials that make those shunts to keep him alive could be restricted from [from availability] . . . .").

<sup>&</sup>lt;sup>18</sup> See 49 U.S.C. § 40101 (1994 & Supp. IV 1999).

<sup>&</sup>lt;sup>19</sup> See Lori Tripoli, *Product Liability Reform, Inch by Inch... ATLA Acquiesces to the New Biomaterials Law, INSIDE LITIG., Sept. 1998, at 5, 6 (quoting Mark Behrens).* 

 $<sup>^{20}</sup>$  *Id.* (quoting Behrens) This article also quotes Behrens as concluding that "[p]ilots supported the aviation bill, and patients supported the biomaterials legislation." *Id.* 

<sup>&</sup>lt;sup>21</sup> Note that the uniformity offered by a federal tort reform enactment in this area is essential. By creating a federal standard limiting the liability and amenability to suit of biomaterials suppliers, such suppliers can be certain of the potential for avoiding high cost litigation in all forums in the United States. By leaving the states to their own tort reform devices, though some states may enact reforms to protect biomaterials suppliers, suppliers could not be certain about their potential liability and amenability to suit and would remain unwilling to enter or reenter the biomaterials supply industry.

<sup>&</sup>lt;sup>22</sup> See 144 CONG. REC. H6740-41 (1998) (statement of Rep Moran) ("Medical implants such as heart valves, joint implants, and brain shunts save or improve the lives of more than 7.5 million people every year. The worldwide market for medical devices exceeds \$100 billion, with about half of that supplied by American firms.").

suppliers from prohibitive litigation expenses. First, the litigation spawned by defective jaw implants is discussed to illustrate that meritless litigation against biomaterials suppliers not participating in the design of the device results in economic waste and creates disincentives for suppliers to continue supplying biomaterials.<sup>23</sup> Second, a survey of breast implant litigation illustrates that the *Third Restatement*'s "substantial participation"<sup>24</sup> provision and the Biomaterials Act's "common ownership"<sup>25</sup> provision are both effective and sufficient means of obtaining liability when the supplier has been negligent.

Throughout the early 1990's, DuPont faced widespread litigation for its role in supplying Teflon for defective temporomandibular joint (TMJ) implants.<sup>26</sup> Dr. Homsy, the founder of Vitek and a former DuPont scientist, designed, manufactured, and sold the "Proplast" jaw implants that resulted in the DuPont litigation.<sup>27</sup> Proplast implants included two different Teflon products manufactured by DuPont.<sup>28</sup> Teflon is a multi-use raw material that is not inherently unsafe.<sup>29</sup> The Teflon material in Vitek's implants comprised of only "a few cents" worth" of the entire material used in each implant.<sup>30</sup> DuPont warned Vitek that the supplier was not responsible for testing Teflon products to determine their safety for Vitek's proposed medical applications.<sup>31</sup> In

<sup>28</sup> The DuPont products sold under the Teflon trademark were polytetrafluoroethylene (PTFE) fiber and powder and fluorinated ethylene propylene (FEP) film. *See id.* at 1052.

<sup>29</sup> See In re TMJ Implants, 872 F. Supp. at 1022 ("For example, PTFE is used in bearings for jet aircraft, submarine piston rings, and most commonly as a non-stick coating for cooking pans. FEP is used in pipe lining, solar collectors, and other items.").

<sup>30</sup> *In re TMJ Implants*, 97 F.3d at 1053 ("Each implant, while selling for at least fifty dollars, contained only a few cents' worth of PTFE resin and FEP film.").

<sup>31</sup> See *id.* at 1053-54 (noting a signed agreement between Homsy and DuPont providing that "[p]ersons proposing to evaluate or to use these products for medical or surgical purposes must rely on their own medical and legal judgment without any representation on

<sup>&</sup>lt;sup>23</sup> The jaw implant litigation best illustrates the above mentioned "biomaterials crisis." *See supra* notes 12-15 and accompanying text; *infra* notes 26-39 and accompanying text.

<sup>&</sup>lt;sup>24</sup> See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5(b)(1) (1998); see also infra notes 112-15 and accompanying text.

<sup>&</sup>lt;sup>25</sup> See Biomaterials Access Assurance Act of 1998, 21 U.S.C. § 1604(b)(2)(C), (c)(2) (Supp. IV 1999); see also supra notes 76 and 79 and accompanying text.

<sup>&</sup>lt;sup>26</sup> See, e.g., Gregory L. Harper, Comment, An Analysis of the Potential Liabilities and Defenses of Bulk Suppliers of Titanium Biomaterials, 32 GONZ. L. REV. 195, 213 & n. 83 (1996-97) ("At any one time, DuPont had 20 cases listed for trial in as many states.") (quoting DuPont senior counsel Ross F. Schmucki in Gary Taylor, Jaw Implant Litigation Highlights Risk of Being a Supplier, PROD. LIAB. L. & STRATEGY, Apr. 1995, at 2. The primary TMJ products liability decision is In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig., 872 F. Supp. 1019 ( D. Minn. 1995), aff'd, 97 F.3d 1050 (8th Cir. 1996). There is a long list of other TMJ cases that have been reported. See, e.g., Roubal, supra note 2, at 635-44 (discussing TMJ case law finding DuPont not liable under the component parts and sophisticated purchaser defenses). As the result in all of the TMJ litigation was consistent, this Note will focus only on the Eighth Circuit's decision in the consolidated action of In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig., 97 F.3d 1050 (8th Cir. 1996).

<sup>&</sup>lt;sup>27</sup> See In re TMJ Implants, 97 F.3d at 1052-53 ("The implants were invented, designed, tested, manufactured, packaged and sold by Vitek, Inc., a now bankrupt company founded by Dr. Charles Homsy.").

another correspondence DuPont noted that published scientific evidence indicated that Teflon products tended to disintegrate when used in applications similar to those proposed by Vitek.<sup>32</sup> Vitek obtained all necessary approvals from the Food and Drug Administration (FDA) and began to market and sell the implants.<sup>33</sup> Within a few years, however, the implants began causing injuries to patients because the FEP (Teflon) film was disintegrating in patients' bodies.<sup>34</sup> In 1989 DuPont notified Vitek that it would no longer supply Teflon products because of its fear of litigation related to the Vitek implants.<sup>35</sup> In 1991 the FDA ordered the removal of Vitek's implants from the market.<sup>36</sup>

The Eighth Circuit disposed of the patients' design defect and failure to warn claims against DuPont by applying the component parts doctrine.<sup>37</sup> The district court had also held that DuPont was not liable under the sophisticated purchaser doctrine, but the Eighth Circuit did not consider that defense because the component part doctrine was sufficient to establish that DuPont was not liable.<sup>38</sup> Despite the court's affirmation of summary judgment in favor of DuPont, the company still sustained substantial monetary losses resulting from the jaw implant litigation, which compelled the company to discontinue supplying biomaterials.<sup>39</sup> This case illustrates that additional restraints must be placed on meritless suits against biomaterials suppliers beyond those created by the common law.

Unlike the TMJ litigation, the breast implant supplier liability litigation involves more than one supplier of raw materials. Cases involving two different suppliers of silicone gel participating at different levels in the design

<sup>33</sup> See id. at 1054 ("The FDA authorized the sale of Proplast TMJ implants in 1983.").

<sup>39</sup> See supra notes 14-15, 30 and accompanying text (discussing DuPont's annual eight million dollar expense resulting from the TMJ implant litigation and the minimal dollar value of Teflon incorporated into each of Vitek's implants).

our part [about the safety of Teflon for medical purposes]").

<sup>&</sup>lt;sup>32</sup> See id. at 1053 ("DuPont's letter also noted several published scientific reports indicating that pure Teflon implants wore badly and had a tendency to disintegrate in load-bearing joints [like the temporomandibular joint]."). In response to this letter, Homsy's agent executed a disclaimer to verify the receipt of DuPont's warnings and Homsy, in a separate letter, distinguished the scientific evidence from his own application. See id.

 $<sup>^{34}</sup>$  See id.

<sup>&</sup>lt;sup>35</sup> See *id*.

<sup>&</sup>lt;sup>36</sup> See id.

<sup>&</sup>lt;sup>37</sup> See Roubal, *supra* note 2, at 618 ("The court recognized that a manufacturer such as DuPont should be entitled to use the component part doctrine to shield it from liability based upon design defect and failure to warn.").

<sup>&</sup>lt;sup>38</sup> See In re TMJ Implants, 97 F.3d at 1055 & n.5 (noting that while the lower court had decided the case on both the component parts doctrine and the sophisticated purchaser doctrine, it "affirmed the grant of summary judgment to the defendants on both the design defect and failure to warn claims on the basis of the raw material/component part supplier doctrine"). Presumably, however, the court would have affirmed the district court's conclusion under the sophisticated purchaser doctrine because all of the traditional elements of that defense were established by the facts of this case. See infra notes 107-10 and accompanying text (discussing the elements of the sophisticated purchaser defense).

of the final products will be examined.<sup>40</sup> These cases indicate that supplier liability doctrines will result in liability for some suppliers when they are sufficiently culpable.<sup>41</sup>

In *In re Silicone Gel Breast Implants*, General Electric (GE) supplied silicone gel to be used in breast implants.<sup>42</sup> The silicone products sold by GE to breast implant manufacturers were found to have many uses and they were not inherently unsafe.<sup>43</sup> According to the court, the silicone products became hazardous when incorporated into implants by manufacturers of breast implants.<sup>44</sup> The court also found that the implant manufacturers were sophisticated purchasers because of their participation in the heavily regulated business of implant design and manufacture and were thus in a position to evaluate the safety of incorporating silicone gel into their implants.<sup>45</sup> Furthermore, the court held that the silicone products supplied by GE were substantially modified by the manufacturers before incorporation into the final

<sup>41</sup> Note, however, that the Biomaterials Act does not apply to companies involved in supplying silicone gel to breast implant manufacturers:

- (iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, except that—
  - (I) neither the exclusion provided by this clause nor any other provision of this Act may be construed as a finding that silicone gel (or any other form of silicone) may or may not cause harm; and
  - (II) the existence of the exclusion under this clause may not—
    - (aa) be disclosed to a jury in a civil action or any other proceeding; and
    - (bb) except as necessary to establish the applicability of this Act, otherwise be presented in any civil action or other proceeding.

Biomaterials Access Assurance Act of 1998, 21 U.S.C. § 1602(2)(D)(iii) (Supp. IV 1999). <sup>42</sup> See 996 F. Supp. at 1114.

<sup>43</sup> See id. ("[The products] were sold to various other companies, including Aerospace Corporation, Goodyear, International Paper, IBM, and Martin Marietta, by whom the compounds were safely incorporated into various products, such as electronic semi-conductors and orthopedic bed pads.").

<sup>44</sup> See id. ("These silicone compounds became potentially harmful, if at all, only in particular applications—here, according to the plaintiffs, when incorporated into breast implants by the various manufacturers using their own designs and manufacturing processes.").

<sup>45</sup> See *id.* at 1115 ("Each was aware of—and was in a position to evaluate (and, to varying degrees, did test and evaluate)—the potential risks of its particular products and their constituent elements.").

<sup>&</sup>lt;sup>40</sup> Compare In re Silicone Gel Breast Implants Prod. Liab. Litig., 996 F. Supp. 1110, 1117 (N.D. Ala. 1997) (holding General Electric not liable for failure to warn under the sophisticated purchaser doctrine), with Dow Chem. Co. v. Mahlum, 970 P.2d 98, 113-21 (Nev. 1998) (holding Dow Chemical liable for the negligent performance of an undertaking). This note will describe the facts and holding of these cases to show that General Electric would not be liable under the *Third Restatement* and Biomaterials Act rubric for biomaterials supplier liability, while Dow Chemical would be liable. The author recognizes that the *Dow* court did not apply the *Third Restatement* or the common law defenses adopted by the *Third Restatement*, but believes that had the court applied these tests, it would have found Dow Chemical liable.

<sup>(</sup>D)Exclusions—such term ["claimant"] does not include—

product.<sup>46</sup> Finally, GE participated in the process only to the extent that it developed silicone products to meet the manufacturer's specifications, recommended mixing ratios, and occasionally provided technical advice to manufacturers.<sup>47</sup> Thus the court concluded that GE was not liable under the sophisticated purchaser doctrine as embodied in the *Third Restatement*.<sup>48</sup>

By contrast, Dow Chemical, as illustrated by *Dow Chemical Co. v. Mahlum*, participated to a much greater extent in the design of the breast implants for which it supplied silicone products.<sup>49</sup> In 1943, Dow Chemical and Corning Incorporated formed Dow Corning to develop and market uses for new silicone technology, with each company owning a fifty percent share in Dow Corning.<sup>50</sup> Similarly, the relationship between Dow Chemical and Dow Corning commissioned a number of studies that indicated silicone gel compounds were potentially unsafe when used for medical purposes.<sup>52</sup> Because Dow Corning

*Id.* The court relied on an illustration provided by the drafters of the *Third Restatement* indicating that "providing mechanical or technical services or advice in the selection or integration of the component into a product over whose overall design, testing, or labeling the component supplier does not exercise control does not constitute substantial participation . . . ." *Id.* at 1117 (quoting RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5 cmt. e, illus. 6 (1998)).

<sup>48</sup> See *id*. ("[T]he court concludes that GE has established that it is shielded from liability under the raw materials supplier and bulk sales/sophisticated purchaser doctrines.").

<sup>49</sup> See generally Dow Chem. Co. v. Mahlum, 970 P.2d 98, 113-21 (Nev. 1998) (holding Dow Chemical liable for negligent performance of an undertaking). While the holding of this case is not particularly germane to the discussion of the common law defenses codified in the *Third Restatement* and the Biomaterials Act, the facts of the case are instructive for the purposes of this note. The fact of this case illustrate the necessity of the "substantial participation" provision of the *Third Restatement, see infra* notes 111-15 and accompanying text, and the "common ownership" provisions of the Biomaterials Act. *See infra* notes 76 and 79 and accompanying text.

<sup>50</sup> See Dow Chem., 970 P.2d at 103; see also Evan Caplan, Note, 'Milking the Dow': Compensating the Victims of Silicone Gel Breast Implants at the Expense of the Parent Corporation, 29 RUTGERS L.J. 121, 122 (1997) ("Corning provided the silicone technology, while Dow Chemical supplied 'chemical processing and manufacturing know-how."").

<sup>51</sup> See Dow Chem., 970 P.2d at 105 (noting that the companies' facilities were close in physical proximity, at times both companies shared research facilities, Dow Chemical offered significant advice on testing and marketing Dow Corning's breast implants, and Dow Chemical even granted Dow Corning a license to use the Dow trade name and trademark on its breast implants).

<sup>52</sup> See Caplan, supra note 50, at 123 ("Over the next 40 years, both Dow Chemical and

<sup>&</sup>lt;sup>46</sup> See *id.* at 1116 (noting that the silicone gel was shipped to the manufacturers in 55 gallon drums and that the raw material was then mixed with a solvent and "baked," resulting in a chemical change to the silicone).

<sup>&</sup>lt;sup>47</sup> The court wrote the following to describe the extent to which GE participated in the design and manufacturer of the breast implants made with its silicone products:

Some of GE's silicone compounds were developed by it to satisfy product requirements specified by MEC. Also, GE provided recommendations regarding ratios for mixing materials—though the manufacturers made their own independent decisions as to what mixing ratios they used. And, from time to time, GE provided technical assistance to implant producers (as it did for its other customers) in solving manufacturing problems.

had become insolvent, plaintiffs seeking recovery for injuries allegedly caused by defective breast implants brought suit against Dow Chemical, a defendant with potentially deep pockets.<sup>53</sup>

The Supreme Court of Nevada upheld the trial court's ruling that Dow Chemical had negligently performed an undertaking under section 324A of the *Second Restatement of Torts*.<sup>54</sup> The court held that Dow Chemical had a duty to use reasonable care in testing its silicone products for toxicity under section 324A because it undertook testing for toxic characteristics.<sup>55</sup> Finally, the court concluded that Dow Chemical was negligent because it failed to further test, or advise Dow Corning to test, the long-term effects of its silicone gel and for failing to intervene in Dow Corning's marketing of the implants.<sup>56</sup>

Based on the facts of this case as outlined above, Dow Chemical could have been found liable for the defects in Dow Corning's breast implants that allegedly caused the plaintiff's injuries under existing common law doctrines.<sup>57</sup> The breast implant cases indicate that there are situations in which the biomaterials supplier may be liable under common law doctrines when the claim is meritorious. The TMJ implant cases, however, illustrate that the common law protections afforded to biomaterials suppliers are insufficient to protect such suppliers from expensive litigation.<sup>58</sup> Taken as a whole, these

<sup>53</sup> Dow Corning's decent into insolvency is described as follows:

Overwhelmed by the thousands of personal injury cases pending against it, Dow Corning filed for Chapter 11 bankruptcy protection in a federal court on May 15, 1995. The practical effect of Chapter 11 protection is a stay of all creditors claims pending against the petitioner/debtor... Another result was that plaintiffs who could no longer bring suit against Dow Corning "ha[d] settled on a new target—Dow Chemical."

Id. at 126-27.

<sup>54</sup> See generally Dow Chem., 970 P.2d at 107, 113-21. Section 324A indicates that one who undertakes to render services for the protection of a third party may be held liable for the physical harm resulting to that party from the failure to use reasonable care in the undertaking. See RESTATEMENT (SECOND) OF TORTS § 324A (1979); Dow Chem., 970 P.2d at 113-14 ("This section reflects the 'Good Samaritan' doctrine.").

<sup>55</sup> See Dow Chem., 970 P.2d at 117. In concluding that Dow Chemical owed a duty of care to Dow Corning breast implant recipients, the court stated:

[T]he jury could have found that Dow Chemical undertook to render testing, advisory, laboratory and personnel services for the purpose of promoting the safety of Dow Corning's silicone fluid in order to benefit third persons and *had significant control* over the development of this fluid.

Because the jury could reasonably conclude that Dow Chemical undertook to completely test the safety of the liquid later used in Dow Corning's silicone breast implants, Dow Chemical had a duty to exercise reasonable care in the performance of this undertaking.

Id. (emphasis added).

<sup>56</sup> See id. at 118.

<sup>57</sup> The *Third Restatement* and common law doctrines will be discussed in greater detail later in this note. *See infra* notes 104-33 and accompanying text.

<sup>58</sup> See supra notes 26-39 and accompanying text (discussing the consolidated TMJ implants pretrial litigation).

Dow Corning continued to perform further toxicological tests on silicone. On many separate occasions, the potential hazards of silicone were revealed in studies commissioned by Dow Corning and/or Dow Chemical, or co-operated by Dow Chemical and/or Dow Corning.").

cases indicate that biomaterials suppliers are in need of greater protection than existing products liability defenses provide and that the Biomaterials Act must provide for procedural safeguards to limit the suppliers' amenability to expensive and unmeritorious litigation.

## D. A Road Map of the Biomaterials Act

## 1. Definitions: "Biomaterials" and "Biomaterials Supplier"

The Biomaterials Act defines "biomaterials" indirectly through its definitions of "component part" and "raw material."<sup>59</sup> Under the Act, a "component part" in general is a manufactured portion of an implant,<sup>60</sup> while the term "certain components" includes a component that may be used in non-implant applications and that alone has no implant value.<sup>61</sup> "Raw materials" are defined as substances that have generic uses and may be used in non-implant applications.<sup>62</sup>

A "biomaterials supplier" under the Act is a direct or indirect supplier of component parts or raw materials to implant manufacturers.<sup>63</sup> Manufacturers, who are not protected by the Act, are those who make medical devices and must register with the Food and Drug Administration (FDA) under Section 510 of the Federal Food, Drug, and Cosmetic Act (FFDCA).<sup>64</sup> A Seller, also not protected by the Act, is a person who in the ordinary course of business "sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce."<sup>65</sup> The term seller does not include one who sells real property, a physician who sells the implant only as incident to providing medical treatment, or an entity acting only in a "financial capacity with respect to the sale of an implant."<sup>66</sup>

2. Liability Scheme

In order to clarify the rules of biomaterial supplier liability without "impair[ing] the recovery of an injured party against the manufacturer or seller of a defective medical device[,]"<sup>67</sup> the Biomaterials Act adopts a system of liability intended to mirror the one developed at common law in most states.<sup>68</sup> The common law has generally held the manufacturer of medical devices responsible for the safety of these devices, including the selection of raw

<sup>&</sup>lt;sup>59</sup> See Biomaterials Access Assurance Act of 1998, 21 U.S.C. § 1602(3), (8) (1999).

<sup>&</sup>lt;sup>60</sup> See id § 1602(3)(A).

<sup>&</sup>lt;sup>61</sup> See id. § 1602(3)(B) ("Certain Components—Such term includes a manufactured piece of an implant that—(i) has significant non-implant applications; and (ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant.").

 $<sup>^{62}</sup>$  See id. § 1602(8) ("The term 'raw material' means a substance or product that—(A) has a generic use; and (B) may be used in an application other than an implant.").

<sup>&</sup>lt;sup>63</sup> See id. § 1602(1)(A).

<sup>64</sup> See id. § 1602(6)(A), (B), (7).

<sup>65</sup> Id. § 1602(10)(A).

<sup>66</sup> Id. § 1602(10)(B)(i)-(iii).

<sup>&</sup>lt;sup>67</sup> H.R. REP. NO. 105-549, pt. 2, at 9 (1998).

<sup>&</sup>lt;sup>68</sup> See H.R. REP. NO. 105-549, pt. 1, at 11.

materials and component parts that can be safely integrated into the device.<sup>69</sup> The Biomaterials Act, according to the drafters, codifies the "bulk supplier" and "learned intermediary" doctrines.<sup>70</sup>

Section 5 of the Biomaterials Act lays out the permissible bases of biomaterials supplier liability.<sup>71</sup> Under the Act, a biomaterials supplier may only be held liable in three situations: (1) when the supplier is a manufacturer of medical implants under the Act; (2) when the supplier is a seller of medical implants; or (3) when the supplier sold materials that did not meet contractual specifications of the manufacturer.<sup>72</sup> Liability under any of these three theories must be premised on "other applicable law."<sup>73</sup> This means that state common law products liability doctrines would govern the actual liability of the biomaterials supplier if it fit within one of the categories of potentially liable biomaterials suppliers as defined by section 5 of the Act.

A biomaterials supplier may be liable as a "manufacturer" in three situations: (1) When the supplier registered, or was required to register, as a medical device manufacturer under the FFDCA;<sup>74</sup> (2) when the Secretary of Health and Human Services issues a declaration that the supplier was required to register as a medical device manufacturer;<sup>75</sup> or (3) when the supplier is "related by common ownership or control" to a medical device manufacturer and the court finds it necessary to impose liability on the supplier because the manufacturer is judgment proof or insolvent.<sup>76</sup>

A biomaterials supplier may also be held liable as a seller under the Act. Seller liability attaches in three situations: (1) if the supplier held title to the

*Id.*; see also infra notes 104-10 and accompanying text (discussing the component part doctrine and sophisticated purchaser doctrine).

<sup>71</sup> See 21 U.S.C. § 1604 (laying out the general premises for liability in subsection (a) manufacturer liability, seller liability, and failure to meet contract specifications—and giving the specific requirements for each potentially liable party in subsections (b)-(d)).

<sup>72</sup> See id. § 1604(a)(1)-(3); see also supra notes 63-66 and accompanying text (discussing the definitions of "manufacturer" and "seller" under the Biomaterials Act).

<sup>&</sup>lt;sup>69</sup> See H.R. REP. NO. 105-549, pt. 2, at 9.

<sup>&</sup>lt;sup>70</sup> See H.R. REP. NO. 105-549, pt. 1, at 9-10.

Biomaterials suppliers are almost never held liable because of two common law doctrines, the "bulk supplier" and "learned intermediary" doctrines. They hold, in general, that the manufacturer of a component part (in this context a biomaterials supplier) is not liable for injuries caused by the component when it is incorporated into a finished product by a third party (in this case, an implant manufacturer) where the component in and of itself was not unreasonably dangerous at the time it left the component manufacturer's control. In the same circumstances, a component manufacturer is generally not liable for failure to warn potential consumers of known or suspected finished product dangers.

<sup>&</sup>lt;sup>73</sup> See id. § 1604(b)(1), (c), (d).

<sup>&</sup>lt;sup>74</sup> See id. § 1604(b)(2)(A)(i), (ii).

<sup>&</sup>lt;sup>75</sup> See id. § 1604(b)(2)(B).

<sup>&</sup>lt;sup>76</sup> See id. § 1604(b)(2)(C); see also Dow Chem. Co. v. Mahlum, 970 P.2d 98, 113-21 (1998) (holding supplier that was a 50 percent shareholder of bankrupt corporation, which manufactured defective breast implants, liable for negligent performance of an undertaking in relation to the defective breast implants marketed by manufacturer); *supra* notes 49-56 and accompanying text (discussing the *Dow Chemical* case in greater detail).

implant after it was sold by the manufacturer in turn sold it to another party;<sup>77</sup> (2) if the supplier acted under contract to arrange to have the implant sold directly to the claimant;<sup>78</sup> or (3) if the supplier was related to the manufacturer by common ownership and the manufacturer cannot afford to pay a judgment in favor of the claimant due to insolvency.<sup>79</sup> A biomaterials supplier may also be held liable for failing to meet contract specifications in a contract with the manufacturer.<sup>80</sup> Finally, the supplier may be liable if it failed to meet other specifications imposed by the supplier itself or other relevant laws.<sup>81</sup> To be liable under this provision, the failure to meet the contract specifications must be an "actual and proximate cause" of the plaintiff's injury.<sup>82</sup>

These liability-defining provisions do not abrogate from the common law defenses available to component parts and raw materials suppliers and should not be controversial.<sup>83</sup> Given that the Act's liability provisions do not greatly vary from the common law, one may wonder why Congress believed this Act to be necessary to further protect patients from a shortage of biomaterials and the resulting shortage of newly developed medical devices.<sup>84</sup> The important aspects of the Biomaterials Act, insofar as the Act reduces social costs and the suppliers' litigation costs, are the Act's procedural devices.<sup>85</sup> These devices raise serious questions about the constitutionality of the Biomaterials Act.<sup>86</sup>

## 3. Procedural Devices

The more novel and substantial changes accorded to biomaterials suppliers by the Biomaterials Act are its expedited dismissal and impleader provisions in sections 6 and 7 of the Act, respectively.<sup>87</sup> The biomaterials supplier may move for dismissal on the grounds that it is not a manufacturer or seller, it did

<sup>83</sup> The common law doctrines recognized by the Biomaterials Act are very well established doctrines, which are available to all raw materials and component parts suppliers. Since these protections have been available to such defendants in most states the enactment of these protections alone by Congress does not add significant protection to the biomaterials supply industry that was not already available. *See supra* notes 68-70 and accompanying text (noting that the Biomaterials Act is intended to codify common law products liability defenses available to suppliers of component parts and raw materials); *see also infra* notes 104-33 and accompanying text (discussing the common law and *Third Restatement*'s supplier liability defenses in detail).

<sup>84</sup> The "biomaterials crisis" is a problem of the social cost of meritless litigation. While the Act responds to and reduces this social cost, it is unclear that the Act is the least costly means of doing that. This note will later raise the question of whether the Act was the best method to handle this problem in this context. *See infra* section III-B.

<sup>85</sup> See Biomaterials Access Assurance Act of 1998, 21 U.S.C. §§ 1605-1606 (Supp. IV 1999).

<sup>86</sup> See infra section III-C (discussing the constitutionality of the Biomaterials Access Assurance Act).

<sup>87</sup> See 21 U.S.C. §§ 1605-1606.

<sup>&</sup>lt;sup>77</sup> See 21 U.S.C. § 1604(c)(1)(A).

<sup>&</sup>lt;sup>78</sup> See id. § 1604(c)(1)(B).

<sup>&</sup>lt;sup>79</sup> See id. § 1604(c)(2).

<sup>80</sup> See id. § 1604(d)(1)(A).

<sup>&</sup>lt;sup>81</sup> See id. § 1604(d)(1)(B)(i)-(v).

<sup>&</sup>lt;sup>82</sup> See id § 1604(d)(2).

not supply materials failing to meet contract specifications, or the claimant failed to join the manufacturer as a defendant in the action.<sup>88</sup> Once the biomaterials supplier has filed a motion to dismiss, discovery may only be obtained regarding the court's jurisdiction to hear the action.<sup>89</sup> If, however, the grounds for the motion are that the supplier did not meet contractual specifications, then discovery may only be allowed if it is relevant to the court's jurisdiction and the pending motion to dismiss.<sup>90</sup> Otherwise, motions to dismiss on the grounds that the biomaterials supplier is not a manufacturer or seller of implants may be granted simply on the basis of the pleadings and the affidavits submitted by the parties.<sup>91</sup> The motion will be granted unless the claimant demonstrates through its affidavits that the defendant was not a biomaterials supplier or the court determines that the defendant may be liable as a manufacturer, seller, or provider of materials not meeting its contractual specifications.<sup>92</sup> Furthermore, the Act provides that the motion may be treated by the court as a motion for summary judgment and any dismissal under the Act "shall be entered with prejudice."93

Section 7 of the Biomaterials Act allows a dismissed biomaterials supplier to be impleaded back into the action.<sup>94</sup>

[This provision] provides for the extraordinary situation where evidence admitted at trial between the claimant and the implant manufacturer clearly shows that the dismissed biomaterials supplier may be liable under other law. The purpose of this section is to leave open the possibility of litigation against a biomaterials supplier in an extreme case so egregious as to overcome the common law limitations on supplier liability.<sup>95</sup>

This provision contemplates the fact that existing common law defenses available to component parts and raw materials suppliers have, in almost all cases, prevented biomaterials suppliers from being held liable for injuries caused by implants in which their materials were incorporated. The Biomaterials Act, therefore, should not shock the conscience of the foes of federal tort reform.

Under section 7 of the Act, the court may allow a manufacturer or claimant to implead the biomaterials supplier within ninety days following the final judgment of the underlying action under certain circumstances.<sup>96</sup> The supplier may be impleaded on motion of the manufacturer if the court determines that there is sufficient evidence on the record to support the supplier's liability for a negligent or an intentional tort that proximately caused the claimant's injury.<sup>97</sup>

<sup>&</sup>lt;sup>88</sup> See id. § 1605(a).

<sup>&</sup>lt;sup>89</sup> See id. § 1605(c)(1)(A)-(B)(i).

<sup>&</sup>lt;sup>90</sup> See id. § 1605(c)(1)(B).

<sup>&</sup>lt;sup>91</sup> See id. § 1605(c)(3).

<sup>&</sup>lt;sup>92</sup> See id. § 1605(c)(3)(A)-(B).

<sup>&</sup>lt;sup>93</sup> See id. § 1605(d), (e).

<sup>&</sup>lt;sup>94</sup> See id. § 1606.

<sup>95</sup> H.R. REP. NO. 105-549, pt. 1, at 19 (1998).

<sup>&</sup>lt;sup>96</sup> See 21 U.S.C. § 1606(a)(1).

<sup>&</sup>lt;sup>97</sup> See id. § 1606(a)(1)(A).

Impleader will be granted to reduce the manufacturer's liability because of the supplier's tortious conduct.<sup>98</sup> The claimant may be granted a motion to implead the biomaterials supplier if the court finds that there is evidence in the record supporting a claim that the supplier was either negligent or engaged in intentionally tortious conduct.<sup>99</sup> Impleader will be granted to the claimant if the tortious conduct was the cause of the claimant's injuries and the "claimant is unlikely to be able to recover the full amount of its damages from the remaining defendants."<sup>100</sup>

The procedural devices of the Biomaterials Act pose the greatest constitutional issues implicating federalism and the Tenth Amendment.<sup>101</sup> Such constitutional concerns arise because of the intricate civil procedure rules that will be forced upon state courts applying the Act.<sup>102</sup> This issue will be examined in greater depth later in this note,<sup>103</sup> but the following sections will examine the appropriateness and effectiveness of the Act through a critical analysis of the common law underpinnings of the Act, the social cost of biomaterials supplier litigation, and the social costs created by the Act.

#### III. ANALYSIS

#### A. Why Change a Good Thing?: A Brief Critical History of Supplier Liability

As the Biomaterials Act does not alter the common law products liability protections afforded to biomaterials suppliers, examining the rationales of the underlying common law defenses available to suppliers of component parts and raw materials will be useful to further this analysis. Such an examination will establish that the Biomaterials Act's liability scheme is an effective and appropriate means of tort reform. This section is not aimed at analyzing the validity of the law as a federal tort law enactment. Rather, it is intended to show that the Act is based on sound public policy and it achieves the underlying goals of tort law.

<sup>103</sup> See infra section III-C-2 (discussing the Court's anti-commandeering doctrine as applied to the Biomaterials Act).

<sup>&</sup>lt;sup>98</sup> See id. § 1606(a)(1)(B).

<sup>&</sup>lt;sup>99</sup> See id. § 1606(a)(2)(A).

<sup>&</sup>lt;sup>100</sup> Id. § 1606(a)(2)(B).

<sup>&</sup>lt;sup>101</sup> See H.R. REP. NO. 105-549, pt. 1, at 24 (1998); infra section III-C.

<sup>&</sup>lt;sup>102</sup> See id.

<sup>[</sup>This bill] sets forth elaborate rules of civil procedure with regard to motions to dismiss, discovery, summary judgment and impleader for the states to follow, disregarding state rules of civil procedure. This unprecedented intervention into state procedural rules may well violate the Tenth Amendment under the *New York v. United States*. In that 1992 case, the Supreme Court held that the federal government cannot commandeer state regulatory process for federal purposes in a way that unduly burdens or takes away political accountability. In [this bill] as well, we are concerned that dictating rules of civil procedure will unduly burden state courts and will remove the political accountability of the state legislatures.

*Id.* (citing New York v. United States, 505 U.S. 144 (1992); Printz v. United States, 521 U.S. 898 (1997)).

#### 1. The Component Part and Sophisticated Purchaser Doctrines

As products liability doctrine has developed, the primary defenses available to component part and raw materials suppliers have been the "component part" and "sophisticated purchaser" doctrines.<sup>104</sup> Important factors considered by courts when applying the component part doctrine are: whether the supplier designed the part specifically for use in the end product; whether the material was safe and had many uses; whether another entity modified the materials before they were incorporated into the end product; and whether the material itself was defective.<sup>105</sup> One rationale underlying this doctrine is that the law should not require the supplier to become an expert in every industry to which it supplies materials, as the contrary rule would require, because it would be costly and the expected benefits would be minimal.<sup>106</sup>

It is also important to understand the rationale behind the "sophisticated purchaser," or "learned intermediary," defense that may be raised by raw materials and component parts suppliers. The rationale for the rule is that a seller, in selling its products to sophisticated parties, should be able to rely on those parties to relay any warnings about the risks of the products to end users.<sup>107</sup> The establishment of a supplier's duty to warn the end product user of potential product dangers would impose a nearly impossible burden on the supplier and the end product manufacturer could more efficiently convey

<sup>&</sup>lt;sup>104</sup> See Roubal, supra note 2, at 617.

There are two defenses that parts manufacturers may invoke against strict liability. The first is the component part doctrine, which is a defense to strict product liability for a component part manufacturer when the component is not inherently dangerous and the component manufacturer had no role in the design or manufacturer of the end product. The sophisticated purchaser doctrine is another defense that allows a seller to rely on an intermediary to convey warnings associated with the product to the end products' users.

Id.

<sup>&</sup>lt;sup>105</sup> See id. at 626 ("If the component part or raw material satisfies all of these factors, courts have consistently held that the component part supplier is not liable for any defect in the end product.").

<sup>&</sup>lt;sup>106</sup> See id. at 628-29 ("[H]olding the part manufacturer liable 'would be contrary to public policy, as it would encourage ignorance on the part of the component part manufacturers,' or alternatively would require the part manufacturer to retain experts in every client's business to assess any foreseeable danger.") (citations omitted). One court explains the public policy rationale of the expert retainer argument as follows:

The added cost of such a procedure both financially and in terms of stifled innovation outweighs the public benefit of giving plaintiffs an additional pocket to look to for recovery. I believe the better view is to leave the liability... where it now is-with the originator and implementer of the design-the assembler of the finished product.

Orion Ins. Co. v. United Techs. Corp., 502 F. Supp. 173, 178 (E.D. Pa. 1980).

<sup>&</sup>lt;sup>107</sup> See Roubal, *supra* note 2, at 639 ("[A] manufacturer [or supplier] should be able to rely upon certain sophisticated individuals to whom it sells a product to relay to the ultimate consumers warnings regarding any product dangers."). This policy seems to be especially poignant when the seller is supplying parts or raw materials that will be incorporated into the final product by the sophisticated buyer of the goods and the seller has no way of knowing how the incorporated materials will effect the safety of the final product without doing independent testing of the final product.

warnings to end users.<sup>108</sup> In the case of medical implants, the component parts or raw materials supplier should be able to rely on the device manufacturer, who is stringently regulated by the FDA, to relay any necessary warnings to the physicians who implant the devices.<sup>109</sup> In general, the consequence of this defense is that suppliers will have no duty to warn end consumers under any theory of tort liability.<sup>110</sup>

## 2. The Restatement (Third) of Torts: Products Liability

Recently, the American Law Institute (ALI) affirmed and codified the principles of supplier liability long recognized under the common law in the *Restatement (Third) of Torts: Products Liability*.<sup>111</sup> Under section 5 of the *Third Restatement* a component parts<sup>112</sup> supplier may only be held liable for product defects or failures to warn in two situations: (1) if the component is defective in itself and the defect causes the harm;<sup>113</sup> or (2) if the component supplier "*substantially participates* in the integration of the component into the design of the product," the integration of the component causes the product defect, and the defect causes the plaintiff's alleged harm.<sup>114</sup> The drafters of the *Third Restatement* explicitly affirmed that it codified the component supplier's common law defenses.<sup>115</sup>

Madden, supra note 1, at 544 (footnotes omitted).

<sup>&</sup>lt;sup>108</sup> See, e.g., In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig., 872 F. Supp. 1019, 1029 (D. Minn. 1995) (holding DuPont, a bulk supplier of Teflon for TMJ implants, not liable for failure to warn in part because "the burden that would be imposed on DuPont if it were required to warn the ultimate users of the implants would be extreme").

<sup>&</sup>lt;sup>109</sup> See *id*. ("[The manufacturer] was required by federal law to provide warnings with its finished product. DuPont reasonably expected that [the manufacturer] would comply with the intricate federal regulations of medical devices.").

<sup>&</sup>lt;sup>110</sup> See id. ("The principle was succinctly described ... as follows: 'Bulk suppliers of products to manufacturers, who are sophisticated users, have no duty in negligence, strict liability, or breach of warranty to warn ultimate purchasers of the manufacturer's product."") (quoting American Law of Products Liability 3d, § 5.23 (Matthew J. Canavan, ed. 1994)).

<sup>&</sup>lt;sup>111</sup> See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5 cmt. a (1998); Madden, supra note 1, at 544.

The objective of the *Third Restatement*, in keeping ALI tradition, is not to reform the law, but rather to rationalize it. It does so by reconciling to the extent possible conflicting state standards and creating a unified presentation of products liability law that might prompt a state high court in a jurisdiction that had not ruled on the matter to adopt the *Third Restatement* position as the optimal rule of law.

<sup>&</sup>lt;sup>112</sup> See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5 cmt. a (defining a product component as including, "raw materials, bulk products, and other constituent products sold for integration into other products").

<sup>&</sup>lt;sup>113</sup> See id. § 5(a) ("[T]he component is defective in itself, as defined in this Chapter, and the defect causes the harm  $\dots$ .").

<sup>&</sup>lt;sup>114</sup> *Id.* § 5(b) (requiring that "(1) the seller or distributor of the component *substantially participates* in the integration of the component into the design of the product; and (2) the integration of the component causes the product to be defective, as defined in this Chapter; and (3) the defect in the product causes the harm.") (emphasis added).

<sup>&</sup>lt;sup>115</sup> See *id.* § 5, cmt. a; *see also id.* § 5, cmt. e (discussing the extent to which a supplier must participate in the integration of the component into the design of the final product in order for the supplier to be held liable under Section 5).

The Biomaterials Act clearly adopts liability rules substantially similar to those of the *Third Restatement*.<sup>116</sup> The Biomaterials Act will only impose liability on a biomaterials supplier when it is a manufacturer or a seller of the implant, or if it supplied materials that did not meet contractual specifications.<sup>117</sup> The Act's imposition of liability on to these limited parties corresponds to the Third Restatement's provisions for supplier liability.<sup>118</sup> For example, the Biomaterials Act will allow the courts to hold a supplier liable for harm caused by an implant in which its biomaterials are incorporated if the supplier meets the Act's definition of "manufacturer."<sup>119</sup> Under the Act, a manufacturer is a supplier: (1) that must register with the FDA pursuant to the FFDCA; (2) the Secretary of Health and Human Services orders to register under the FFDCA; or (3) who is related by common ownership to the manufacturer of the implant.<sup>120</sup> If the biomaterials supplier is required to register with the FDA as a manufacturer of medical devices or is under common ownership with the manufacturer it is likely to have "substantially participated" in the integration of the materials into the end product.<sup>121</sup> Thus,

<sup>117</sup> See id. § 1604(a) (defining the terms manufacturer, seller, and failure to meet contractual specifications for the purposes of the Act).

<sup>118</sup> Specifically, it is the "substantial participation" requirement of the *Third Restatement* that creates the parallel between section 5 and the Biomaterials Act. As the following discussion will show, the manufacturer or the seller that can be held liable under the Biomaterials Act likely will have substantially participated in the integration of the component part or raw materials into the design of the medical device into which the materials are incorporated. *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5(b)(1) (1998).

<sup>120</sup> See id. § 1604(b)(2).

<sup>121</sup> Compare id. § 1604(b)(2) (requiring a high level of control over the final product by the supplier before the supplier can be held liable as a "manufacturer"), with RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5(b)(1) (requiring "substantial participation" in the design or manufacturing process before a component supplier can held liable under products

The refusal to impose liability on sellers of non-defective components is expressed in various ways, such as the "raw material supplier defense" or the "bulk sales/sophisticated purchaser rule." However expressed, these formulations recognize that component sellers who do not participate in the integration of the component into the design of the product should not be liable merely because the integration of the component causes the product to become dangerously defective.

Id. § 5 cmt. a.

<sup>&</sup>lt;sup>116</sup> By saying that the Biomaterials Act adopts rules similar to those adopted by section 5 of the *Third Restatement*, it appears that the Biomaterials Act will allow a finding of liability against the same parties as may be liable under the *Third Restatement*. In fact, the Biomaterials Act permits a finding of liability against a supplier *only when there is applicable law defining the liability of the supplier. See* Biomaterials Access Assurance Act of 1998, 21 U.S.C. § 1604(b)(1) (Supp. IV 1999) ("A biomaterials supplier may, *to the extent required and permitted by any other applicable law*, be liable for harm to a claimant caused by an implant . . . .") (emphasis added). Thus, the Biomaterials Act would require that a preexisting legal doctrine, e.g., the *Third Restatement*'s supplier liability provision, is in place in order to evaluate the liability of any party that meets the definitions of manufacturer, seller, or party failing to meet contractual requirements.

<sup>&</sup>lt;sup>119</sup> See 21 U.S.C. § 1604(b)(1) ("A biomaterials supplier may . . . be liable for harm to a claimant caused by an implant if the biomaterials supplier is the manufacturer of the implant.").

if a biomaterials supplier is found to be a manufacturer under the Biomaterials Act it will also meet the requirements of section 5 of the *Third Restatement*.

Similarly, if a biomaterials supplier is found liable as a seller of medical implants under the Biomaterials Act it will also meet the requirements for liability under the *Third Restatement*.<sup>122</sup> Liability under the *Third Restatement*, however, will not attach pursuant to section 5. Rather, it will attach under section 6(e), which defines the liability of retail sellers and other distributors of implants.<sup>123</sup> If a biomaterials supplier is a seller as defined by the Biomaterials Act, then the supplier may be strictly liable under the *Third Restatement* when there is a manufacturing defect in the implant that caused injury to the plaintiff.<sup>124</sup> As in the context of manufacturer liability under the Act, seller liability is incumbent upon the existence of "other law" defining the liability of the seller.<sup>125</sup> The *Third Restatement* would thus supply such other law as is necessary under the Biomaterials Act and the biomaterials supplier acting as a seller would be exposed to liability under section 6 of the *Third Restatement*. However, there would be less liability exposure than to biomaterials supplier that is a manufacturer for the purposes of the Act.<sup>126</sup> Finally, if the biomaterials supplier sells the medical device and is under common ownership with a party deemed a manufacturer under the Biomaterials Act, then it will

#### Id.

<sup>124</sup> See id. § 2(a) ("A product ... contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product.").

<sup>125</sup> See 21 U.S.C. § 1604(c) ("A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant . . . .") (emphasis added).

<sup>126</sup> The seller liability provisions in section 6 of the *Third Restatement* provide for strict liability for the seller when the plaintiff's injuries are caused by manufacturing defects. *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(e)(1) (allowing for seller liability only when there is a manufacturing defect causing the plaintiff's injury). However, under section 6(e)(2) the biomaterials supplier found to be a seller for the purposes of the Act could only be liable for a failure to exercise reasonable care in handling the device as a seller. *See id.* § 6(e)(2). The comments to section 6 explain that courts historically have refused to find a retail or wholesale seller of medical devices liable for design defects and failures to warn; this rule is based on concerns about the manufacturer's special expertise and patients' need for ready access to medically necessary devices and drugs. *See id.* § 6 cmt. h.

liability theories).

<sup>&</sup>lt;sup>122</sup> A biomaterials supplier may be considered a seller of implants under the Act if it held title to the implant and sold the implant, acted under contract to sell or arrange for the sale of the implant, or if it was related by common ownership to another party that meets the requirements to be a seller under the Act. *See* 21 U.S.C. § 1604(c).

<sup>&</sup>lt;sup>123</sup> See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(e).

<sup>(</sup>e) A retail seller or other distributor of a  $\ldots$  medical device is subject to liability for harm caused by the  $\ldots$  device if:

<sup>(1)</sup> at the time of sale or other distribution the . . . medical device contains a manufacturing defect as defined in § 2(a); or

<sup>(2)</sup> at or before the time of sale or other distribution of the . . . medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.

also be a seller under section 6(e) of the *Third Restatement*.<sup>127</sup>

Finally, if the biomaterials supplier is found to have failed to meet contractual requirements under the Biomaterials Act it will also be liable under section 5 of the *Third Restatement*.<sup>128</sup> If the biomaterials supplied did not meet contractual specifications as defined in section 1604(d)(1) of the Act it may only be held liable if the failure to meet contractual specifications caused the plaintiff's injury.<sup>129</sup> The Act's requirement for failure to meet contractual specifications corresponds to the *Third Restatement*'s provision for supplier liability when the component is defective in itself.<sup>130</sup> That is, if the supplier fails to meet a contractual requirement and the failure to meet the contractual requirement causes the plaintiff's harm, then the supplied material presumably will be defective in itself as required by section 5(a) of the Third *Restatement*.<sup>131</sup> The congruence between these sections of the Biomaterials Act and the Third Restatement results from the requirement that the manufacturing defect and the failure to meet contractual specifications must cause the plaintiff's injury.<sup>132</sup> Presumably, if the biomaterials supplier's failure to meet contract specifications caused the plaintiff's injury, then the components supplied necessarily would be defective manufactured under the Third Restatement. Thus, the Biomaterials Act likely will hold the same biomaterials suppliers liable as the *Third Restatement* would hold liable.<sup>133</sup>

<sup>&</sup>lt;sup>127</sup> Compare 21 U.S.C. § 1604(c)(2) (allowing liability if the biomaterials supplier is under common ownership with a seller and other law requires or permits a finding of liability), *with* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(e) (creating strict liability for a seller of implants that contain manufacturing defects and allowing for the seller's liability if the seller fails to exercise reasonable care).

<sup>&</sup>lt;sup>128</sup> Compare 21 U.S.C. § 1604(d)(2) (allowing liability if the biomaterials supplier fails to meet the specifications in its contract with the manufacturer), *with* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5(a) (creating supplier liability when the supplier provides defective component parts to the manufacturer).

 $<sup>^{129}</sup>$  See 21 U.S.C. § 1604(d)(2) ("[S]uch failure to meet applicable contractual requirements or specifications was an actual and proximate cause of the harm to the claimant.").

<sup>&</sup>lt;sup>130</sup> See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5(a) (A supplier will be held liable if "the component is defective in itself, as defined in this Chapter, and the defect causes the harm").

<sup>&</sup>lt;sup>131</sup> See id.

<sup>&</sup>lt;sup>132</sup> See 21 U.S.C. § 1604(d)(2); RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5(a).

<sup>&</sup>lt;sup>133</sup> As the *Third Restatement* is a codification of the component part and sophisticated purchaser doctrines, the Biomaterials Act would also hold the same biomaterials suppliers liable as the common law would hold liable. *See supra* note 115 and accompanying text (discussing the *Third Restatement*'s codification of the traditional supplier liability defenses).

## The Third Restatement and Common Law Supplier Liability Doctrines Meet the Traditional Goals of Tort Law: Corrective Justice & Economic Efficiency<sup>134</sup>

When a product is defective because a defective part or material was incorporated in the product, the defect is not obvious, and the product is not unsuitable for its intended use, public policy clearly supports holding the supplier of that part liable.<sup>135</sup> However, when a product is defective because a non-defective part or material is incorporated into that product, the product becomes defective only because of the decision to incorporate that part into the whole system. As this note will demonstrate below, the supplier not participating in the design should not be held liable.<sup>136</sup>

There are two competing theoretical approaches to justifying tort liability: the corrective justice, or "morality," approach and the economic efficiency, or "deterrence," approach.<sup>137</sup> If the raw material or component part supplier did not participate in the design or manufacture of the product and is held liable the tort system's goals of corrective justice and efficiency and deterrence are not met.<sup>138</sup> While these two theoretical approaches to tort liability are competing, the goals of both approaches are met by the liability system embodied in the *Third Restatement*, the common law, and consequently the

<sup>136</sup> RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5 cmt. a.

As general rule, component sellers should not be liable when the component itself is not defective as defined in this Chapter. If the component is not itself defective, it would be *unjust and inefficient* to impose liability solely on the ground that the manufacturer of the integrated product utilizes the component in a manner that renders the integrated product defective.

Id. (emphasis added).

<sup>138</sup> See generally Madden, *supra* note 1, at 555-61 (discussing the nature of these goals of tort liability in general); *id.* at 564-70 (discussing whether or not the component part and raw materials sellers' duties meet the goals of the tort liability system).

<sup>&</sup>lt;sup>134</sup> Note that this portion of the argument is premised on the Biomaterials Act's requirement of independent grounds for the supplier's liability found outside of the Act. *See* 21 U.S.C. § 1604(b)(1), (c), (d). If the *Third Restatement* and the common law, both of which supply the underlying grounds of liability for biomaterials suppliers, meet the goals of tort liability in general, then those grounds of liability also support the system of liability in the Act.

<sup>&</sup>lt;sup>135</sup> See, e.g., RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5 cmt. b (discussing the reasons why a supplier of defective component parts ought to be held liable for the plaintiff's injuries). Thus, the common law and the *Third Restatement*'s allowance for supplier liability when the products supplied and later integrated into a finished product were defective need not be analyzed in depth; liability in that situation is perfectly justified on the grounds of corrective justice. *See infra* notes 140-77 and accompanying text (discussing the corrective justice and economic efficiency justifications for tort liability in general and as applied to the common law concepts embodied in Section 5 of the *Third Restatement*).

<sup>&</sup>lt;sup>137</sup> See, e.g., Gary T. Schwartz, *W. Page Keeton Symposium on Tort Law: Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice*, 75 TEX. L. REV. 1801, 1801 (1997) ("Currently there are two major camps of tort scholars. One understands tort liability as an instrument aimed largely at the goal of deterrence, commonly explained within the framework of economics. The other looks at tort law as a way of achieving corrective justice between the parties.").

Biomaterials Act, which premises liability on the existence of another source of law defining the supplier's liability. All of these approaches to supplier liability refuse to impose liability on suppliers not participating in the integration of the materials into the finished product.<sup>139</sup>

## a. Cheapest Cost Avoider Approach to Economic Efficiency

One commentator argues that the economic efficiency goal of tort law is met under the *Third Restatement* and common law approaches to supplier liability.<sup>140</sup> Economic efficiency is a more modern approach to understanding tort liability than corrective justice and is most closely associated with the work of Judge Richard Posner.<sup>141</sup> While there are a number of strains of economic analysis in tort law, two in particular are the "cheapest cost avoider" approach<sup>142</sup> and the "Hand Formula" method.<sup>143</sup>

The basic goal of economic analyses of tort law is to minimize total costs of accidents.<sup>144</sup> The cheapest cost avoider approach indicates that accident costs should be allocated to the party who can most cheaply avoid the accident.<sup>145</sup> The cheapest cost avoider of primary accident costs in the market, according to Calabresi, is the party that could most cheaply avoid accident costs.<sup>146</sup> Calabresi also argued that in a pure market allocation of accident costs, the party to whom the accident cost burdens were levied would "bribe," or enter into a market transaction with, the party who could most easily avoid the accident costs, <sup>147</sup> Thus, regardless of who initially bears the cost of an accident, the bearer of the costs, absent transaction costs, will enter into market

<sup>142</sup> See generally GUIDO CALABRESI, THE COSTS OF ACCIDENTS 135-40 (1970) (discussing the concept of the "cheapest" or "least" cost avoider, a theory authored by Calabresi).

<sup>143</sup> See generally Richard A. Posner, *A Theory of Negligence*, 1 J. LEGAL STUD. 29, 32-36 (1972) (discussing the Hand Formula).

<sup>145</sup> See id. at 27-28.

<sup>&</sup>lt;sup>139</sup> See supra sections II-D, III-A-1, III-A-2.

<sup>&</sup>lt;sup>140</sup> See Madden, supra note 1, at 557-64 (discussing the economic efficiency approach to tort liability in general); *id.* at 566-70 (discussing the economic efficiency approach to tort liability as applied to the supplier liability provisions of the *Third Restatement*).

<sup>&</sup>lt;sup>141</sup> See, e.g., *id.* at 556 (noting that this newer approach to tort law emphasizes "evaluation of such considerations as wealth maximization, avoidance of waste, and overdeterrence"); Richard A. Posner, *Symposium on Efficiencies as a Legal Concern: The Ethical and Political Basis of the Efficiency Norm in Common Law Adjudication*, 8 HOFSTRA L. REV. 487, 487 (1980).

<sup>&</sup>lt;sup>144</sup> See CALABRESI, supra note 142, at 26 ("I take it as axiomatic that the principle function of accident law is to reduce the sum of the costs of accidents and the costs of avoiding accidents."). The goal of reducing the costs of accidents includes the reduction of the "number and severity of accidents," the social cost of accidents (i.e., the degree and severity of accidents), and the "cost of administering our treatment of accidents." *Id.* at 27-28.

<sup>&</sup>lt;sup>146</sup> See id. at 135 ("A pure market approach to primary accident cost avoidance would require allocation of accident costs to those acts or activities (or combinations of them) which could avoid the accident costs most cheaply.").

<sup>&</sup>lt;sup>147</sup> See id. at 135. Note that this assumes that there are no transaction or information costs for the initial arbitrary bearer of accident costs to enter into transactions with the cheapest cost avoider. See id.

transactions with the cheapest cost avoider to avoid the accident costs in the future.<sup>148</sup> In a world where there are transaction costs, it is most efficient to place the initial burden of accident costs and avoidance costs on the cheapest cost avoider because the "bribes" would be more expensive and would unnecessarily increase the cost of accident avoidance.<sup>149</sup> The cheapest cost avoider conception of economic efficiency thus indicates that the party who could most cheaply discover the risk and avoid the accident creating the plaintiff's costs should bear the expense of remediating the hazard.<sup>150</sup>

Logically, then, the next step in the analysis is to identify the party who is in fact the cheapest cost avoider.<sup>151</sup> To make an initial rough guess, one must first rule out those parties for whom avoidance costs "would *obviously* be too great an expense."<sup>152</sup> Also, Calabresi's approach aims to reduce the externalization of costs (i.e., to avoid transference of accident costs to parties not involved in the accident).<sup>153</sup>

This approach to economic analysis supports a finding of no liability, as under the *Third Restatement* and the common law, for a supplier of components or raw materials that are later integrated into a final product by a third party. A finding of no liability is indicated because the manufacturer of the end product is in the best position to evaluate the risks of using that material in the product and taking measures to communicate and avoid those risks.<sup>154</sup> Under this analysis, it would be extremely costly for a supplier of

<sup>150</sup> See Madden, *supra* note 1, at 562 ("[I]n matters of compensation for accidents, civil liability should ordinarily be laid at the door of the 'cheapest cost avoider,' the actor who could most easily discover and inexpensively remediate the hazard."); This approach requires the courts to do the following:

[This approach requires] only a decision as to which of the parties to the accident is in the best position to make a cost-benefit analysis between the accident costs and accident avoidance costs and to act on the decision once it is made. The question for the court reduces to a search for the cheapest cost avoider.

Id. at 563 n.93 (quoting Guido Calabresi & John T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055, 1060 (1972)).

<sup>151</sup> See CALABRESI, supra note 142, at 139 ("The question for a pure market approach is, then, how we should determine who, in practice, is the cheapest cost avoider...."). Calabresi gives a number of guidelines to identify who is the cheapest cost avoider, ranging from the "initial rough guess," which is based on intuitions about who can most cheaply avoid accident costs, to determining who can avoid externalizing the accident costs most effectively. See id. at 139-52.

<sup>152</sup> Id. at 140.

<sup>153</sup> See generally id. at 144-50 (arguing that there are three types of accident cost externalization: (1) "externalization due to insufficient subcatergorization;" (2) "externalization due to transfer;" and (3) "externalization due to inadequate knowledge.").

<sup>154</sup> See Madden, *supra* note 1, at 563 ("It is seen readily that a cheapest cost avoider leads us to the conclusion that the component parts supplier, or a raw materials supplier, is not ordinarily the entity that can most readily detect risks posed by a completed product, or reduce such risks to a reasonable level.").

<sup>&</sup>lt;sup>148</sup> See id. at 136 ("The result is the same simply because the cost of avoiding the accident is in all instances smaller than the cost of compensating for it. Wherever this is so, and wherever it costs nothing to bribe . . . the market will seek the cheapest way to avoid the accident.").

<sup>&</sup>lt;sup>149</sup> See id. at 137-38.

materials for which there are many possible uses to determine all possible uses, the risks accompanying each use, and issue effective warnings for each possible use.<sup>155</sup> On the other hand, the downstream manufacturer or assembler of the finished product will be in a superior position to evaluate the safety of the final product and the safety of including the supplier's materials in the design of the product.<sup>156</sup> The manufacturer and designer of the final product, under the "rough guess," is clearly the party who can more easily identify the risks of the product and take avoidance measures. Also, the transference of accident costs to the supplier of parts and raw materials externalizes costs from the integrating manufacturer and the injured plaintiff to the supplier, a party not involved in the transaction causing the accident (provided that the supplier did not participate in the integration of its materials into the end product and its materials were not themselves defective). Thus, the *Third Restatement* and common law approaches to supplier liability create economically efficient rules of law under the cheapest cost avoider approach.

It is important to note that Calabresi argued for strict liability for the party who could most cheaply avoid accident costs.<sup>157</sup> Calabresi's approach outlined above certainly supports the position that *the supplier of non-defective biomaterials should not be held liable*. However, the question of whether the manufacturer of medical implants should be held strictly liable as the cheapest cost avoider is not addressed here. One reason not to hold the suppliers strictly liable is that suppliers will not be able to increase the quality of the implants sold to consumers. Rather, they will merely reduce the amount of biomaterials supplied and manufacturers will switch to new materials in their implants. Thus, holding the supplier strictly liable will not necessarily reduce overconsumption of the dangerous implants. A strict liability rule, which is intended to reduce consumer consumption of dangerous products, would not result in the optimal amount of consumer protection in the case of biomaterials suppliers.<sup>158</sup>

Madden, supra note 1, at 568-69.

<sup>157</sup> See generally Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Tort*, 81 YALE L.J. 1055 (1972).

<sup>158</sup> See, e.g., James M. Buchanan, *In Defense of Caveat Emptor*, 38 U. CHI. L. REV. 64, 72-73 (1970) (arguing that stricter product liability rule will result in a reduction of the quantity of products with a concomitant increase in the quality and cost of the products; this trade-off, according to Buchanan, is inappropriate and a rule of caveat emptor should be

<sup>&</sup>lt;sup>155</sup> See supra note 106 and accompanying text (discussing the fact that imposing a duty to warn on a supplier will result in the requirement that a supplier retain an expert in each field it supplies).

<sup>&</sup>lt;sup>156</sup> On the least cost avoider approach to the *Restatement's* supplier liability provisions, Madden writes:

<sup>[</sup>T]he *Third Restatement* promotes an efficient rule that would relieve the component or ingredient supplier of liability when the component or ingredient is not itself defective. In such circumstances, the component or ingredient supplier ordinarily has no meaningful control over the hazard level, if any, of the finished product. As between the ingredient supplier and the downstream assembler or formulator, the proper conclusion is that the downstream formulator, with its superior (and often exclusive) knowledge of the product's end use, and which is responsible for ultimate design, packaging, risk information, and marketing, should remain the principle locus of potential liability.

#### b. Hand Formula Approach to Economic Efficiency

An alternative method of analyzing the efficiency of rules of law is the socalled "Learned Hand Formula" approach championed by Richard Posner.<sup>159</sup> The Hand Formula was originally exposited in Learned Hand's opinion in *United States v. Carroll Towing Co.*<sup>160</sup> This formula provides that a party's duty to take precautions to prevent accidents is a function of three variables: (1) the probability of the accident occurring (P), (2) the gravity of the harm if the accident occurs (L), and (3) the burden of taking precautions to avoid the accident (B).<sup>161</sup> Liability will attach under this formula when the burden is less than the product of the probability multiplied by the gravity of the harm. That is, liability should follow when B<PL and the defendant fails to meet that burden.<sup>162</sup>

When this formula is applied to the biomaterials supplier liability scenario in which non-defective, multi-use biomaterials are supplied and where the supplier did not substantially participate in the integration of the biomaterials into the design of the product, the result is that the supplier should not be held liable. Since the product of P and L in this scenario is equal for both the supplier and the manufacturer, the only comparison necessary is that of the precautionary burdens required of each party to avoid the accident. In the case of the supplier's duty to take precautions, the supplier's burden is much greater than that of the manufacturer. Thus, the supplier should not bear the responsibility of paying the injured party's damages.

More concretely, assume that the medical device manufacturer can identify and take measures to avoid the potential accident costs of its product that incorporates the supplier's biomaterials for cost "B." This precautionary burden would include, among other things, the cost of scientifically testing the product for any dangers posed by the integration of the supplier's materials into the end product, the cost of taking measures to avoid those dangers implicated by the testing (e.g., by changing the materials used in the product), and dispensing warnings to the end product users.

If the biomaterials supplier was responsible for identifying the risks, suggesting actions to limit the risks, and dispensing warnings to the end product consumers, the accident avoidance burden would be greater for a number of reasons. For example, there would be informational costs imposed on the supplier to determine applications in which the manufacturer may use

considered in order to increase the amount of consumer choice). In the biomaterials situation, however, a rule of strict liability for suppliers would result in a decrease in the amount of materials supplied but would not result in safer consumer products.

<sup>&</sup>lt;sup>159</sup> See generally RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW § 6.1, at 147-51 (3d ed. 1986) (discussing the Hand Formula standard for adjudging tortious negligence); *id.* §§ 6.2-6.16, at 151-97 (applying the Hand Formula to various rules of tort law, e.g., the reasonable person standard, strict liability, and defamation.).

<sup>&</sup>lt;sup>160</sup> 159 F.2d 169, 173 (2d Cir. 1947).

<sup>&</sup>lt;sup>161</sup> See id.

<sup>&</sup>lt;sup>162</sup> See id. The product of P and L is the expected accident cost. See POSNER, supra note 159, § 6.1, at 147. Thus, the Hand Formula indicates that when the expected accident cost exceeds the burden of taking adequate precautions, the defendant should be held liable if she fails to take those precautions.

its materials.<sup>163</sup> Similarly, the supplier would be responsible for the additional cost of educating itself in the industries to which it supplied its materials in order to evaluate the potential risks posed by the products in which its materials may be used.<sup>164</sup> Finally, expensive burdens would be imposed on the supplier if it were responsible for identifying, and dispensing sufficient warnings to, all potential end users of the various products in which its materials were ultimately integrated.<sup>165</sup> These additional burdens would impose a greater burden on the supplier than if the duties were imposed on the manufacturer. In other words, the accident cost burden would result in lower social costs (i.e., overall reduction in accident costs) if the prevention burden was shifted to the party responsible for integrating the component parts and raw materials into the defective implants.

Additionally, imposing burdens on the supplier beyond the duty to remove inherent defects would be economically inefficient under the Hand Formula analysis. In other words, if the supplier was required to take measures beyond the minimal requirement of supplying non-defective goods, the burden of the additional precautions to avoid defects in the end product would likely be greater than the expected accident cost and perhaps even the reduction in expected accident cost.<sup>166</sup> The first point, i.e., that the additional burden likely would be greater than the expected accident cost, would be the case whenever the total accident avoidance burden placed on the supplier (e.g., the cost of becoming an expert in other fields, identifying the risks of the end product, and dispensing warnings to the end users) exceeds the product of the likelihood of injury and the expected loss caused by the injury.

To illustrate the latter point, i.e., that the additional burden would be greater than the reduction in expected accident cost, let us slightly modify Hand's algorithm:  $P_1$  = probability of harm without precautions beyond those necessary for non-defective materials;  $P_2$  = probability of harm with additional precaution. In this scenario, assume that there is a baseline fifty percent chance of harm if the supplier takes sufficient precaution to avoid selling defective materials ( $P_1 = 0.50$ ) and the potential loss was \$1,000 (L = \$1,000). While the burden of taking additional precautions to prevent improper integration of the supplied materials into the end product would be great, the reduction in the probability would not likely decrease greatly because the supplier is not in a good position to take effective precautions. Assume, then, that the resulting probability of harm is reduced only to forty-five percent by virtue of the supplier's additional precautions ( $P_2 = 0.45$ ). The expected loss

<sup>&</sup>lt;sup>163</sup> See supra note 106 and accompanying text (discussing the supplier's heightened cost of identifying all potential uses of its multi-use raw materials and component parts).

<sup>&</sup>lt;sup>164</sup> See supra note 106 and accompanying text (discussing that the supplier should not be responsible for the burden of retaining an expert in each field to which it supplies its parts and materials).

<sup>&</sup>lt;sup>165</sup> See supra note 108 and accompanying text (discussing the difficulty of warning ultimate consumers of the dangers of products in which a supplier's materials are integrated).

<sup>&</sup>lt;sup>166</sup> The "expected accident cost" is the probability of the accident multiplied by the expected loss if the accident occurs. *See supra* note 159-62 and accompanying text (discussing the Hand Formula as it is presented in the *Carroll Towing* opinion).

without the additional precautions would be \$500 ( $P_1L = 0.05 \times 1,000$ ), while the expected accident cost if additional precautions were taken would be reduced only to \$450 ( $P_2L = 0.45 \times 1,000$ ). Thus, unless the additional burdens cost less than \$50, imposing them on the supplier would be economically inefficient.

Thus, all variations of the Hand Formula above indicate that a rule of law imposing liability on the manufacturer of medical devices rather than a supplier of non-defective, multi-use component parts and raw materials not participating in the integration of those materials in the medical device is an economically efficient rule.<sup>167</sup>

#### c. Corrective Justice

The corrective justice approach to tort liability analyzes the defendant's liability on the grounds of correcting the moral wrongs caused by its behavior.<sup>168</sup> This school of thought stems out of a rich philosophical tradition. The term "corrective justice" is rooted in Aristotelian philosophy.<sup>169</sup> A major part of the rectification of the defendant's moral wrongs under this theoretical framework is the notion of compensation for the losses caused by the defendant's tortious conduct.<sup>170</sup> Also, this approach is aimed at protecting personal liberty and individual autonomy.<sup>171</sup> Additionally, this approach also

<sup>&</sup>lt;sup>167</sup> Note also that if parties to these sorts of supply contracts were rational parties and they entered into a contract to allocate the risks of paying for injuries caused by defective products they would likely place the burden on the manufacturer. This is because it would be cheaper for that party to inspect and avoid the risks of the integrated end product. In other words, the manufacturer of the medical device would be in a superior position to inspect for product defects and the duty to make such inspections should be placed on that party. *See, e.g.*, MacPherson v. Buick Motor Co., 111 N.E. 1050, 1055 (N.Y. 1916) (Cardozo, J.) (emphasis added):

<sup>[</sup>T]he defendant was not absolved from a duty of inspection because it bought the wheels from a reputable manufacturer... It was a *manufacturer* of automobiles. It was responsible for the finished product. It was not at liberty to put the finished product on the market without subjecting the component parts to ordinary and simple tests.

<sup>&</sup>lt;sup>168</sup> See Madden, supra note 1, at 555-56 ("[S]cholars [in this school of thought] hew to the position that the original and primary goal of tort law, including the law of products liability, is righting the wrongs caused by tortious behavior.").

<sup>&</sup>lt;sup>169</sup> The term refers to the return to the status quo of wealth distribution in society following an injury caused by one person's action injuring another. *See* Schwartz, *supra* note 137, at 1802 & n.5 (citing GEORGE P. FLETCHER, BASIC CONCEPTS OF LEGAL THOUGHT 80 (1996)). Corrective justice scholars have also interpreted the work of Rawls and Kant in their justifications of tort liability. *See id.* at 1803.

<sup>&</sup>lt;sup>170</sup> See Richard J. Epstein, A Theory of Strict Liability, 2 J. LEGAL STUD. 151, 151 (1973) ("The task is to develop a normative theory of torts that takes into account common sense *notions of individual responsibility*....") (emphasis added); Madden, *supra* note 1, at 556 ("[T]he corrective justice approach posits that tort's principle raison d'etre is to return parties suffering personal physical injury or property damage due to another's tortious conduct to the status quo ante, at least insofar as money damages can so do.").

<sup>&</sup>lt;sup>171</sup> See id. at 557 ("Corrective justice principles in tort are intended . . . also to lessen the intrusions such accidents work upon others' autonomy and liberty interests.").

has the secondary goal of deterring similar accidents in the future.<sup>172</sup>

One commentator argues that the corrective justice goal of tort liability is met under the Third Restatement and common law approaches to supplier liability.<sup>173</sup> In the context of the *Third Restatement*'s refusal to place a duty on the supplier to warn of potential misuses of its supplied materials, he claims that the Restatement's rule vindicates "the personal autonomy interest that underpins corrective justice."<sup>174</sup> Also, when the supplier sells materials that can be transformed for use in an endless variety of final products and another party is responsible for the transformation into the final useful product, the supplier's actions are not the cause of the plaintiff's harm.<sup>175</sup> As the supplier of the component part or raw material integrated into the final product by another party is not responsible for the plaintiff's injuries, the corrective justice approach rejects subjecting the supplier to liability for the plaintiff's injuries.<sup>176</sup> More concretely, the supplier of materials later integrated into a finished product by another party simply is not morally culpable for the plaintiff's injuries and the supplier should not be held accountable through the imposition of damages.

Under both corrective justice and economic efficiency justifications for tort liability the component part and sophisticated purchaser doctrines and the *Third Restatement*'s codification of these doctrines are theoretically sound.<sup>177</sup> The corrective justice and economic efficiency arguments thus illustrate that the Biomaterials Act's liability provisions, which require the existence of independent grounds for a finding of liability, stand on firm ground doctrinally. These arguments also illustrate that the substantive protections afforded to the

<sup>175</sup> See id. at 566. This principle was accepted by the drafters of the *Third Restatement* in section 5's "substantial participation" provision. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5(b)(1) (1998). The component part and raw materials supplier will only be held liable under section 5 when it "substantially participated in the integration of the component into the design of the product." *Id.* 

<sup>176</sup> See Madden, supra note 1, at 566.

[T]he sellers of raw materials [and component parts], many of which are transformed into a seemingly limitless array of applications by downstream participants in the commercial chain, have not, in any meaningful way, caused a plaintiff's harm. As a plaintiff may pursue a remedy against the distributive participant who did work the allegedly harmful change or modification in the material that triggered a warning obligation, the principles of corrective justice likewise are preserved.

Id.

<sup>&</sup>lt;sup>172</sup> See id. at 556 (citing William Schofield, *Davies v. Mann: Theory of Contributory Negligence*, 3 HARV. L. REV. 263, 269 (1890), for the proposition that the defendant found liable for his wrongs in tort both penalizes the defendant and deters similarly situated parties from engaging in the same behavior).

<sup>&</sup>lt;sup>173</sup> See Madden, supra note 1, at 564-66.

<sup>&</sup>lt;sup>174</sup> *Id.* at 565. Madden argues that in the context of the supplier's duty to warn the ultimate consumer of the finished product, imposing such a duty on a supplier of materials for use in the creation of new products violates that supplier's autonomy interest. *See id.* That is, if the supplier is required to know and warn the downstream purchaser of the finished products, that supplier's autonomy would be violated because the supplier would have no way of knowing about all of the potential uses and risks of its materials when used in those contexts. *See id.* 

<sup>&</sup>lt;sup>177</sup> See supra notes 140-76 and accompanying text.

biomaterials supplier by the Act are well-supported by public policy.

## *B.* The Social Cost of Biomaterials Supplier Litigation and the Biomaterials Act

The biomaterials supplier liability situation implicates additional law and economics issues. This section of the argument discusses the problem of socially costly biomaterials supplier litigation and the problem of social costs imposed by the Biomaterials Act in responding to the biomaterials crisis. First, however, it is important to understand why plaintiffs who are allegedly injured by medical devices bring actions against biomaterials suppliers, even though the law (e.g., the component part and sophisticated purchaser doctrines and the *Third Restatement*) indicates that the suppliers likely will not be held liable.

### 1. Why do Plaintiffs Bring Products Liability Suits Against Biomaterials Suppliers Despite the Unlikelihood of a Favorable Verdict?

A finding of biomaterials supplier liability is nearly impossible unless the supplier either participated in the decision to integrate its materials into the design of the medical device or it supplied defective materials to the manufacturer.<sup>178</sup> Significant scholarship has explored the issue of why plaintiffs bring suit when the expected value of the suit to the plaintiff is negative.<sup>179</sup> Before the reasons why plaintiffs sue biomaterials suppliers are examined some relevant terminology should be clarified first. The term "negative expected value" ("NEV") suit<sup>180</sup> means one in which the plaintiff's litigation costs exceed the expected judgment (i.e., the probability of a favorable verdict multiplied by the value of the verdict).<sup>181</sup>

<sup>&</sup>lt;sup>178</sup> See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 5 (1998); supra notes 104-33 and accompanying text (discussing the common law and *Third Restatement* protections against supplier liability). A finding of liability under these provisions would be necessary for liability under the Biomaterials Act. *See* Biomaterials Access Assurance Act of 1998, 21 U.S.C. § 1604(b)(1), (c), (d) (Supp. IV 1999).

<sup>&</sup>lt;sup>179</sup> See, e.g., Lucian Arye Bebchuk, A New Theory Concerning the Credibility and Success of Threats to Sue, 25 J. LEGAL STUD. 1 (1996) [hereinafter Bebchuk, A New Theory]; Lucian Arye Bebchuk, Suing Solely to Extract a Settlement Offer, 17 J. LEGAL STUD. 437 (1988) [hereinafter Bebchuk, Suing for Settlement]; Robert G. Bone, Modeling Frivolous Suits, 145 U. PA. L. REV. 519 (1997); D. Rosenberg & S. Shavell, A Model in Which Suits are Brought for Their Nuisance Value, 5 INT'L REV. L. & ECON. 3 (1985).

<sup>&</sup>lt;sup>180</sup> This term should not be conflated with the term "frivolous litigiation." Not all negative expected value suits (e.g., environmental suits to enjoin a nuisance) are frivolous. *See* Bone, *supra* note 179, at 529; *see also* Bebchuk, *Suing for Settlement, supra* note 179, at 437 ("[T]he potential plaintiff recognizes that the expected value to him of going to trial is negative. This might be the case either because the chances of winning a trial are small (the suit is 'frivolous') or because the expected judgment is small relative to the expected litigation costs."). Since the term "frivolous lawsuit" does not have a clear meaning, *see generally* Bone, *supra* note 179, at 529-37, this note will withhold judgment on whether biomaterials supplier litigation is frivolous, referring to such litigation only as a negative expected value scenario.

<sup>&</sup>lt;sup>181</sup> See Bebchuk, A New Theory, supra note 179, at 1 ("[A] negative-expected-value (NEV) suit is one in which the plaintiff would obtain a negative expected return from pursuing his suit all the way to trial.").

Two types of suits must first be distinguished before this analysis continues. The first type is the "positive expected value" ("PEV") suit. This note assumes that in suits that fit this description, the expected judgment is greater than the costs of bringing suit. This situation may occur when there is a small probability of obtaining a favorable judgment, but the expected recovery in the case of a favorable judgment is extremely high. Such a situation may also arise when there is a high likelihood that the court will make an error and find for the plaintiff. The plaintiff will clearly bring suit whenever there is a PEV scenario.

The second possible scenario is the NEV scenario. Products liability actions against biomaterials suppliers tend to fit this pattern. A biomaterials supplier is unlikely to be held liable under the common law and the *Third Restatement* except under certain, limited circumstances.<sup>182</sup> Thus, assuming that the probability of a judgment for the plaintiff is zero (or close to zero) due to the weight of legal authority, the suits against biomaterials suppliers are NEV suits because the cost to bring suit will exceed the expected judgment.<sup>183</sup> Why, then, do plaintiffs allegedly injured by medical devices pursue litigation against such suppliers through trial?

Plaintiffs most probably bring these suits, even though these suits have a negative expected return, in order to obtain a settlement from the defendant.<sup>184</sup> But what makes plaintiffs believe that they may extract a favorable settlement offer?<sup>185</sup> A number of models have been proposed to explain the phenomenon of plaintiffs' anticipation of a positive settlement offer, even though they have a NEV claim. Rosenberg and Shavell's model suggests that some NEV suits are filed, assuming that both parties know that the suit is a NEV suit from the outset, because the plaintiff's cost to file the suit is less than the defendant's response cost and the defendant will be liable for a default judgment if it fails to respond.<sup>186</sup> This model does not fit the biomaterials litigation scenario perfectly because both parties do not know about the value of the plaintiff's claim at the time the claim is filed.<sup>187</sup> Another model suggested by Bebchuk posits that a plaintiff with a NEV suit may extract a settlement offer because there is asymmetric information in favor of the plaintiff (e.g., the plaintiff has private information about her damages or litigation costs not available to

<sup>&</sup>lt;sup>182</sup> See supra notes 104-33 and accompanying text (discussing the common law and *Third Restatement* limitations on holding component part and raw materials suppliers liable).

<sup>&</sup>lt;sup>183</sup> This argument assumes facts similar to the TMJ implant litigation, in which the biomaterials supplier supplied non-defective materials and where the supplier did not participate in the integration of its materials into the end product. *See supra* notes 26-41 and accompanying text (discussing the TMJ implant litigation).

<sup>&</sup>lt;sup>184</sup> See Bebchuk, Suing for Settlement, supra note 179, at 437.

<sup>&</sup>lt;sup>185</sup> See id. ("[T]o explain why plaintiffs with NEV suits might file a claim, we must first understand why they might hope to get a settlement offer.").

<sup>&</sup>lt;sup>186</sup> See Rosenberg & Shavell, *supra* note 179, at 4 (arguing that the defendant would be willing to pay any amount up to its litigation costs). Thus, "the plaintiff will find it profitable to file his nuisance claim; indeed, this will be so whenever the cost of filing is less than the defendant's cost of defense." Id.

<sup>&</sup>lt;sup>187</sup> See supra notes 26-41 and accompanying text (discussing the TMJ implant litigation in which the defendants refused to settle).

defendant).<sup>188</sup> This model, however, does not apply in the biomaterials scenario because such suits are products liability actions, which scrutinize the defendant's actions (e.g., manufacturing defects, design defects, or insufficient warnings). Products liability actions would thus involve information about which the defendant would have more knowledge at the time suit is filed.

The more plausible model for the biomaterials situation is one in which the defendant has an informational advantage over the plaintiff. Professor Bone offers a model for this type of scenario.<sup>189</sup> In Bone's model, the plaintiff cannot identify at the outset whether her suit has merit and is a "positive expected value" ("PEV") suit.<sup>190</sup> Bone suggests that there are three ways for the plaintiff to identify the nature of her suit: (1) to conduct her own investigation, potentially at great expense before filing suit; (2) to file suit and hope that settlement offers will help gauge her judgment about what kind of claim she has; or (3) to file suit and proceed through discovery.<sup>191</sup>

Professor Bone's model predicts three sets of equilibriums. The first and third sets of equilibriums are not relevant to the biomaterials situation and thus will not be discussed here.<sup>192</sup> The relevant equilibrium occurs when the plaintiff's "investigation costs are very high—greater than expected total filing and discovery [costs] in a meritless suit."<sup>193</sup> When this equilibrium occurs the plaintiff will file without investigating and the defendant will *never* settle meritless suits.<sup>194</sup> In this second equilibrium, the "filing equilibrium," the defendant, exploiting the plaintiff's lack of information, will offer to settle meritorious claims only in some cases.<sup>195</sup> By including some meritless suits, this equilibrium produces the inefficient effects of distorting incentives and increasing litigation costs.<sup>196</sup>

The biomaterials litigation, e.g., the TMJ implant litigation,<sup>197</sup> is an example of filing equilibrium because of the presumably expensive investigation costs. Also, the excessive litigation costs of biomaterials supplier litigation, i.e., DuPont's eight million dollar annual jaw implant litigation expense, and the distorted incentives of biomaterials suppliers, i.e., DuPont's withdrawal from

<sup>196</sup> See id. at 562.

<sup>197</sup> See, e.g., In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig., 97 F.2d 1050 (8th Cir. 1996); *supra* notes 26-41 and accompanying text.

<sup>&</sup>lt;sup>188</sup> See Bebchuk, Suing for Settlement, supra note 179, at 440.

<sup>&</sup>lt;sup>189</sup> See Bone, supra note 179, at 550-63.

<sup>&</sup>lt;sup>190</sup> See id. at 550-52.

<sup>&</sup>lt;sup>191</sup> See id. at 552.

<sup>&</sup>lt;sup>192</sup> These are the so-called "investigation equilibrium" and "mixed equilibrium" situations. *See id.* at 560, 563. The filing equilibrium is not relevant because it applies when the pre-filing investigation costs are lower than the filing and discovery costs. *See id.* at 560. The investigation costs in medical device product liability cases would certainly be excessive because the defendant would have the relevant information. The mixed equilibrium does not apply because it involves cases where the plaintiffs sometimes investigate and other times do not. *See id.* at 563. Due to the excessive investigational expense of a medical device products liability action, it is unlikely that plaintiffs will ever investigate prior to filing.

<sup>&</sup>lt;sup>193</sup> Id. at 560.

<sup>&</sup>lt;sup>194</sup> See id. at 561-62.

<sup>&</sup>lt;sup>195</sup> See id. at 560-61.

the biomaterials supply market,<sup>198</sup> provides anecdotal evidence that Professor Bone's model is correct for "filing equilibrium." This model also helps to explain why the TMJ implants litigation was not settled; it indicates that in filing equilibrium the defendant will *never* settle such meritless suits.<sup>199</sup>

## 2. Biomaterials Supplier Litigation is Socially Costly

Steven Shavell created a model of socially costly litigation.<sup>200</sup> According to this model, litigation is socially undesirable when the social costs exceed the social benefits.<sup>201</sup> The social cost of litigation is the sum of the "prevention costs plus the expected losses plus the expected legal expenses of the plaintiffs and defendants."<sup>202</sup> The social benefit of litigation is the reduction in expected losses net of the prevention costs.<sup>203</sup> This model indicates that litigation should occur when the social benefit exceeds the social cost and should not occur when the opposite holds true.<sup>204</sup> However, litigation expenses, regardless of the social cost of the litigation.<sup>205</sup> Shavell cites a number of factors that may lead to situations in which the plaintiff's incentives to sue will not correspond with the social cost of the suit. For example, a socially undesirable suit will be brought when the suit will result in "low liability-induced reduction expected losses net of prevention costs."<sup>206</sup>

While negative expected value suits are not per se socially costly (and therefore socially undesirable), the NEV suits brought against biomaterials suppliers have tended to be examples of socially undesirable litigation. Biomaterials supplier suits are socially undesirable because they result in minimal social benefits. In other words, biomaterials suppliers have very little control over the reduction in expected losses due to end product defects in medical devices produced by a manufacturer.<sup>207</sup> Furthermore, it is questionable whether the supplier could enact any effective reductions in

<sup>&</sup>lt;sup>198</sup> See supra notes 14-15 and accompanying text (discussing DuPont's exit from the biomaterials supply industry).

<sup>&</sup>lt;sup>199</sup> See supra text accompanying note 194.

<sup>&</sup>lt;sup>200</sup> See Steven Shavell, *The Social Versus the Private Incentive to Bring Suit in a Costly Legal System*, 11 J. LEGAL STUD. 333, 333 (1982).

<sup>&</sup>lt;sup>201</sup> See id. at 336.

<sup>&</sup>lt;sup>202</sup> *Id.* at 335.

<sup>&</sup>lt;sup>203</sup> See id. at 336.

<sup>&</sup>lt;sup>204</sup> See id.

<sup>&</sup>lt;sup>205</sup> See id. at 335.

<sup>&</sup>lt;sup>206</sup> *Id.* at 336. "[T]he following factors tend to make it more likely that there will be suit when it is not socially desirable: low legal expenses of plaintiffs, high legal expenses of defendants, high levels of loss, or low liability-induced reduction in expected losses net of prevention benefits." *Id.* 

<sup>&</sup>lt;sup>207</sup> See supra notes 106 and 108 and accompanying text (discussing the rationales of the common law defenses, which reject the placement of inordinate prevention expenses on the supplier of component parts and raw materials); *supra* notes 163-67 and accompanying text (discussing the inordinate expense of biomaterials supplier precautions against end product defects).

losses through these expensive additional precautions.<sup>208</sup> Thus, the social benefit of biomaterials litigation is low and measures should be taken to minimize the social cost of such suits. Shavell's model predicts that societal measures may be taken to avoid socially costly litigation.<sup>209</sup> The Biomaterials Act serves as such a measure to avoid socially undesirable litigation.<sup>210</sup>

3. The Biomaterials Act Externalizes Some of the Social Costs of Litigation

While the Biomaterials Act is clearly an attempt to reduce the social cost of undesirable litigation against biomaterials suppliers, it is not clear that it is the most desirable manner of reducing the social cost. The Biomaterials Act creates a new social cost problem by externalizing some of the litigation costs to society at large. In other words, the additional and unique procedural devices of the Act will impose increased costs on the court system because the courts, particularly the state courts, will be forced to interpret procedural rules that benefit only one segment of society. The externalized costs will result from the increasing complexity and number of procedural rules that the courts must deal with and from the uncertainty that result from these procedural variations. Similarly, the biomaterials supply industry must have expended a great deal of resources in lobbying Congress for special statutory treatment, thus reducing social wealth on the whole for the benefit of one sector of society. Also, the biomaterials suppliers' success in Congress may signal to other industries vexed by costly litigation to lobby for similar treatment, thereby increasing the overall social cost through increased lobbying expenditures and added complexity when other industries successfully lobby Congress.

# 4. A Proposed Alternative to the Biomaterials Act: Arbitration Agreements

While the Biomaterials Act reduces socially undesirable litigation, private means of dispute resolution may be a preferable option.<sup>211</sup> Such agreements would reduce the overall societal litigation burden and would not externalize

<sup>&</sup>lt;sup>208</sup> See Shavell, supra note 200, at 336.

<sup>&</sup>lt;sup>209</sup> On this subject Shavell writes: "[O]ne might see social attempts to reduce the volume of suits, passage of statutes to circumvent the legal system (automobile no-fault schemes, workers' compensation), and, perhaps, the notion that society is on balance too litigious, as reflecting problems of excessive private incentives to bring suit." *Id.* at 339.

<sup>&</sup>lt;sup>210</sup> To expand on this point, the Biomaterials Act reduces the social cost of litigation by allowing for the expedited dismissal of biomaterials suppliers from products liability actions and limiting the liability of the potential defendant biomaterials suppliers to those likely to be found liable under existing common law doctrines. *See* Biomaterials Access Assurance Act of 1998, 21 U.S.C. § 1605 (Supp. IV 1999); *supra* section II-D-3 (discussing the procedural devices of the Act). These devices can be seen as mechanisms to limit biomaterials supplier litigation to defendants against whom meritorious suits are brought.

<sup>&</sup>lt;sup>211</sup> See generally Keith N. Hylton, Agreements to Waive or to Arbitrate Legal Claims: an *Economic Analysis*, 8 SUP. CT. ECON. REV. 209, 217-42 (2000) (discussing waiver and arbitration agreements as potential means of avoiding costly litigation).

costs in the same manner as the Biomaterials Act.<sup>212</sup> One private means of litigation cost reduction is the use of pre-dispute arbitration agreements.<sup>213</sup> Professor Keith Hylton argues in his economic analysis of arbitration agreements that when litigation is socially undesirable,<sup>214</sup> pre-dispute arbitration agreements will arise.<sup>215</sup>

Pre-dispute arbitration agreements are essentially agreements by potential litigants to litigate in certain "alternative" courts, rather than the default state courts.<sup>216</sup> Professor Hylton argues that pre-dispute arbitration agreements will be more economically efficient (wealth enhancing) than litigation if the magnitude of the difference between the deterrence benefits and the litigation costs of the default court system is less than the difference between the deterrence benefits and the litigation costs of the default forum.<sup>217</sup> Deterrence benefits are defined "as the reduction in harms, net of the precaution costs."<sup>218</sup> In the biomaterials situation, the deterrence benefits in traditional court are minimal because the precaution costs for the supplier would be great while the reduction in harms would be limited.<sup>219</sup> Thus, as long as the arbitration expenses are less than the litigation costs, the alternative forum is preferable. Pre-dispute arbitration agreements would have the additional advantage of reducing the social cost imposed on society at large since such agreements would have avoided the lobbying costs and the additional complexity created by the Biomaterials Act.<sup>220</sup>

## C. Constitutionality of the Biomaterials Access Assurance Act of 1998

#### 1. The Commerce Clause

When a biomaterials supplier is sued by an injured medical device recipient, the threshold issue will be whether Congress had the power to enact a law that regulates an area traditionally governed by the states. The Biomaterials Act

<sup>215</sup> See Hylton, supra note 211, at 213, 223-25.

<sup>216</sup> See id. at 223.

<sup>218</sup> *Id.* at 220. Professor Hylton illustrates this concept as follows: "If the expected costs of litigation exceed the deterrence benefit, then litigation reduces social wealth. [For] example, the reduction in expected harms is \$75 - \$25 = \$50; and the precaution cost is \$25. Thus, the deterrence benefit is \$25." *Id.* 

<sup>219</sup> See supra notes 163-67 and accompanying text (discussing the minimal reduction in expected losses despite large precautionary burdens if the biomaterials supplier were owed a duty of care to the patient receiving the medical device in which its materials were incorporated by another party).

<sup>220</sup> That is, the arbitration regime would not externalize costs as the Biomaterials Act does. *See supra* section III-B-3 (discussing the costs externalized by the Act).

<sup>&</sup>lt;sup>212</sup> See supra section III-B-3 (discussing the Biomaterials Act's externalization of litigation costs).

<sup>&</sup>lt;sup>213</sup> See Hylton, supra note 211, at 213, 223.

<sup>&</sup>lt;sup>214</sup> See supra section III-B-2 (discussing the concept of socially undesirable litigation and Professor Shavell's model of undesirable and socially costly litigation).

<sup>&</sup>lt;sup>217</sup> See id. at 223-24 ("[A] commitment to the alternate court enhances wealth if the litigation cost savings generated by moving to the alternate regime exceed the increased deterrence benefits provided by the default regime.").

was enacted pursuant to congressional power created by the Commerce Clause of the Constitution.<sup>221</sup> The Commerce Clause has been interpreted to justify broad federal regulation.<sup>222</sup> The Supreme Court has delineated types of activities that may be regulated under the Commerce Clause: "(1) the use of the channels of interstate commerce; (2) the instrumentalities of interstate commerce or persons or things in interstate commerce; and (3) activities having a substantial relation to interstate commerce, regardless of whether the activity is local or extends across state boundaries."<sup>223</sup>

While component parts and raw materials used in medical devices typically move in interstate commerce, the Biomaterials Act may be conceived of as regulating tort liability of distributors of these materials, rather than the materials themselves.<sup>224</sup> However, the tort suits relating to those materials have an aggregate economic effect on interstate commerce in the sense that the litigation affects the cost of such devices in all fifty states.<sup>225</sup> Additionally, the procedural rules of the states employed in these suits contribute to the aggregate economic effects on interstate commerce are sufficient to establish a connection to interstate commerce, <sup>226</sup> the Court's recent decision in *United States v. Lopez* may affect the Commerce Clause analysis for the Biomaterials Act.<sup>227</sup>

Although the Supreme Court's decision in *Lopez* may be seen as a bar to federal enactment of the Biomaterials Act as a tort reform policy, the case can

<sup>227</sup> See Lopez, 514 U.S. at 558-68.

<sup>&</sup>lt;sup>221</sup> See U.S. CONST. art. I, § 8, cl. 3 ("[Congress shall have the power] . . . [t]o regulate Commerce with Foreign nations, and among the several States and with the Indian Tribes."); Biomaterials Access Assurance Act of 1998, 21 U.S.C. § 1601(3) (Supp. IV 1999) ("[M]ost of the medical devices are made with raw materials and component parts that—(A) move in interstate commerce. . . .").

<sup>&</sup>lt;sup>222</sup> See, e.g., United States v. Lopez, 514 U.S. 549, 553-61 (1995) (discussing the breadth and limits of congressional power under the Commerce Clause).

<sup>&</sup>lt;sup>223</sup> Victor E. Schwartz et al., *Federalism and Federal Liability Reform: The United States Constitution Supports Reform*, 36 HARV. J. ON LEGIS. 269, 273 (1999) (citing *Lopez*, 514 U.S. at 558-59).

<sup>&</sup>lt;sup>224</sup> *Cf.* Gun-Free Schools Zone Act of 1990, Pub. L. No. 101-647, § 1702(b), 104 Stat. 4844, 4844-45 (1990) (making the knowing possession of a firearm in a school zone a federal offense); Schwartz et al, *supra* note 223, at 278-79 (discussing *Lopez*, 514 U.S. at 551, holding that Congress was "not regulating the firearms market or any other economic activity" through the Gun-Free School Zones Act; rather, Congress was regulating criminal activity). Similarly, the Biomaterials Act does not regulate the biomaterials themselves, but the liability and amenability to suit of the suppliers of biomaterials to the medical device industry.

<sup>&</sup>lt;sup>225</sup> See supra section II-B (discussing the expense of defense of products liability actions in which suppliers will inevitably be found not liable).

<sup>&</sup>lt;sup>226</sup> See Wickard v. Filburn, 317 U.S. 111, 128-29 (1942) (holding that the local activity of growing wheat for personal consumption may effect interstate commerce because the cumulative effect of such consumption will effect the price of wheat in interstate commerce). In the case of regulating tort liability of biomaterials suppliers, the cumulative effect of biomaterials suppliers litigating meritless products liability actions affects the cost of medical devices sold in interstate commerce and the cost of biomaterials sold in interstate commerce. See supra section II-B.

be distinguished.<sup>228</sup> In *Lopez*, the Court addressed Congress's power to criminalize the possession of a handgun in school zones under the Gun Free School Zones Act of 1990.<sup>229</sup> The Court held that the enactment did not regulate commercial activity and it did not "contain[] a requirement that the possession be connected in any way to interstate commerce."<sup>230</sup> As a general matter, since state court procedures are a matter of purely local effect, federally mandated procedural rules to be applied by state courts would lack a sufficient connection to interstate commerce under *Lopez*.

However, the analysis is quite different when state court procedures are employed in products liability actions. The procedural rules used in products liability suits have a more direct and less attenuated effect on products in interstate commerce than those used in other state law causes of action. Products liability suits tend to involve products that move in interstate commerce. The judgments resulting from state court application of substantive and procedural rules may affect the movement of products between states and such litigation may affect the availability of such products in interstate commerce in the future. Thus, the aggregate effect of state procedural rules employed in products liability litigation creates a sufficient nexus to interstate commerce to justify the enactment of federal procedural rules for products liability suits.<sup>231</sup> Since the procedures employed by state courts in products liability suits will have such close ties to products in interstate commerce and would have substantial effects on the cost and availability of such products, Lopez should not hinder Congress from enacting legislation, like the Biomaterials Act, governing the court procedures to be applied in products liability actions.

There are other factors that weigh in favor of a finding that Congress had power under the Commerce Clause to enact the Biomaterials Act. First, federal products liability reform, such as the Biomaterial Act, is consistent with the thirty-year trend toward increasing federal regulation of consumer product safety.<sup>232</sup> Second, the Supreme Court's decision in *Lopez* is anomalous in light

<sup>230</sup> Id.

<sup>&</sup>lt;sup>228</sup> See Victor E. Schwartz & Mark A. Behrens, Is H.R. 956 Really "Common Sense"?: A Symposium on Federal Tort Reform Legislation: Federal Product Liability Reform in 1997: History and Public Policy Support its Enactment Now, 64 TENN. L. REV. 595, 606-07 (1997) ("The Lopez decision is clearly distinguishable from those cases upholding regulation of activities that arise out of or are connected with commercial transactions that, viewed in the aggregate, substantially affect interstate commerce ...."); Schwartz et al., supra note 223, at 278-80 ("The Lopez decision is distinguishable both legally and factually from those cases upholding regulation of activities that arise out of or are connected with commercial transactions, which viewed in the aggregate, substantially effect interstate commerce.").

<sup>&</sup>lt;sup>229</sup> See Lopez, 514 U.S. at 551.

<sup>&</sup>lt;sup>231</sup> See Wickard v. Filburn, 317 U.S. 111, 128-29 (1942) (holding that local activity can have a cumulative effect on interstate commerce thereby triggering congressional power under the Commerce Clause.

<sup>&</sup>lt;sup>232</sup> See Schwartz & Behrens, *supra* note 228, at 605 ("Federal product liability reform legislation . . . . is also consistent with the trend since the mid-1960's toward increased federal involvement in consumer product safety, an inherent part of interstate commerce.") (citing a number of federal consumer protection statutes). Schwartz and Behrens cite a

of the Court's traditionally broad interpretation of the Commerce Clause in economic regulation.<sup>233</sup>

### 2. Anti-Commandeering Theory

Historically, the Supreme Court has been deferential to Congress's authority to regulate under the Commerce Clause, rarely invoking other limitations on the legislature's authority.<sup>234</sup> Lately, however, the Court has employed the Tenth Amendment and related structural inferences from the Constitution to limit congressional authority to enact legislation that "commandeers" state governmental bodies. The so-called "anti-commandeering" line of cases may pose a problem for the Biomaterials Act.<sup>235</sup>

Recently, the Supreme Court has revived the doctrine of federalism in order to delineate "the proper distribution of authority between the federal government and the several states ....."<sup>236</sup> The Biomaterials Act will

<sup>234</sup> One group of commentators note that:

Historically, the Supreme Court has recognized Congress's "extraordinary power" to enact legislation and has been reluctant to invoke the Tenth Amendment to limit that authority. *Maryland v. Wirtz* is the archetypical case adopting the traditional view that courts should not apply substantive limits on federal authority under the Tenth Amendment if Congress is exercising one of its enumerated powers and has a rational basis to do so. In *Wirtz*, the Court upheld the constitutionality of amendments to the Fair Labor Standards Act... and declared that courts should not use the Tenth Amendment to "carve up the commerce power to protect enterprises... simply because those enterprises happen to be run by the States."

Schwartz et al, *supra* note 223, at 304-05 (quoting Maryland v. Wirtz, 392 U.S. 183, 197-99 (1968)).

<sup>235</sup> See id. at 310-11 ("The Supreme Court has signaled in two recent cases that the Tenth Amendment may once again return from its basic dormancy. In those decisions—*New York v. United States* and *Printz v. United States*—the Court addressed the federal government's ability to force states to implement or administer federal regulatory schemes."); *see also infra* notes 236-51 and accompanying text (discussing the application of the Court's recent "anti-commandeering" theory to the Biomaterials Access Assurance Act).

<sup>236</sup> Lebow, *supra* note 10, at 665; *see, e.g.*, 521 Printz v. United States 898, 925-33 (1997) (holding that the Brady Handgun Violence Prevention Act's provision requiring state executive officials to run background checks on gun purchasers unconstitutional because it commandeers state executive officials into a federal legal regime for which the state officials are not politically accountable; holding that commandeering state executive officials violates the states' sovereignty); New York v. United States, 505 U.S. 144, 174-77 (1992) (holding that the Low-Level Radio Active Waste Policy Act's "take title" provision, a provision requiring States to accept ownership of radioactive waste produced within their borders, was unconstitutional because it coerced state governments into implementing

number of federal consumer safety statutes enacted within the last 30 years. *See id.* at 605-06 n.67.

<sup>&</sup>lt;sup>233</sup> The Supreme Court transformed from being predominantly conservative to a more liberal incarnation during the New Deal. *See* ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES § 3.3.4, at 185-89 (1997). The New Deal era was a response to the economic hardship caused by the Depression. *See id.* As a result, Congress attempted to enact a wide variety of economic legislation. *See id.* Prior to the New Deal Court, the conservative Court narrowly construed the Commerce Clause. *See id.* The New Deal Court set in motion a tradition of deference to Congress's power to regulate economic activity by means of the Commerce Clause. *See id.* 

undoubtedly face constitutional challenge under the "anti-commandeering" theory, which was espoused in *New York v. United States*<sup>237</sup> and *Printz v. United States*,<sup>238</sup> when a biomaterials supplier first files an expedited motion to dismiss from a supplier liability action.<sup>239</sup> In a nutshell, the commandeering problem raised by the procedures of the Biomaterials Act is that the Act creates federal judicial procedures, which must be followed by state courts.<sup>240</sup> In order to predict how the Court may decide a constitutional challenge to these procedural provisions of the Biomaterials Act, it is important to examine the Court's decisions in *New York* and *Printz* in greater detail.

In *New York*, the relevant issue was a provision in the Low-Level Radioactive Waste Policy Amendments of 1985,<sup>241</sup> which provided, as an incentive to states to create radioactive waste disposal sites within their borders, that the states must "take title" to any radioactive waste generated within their borders and that they became liable for all damages incurred by the generator of the waste for their failure to take possession of the waste.<sup>242</sup> The Court noted that Congress can encourage states to regulate in a manner consistent with federal goals, but only through non-coercive measures (e.g.,

federal legislation).

<sup>239</sup> See supra section II-D-3 (discussing the procedural devices of the Biomaterials Act). The fact that this enactment is constitutionally suspect was recognized by those members of Congress who dissented against the Biomaterials Act. In the House Report accompanying the passage of the Biomaterials Act, these members noted that these Court doctrines prevent the federal government from commandeering the state governments in a manner that hinders the state officials' political accountability. *See* H.R. REP. No. 105-549, pt. 1, at 23-24 (1998) (Dissenting Views on H.R. 872) ("This unprecedented intervention into state procedural rules may well violate the Tenth Amendment under the [sic] *New York v. United States*. In that 1992 case, the Supreme Court held that the federal government cannot commandeer state regulatory processes for federal purposes in a way that ... takes away political accountability."); *see also supra* section II-A (discussing the traditional deference to the states in regulating tort law and policy).

<sup>240</sup> The Biomaterials Act sets forth the requirements for dismissal, limits discovery, requires the courts to rule on the motion based on the pleadings and affidavits, creates rules for the grant of summary judgment, and sets other procedural rules for motions to implead the biomaterials supplier. *See* Biomaterials Access Assurance Act of 1998, 21 U.S.C. §§ 1605-1606 (Supp. IV 1999); H.R. REP. NO. 105-549, pt. 1, at 24 & n.8; *supra* section II-D-3. In one commentary on the proposed Biomaterials Act, as packaged in the Common Sense Products Liability Legal Reform Act, a more expansive and all-encompassing attempt at federal products liability reform, the commentator wrote the following:

Title II of the PLLRA, the "Biomaterials Access Assurance Act of 1996," attempts to provide a defense to suppliers of parts or materials which are used to manufacture implantable medical devices by mandating procedures for dismissal of civil actions against such defendants, including complex discovery rules and evidentiary findings to be made by the court. This last component of the bill affects such a sweeping takeover of state judicial processes that it merits its own report. However, the "commandeering" of state judges and state courts to promulgate and enforce Congressional notions of tort reform is a presumption that pervades the legislation as a whole.

Lebow, supra note 10, at 677.

<sup>241</sup> See 42 U.S.C. § 2021e(d)(2)(C) (1992).

<sup>242</sup> See id.; New York, 505 U.S. at 153-54.

<sup>&</sup>lt;sup>237</sup> 505 U.S. at 174-77.

<sup>&</sup>lt;sup>238</sup> 521 U.S. at 925-33.

through the spending power of Congress, by exacting conditions on the receipt of federal funds, and through programs giving states the option to regulate activities in the manner prescribed by the federal government or be preempted from regulating in the area by federal law).<sup>243</sup> Under this test, the Court held that the "take title" provision, in practical effect, offered states no choice but to be coerced by the federal government to adopt the federal regulatory system.<sup>244</sup> That is, the states cannot either regulate according to the federal law or be preempted by federal law. Furthermore, one of the motivating factors behind the *New York* decision was that the anti-commandeering theory is the notion of political accountability. If Congress coerces state legislatures into enacting federal legislation, Congress escapes accountability and state officials may be held accountable for a decision federal officials compelled them to make.<sup>245</sup>

In *Printz v. United States*, with Justice Scalia writing for the Court, the Court decided a challenge to the Brady Handgun Violence Prevention Act.<sup>246</sup> The particular Brady Act provision at issue in *Printz* required local law enforcement officials to conduct background checks on individuals attempting to buy handguns until a national system of background checking was promulgated.<sup>247</sup> The Court held that Congress cannot commandeer state legislatures or executive officials through federal mandate.<sup>248</sup> The Court also reinforced its holding in *New York* that Congress may permissibly require state courts to enforce federal enactments (i.e., if Congress creates substantive rules, the state courts must apply them).<sup>249</sup>

New York, 505 U.S. at 174-75.

<sup>245</sup> See *id.* at 168 ("Where Congress encourages state regulation rather than compelling it, state governments remain responsive to the local electorate's preferences; state officials remain accountable to the people.").

<sup>246</sup> 521 U.S. 898, 902 (1997).

<sup>247</sup> See Schwartz et al, *supra* note 223, at 316 (citing the Brady Act, 18 U.S.C. §§ 921-25A (1994)). "The Brady Act required the Attorney General to establish a national system for instant background checks on prospective handgun purchasers and commanded the chief law enforcement officer" ('CLEO') of each local jurisdiction to conduct the background checks and perform related tasks until the national system became operative." *Id.* 

<sup>248</sup> Specifically, the Court wrote that:

We held in *New York* that Congress cannot compel the States to enact or enforce a federal regulatory program. Today we hold that Congress cannot circumvent that prohibition by conscripting the State's officers directly. The Federal Government may neither issue directives requiring States to address particular problems, nor command the States' officers, or those of their political subdivisions, to administer or enforce a federal regulatory program.

Printz, 521 U.S. at 935.

<sup>249</sup> Bolstering its holding to this effect in *New York*, Justice Scalia writing for the *Printz* Court, wrote:

<sup>&</sup>lt;sup>243</sup> See New York, 505 U.S. at 166-67; Schwartz et al, supra note 223, at 313.

<sup>&</sup>lt;sup>244</sup> The Court described the choice offered to the states as failing the test of encouraging state acceptance of federal regulation. The Court wrote:

This third so-called "incentive" offers States, as an alternative to regulating pursuant to Congress' direction, the option of taking title to and possession of the low level radioactive waste generated within their borders and becoming liable for all damages waste generators suffer as a result of the States' failure to do so promptly. In this provision, Congress has crossed the line distinguishing encouragement from coercion.

The *New York* and *Printz* standards seem fatal to the Biomaterials Act's procedural provisions because the Act commandeers state courts to apply federal procedures and does not create any alternative to the states' adoption of those procedures. Nevertheless, the anti-commandeering theory should not apply to the Biomaterials Act; a narrow exception should be recognized. The exception should be based on the distinction between procedural rules and substantive rules. Unlike the statutes involved in *New York* and *Printz*, the Biomaterials Act merely instructs the state courts to employ certain procedures when deciding a products liability action involving a biomaterials supplier. Significantly, the Act does not prescribe a particular regulatory scheme for the state to enact or enforce.

Additional factors weigh in favor of recognizing an exception for the federally mandated products liability procedures created by the Biomaterials Act. First, the intimate tie between products liability actions and interstate commerce should create a presumption that federal regulation related to products liability law, particularly where the substantive state tort laws are unaffected, is strongly supported by the Commerce Clause.<sup>250</sup> Second, the Biomaterials Act does not run the risk of shifting Congress's political accountability for the Act to the states; political accountability was central to the anti-commandeering theory.<sup>251</sup> Thus, since the Biomaterials Act has been enacted in full view of the electorate and state officials run no risk of bearing the burden of political accountability for the Act's procedural provisions, the Act passes muster under the *New York* decision's goal of retaining political accountability in our dual sovereignty system of government.

#### IV. CONCLUSION

The Biomaterials Access Assurance Act of 1998 is a viable, effective, and appropriate form of public policy, meeting the competing tort law goals of corrective justice and economic efficiency. This law is particular important because of the peril faced by patients in need of medical implants, which may become unavailable because biomaterials suppliers are withdrawing from the market due to expectations of excessive litigation costs. While there is substantial protection from *liability* available for innocent biomaterials suppliers, there is inadequate protection for such suppliers to avoid defending

<sup>[</sup>T]he Constitution was originally understood to permit imposition of an obligation on state judges to enforce federal prescriptions, insofar as those prescriptions related to matters appropriate for the judicial power . . . It is understandable why courts should have been viewed distinctly in this regard; *unlike legislatures and executives, they applied the law of other sovereigns all the time.* The principle underlying so-called "transitory" causes of action was that laws operated elsewhere created obligations in justice that courts of the forum state would enforce. The Constitution itself, in the Full Faith and Credit Clause generally required such enforcement with respect to obligations arising in other States.

Printz, 521 U.S. at 907 (citations omitted) (emphasis added).

<sup>&</sup>lt;sup>250</sup> See supra section III-C-1. The Biomaterials Act's uniform procedural rules allow for uniformity in an area of law that substantially affects interstate commerce and helps to create predictability for firms involved in the interstate commercial activity of selling materials used in products sold in interstate commerce.

<sup>&</sup>lt;sup>251</sup> See supra note 245 and accompanying text.

the meritless lawsuits into which they are inevitably drawn because of their status as "deep pockets." The Biomaterials Act, as a federal enactment, provides for a uniform approach to biomaterials supplier liability that may avert the so-called "biomaterials crisis." The key aspect of the Biomaterials Act that may allow it to be a more effective means of protecting biomaterials suppliers, and hence support the production of innovative medical devices, is its unique procedural modifications. These procedural devices are necessary to protect biomaterials suppliers because traditional legal doctrines do not adequately prevent the filing of meritless lawsuits against innocent biomaterials suppliers.

Also, it can be concluded that products liability actions against biomaterials suppliers who supplied non-defective, multi-use materials for integration into medical implants by third parties tend to be negative expected value suits. Plaintiffs tend to pursue these suits through trial, despite the low probability of success, because they lack information about the suppliers' participation in the integration of the materials into the end product and because suppliers tend to refuse to settle any meritless claims in this type of situation. The biomaterials litigation is an example of socially undesirable litigation and the Biomaterials Act was one way to address the problem. This note has suggested that private agreements to litigate in alternative forums, as an alternative to the enactment of federal tort reform legislation, may have the dual benefits of reducing litigation costs for suppliers and avoiding the externalization of costs on society as a whole.

While the Biomaterials Act may not by the most effective means of reducing the litigation costs of biomaterials supplier litigation, it is a constitutional means of protecting an interest that is national in scope. Congress has the affirmative constitutional authorization of the Commerce Clause to engage in this sort of federal products liability reform because products liability suits against biomaterials suppliers affect the availability and cost of medical implants, which move in interstate commerce. Furthermore, the anti-commandeering doctrine, a structural inference from the Tenth Amendment and the dual sovereignty system of government established by the Constitution, does not bar Congress from enacting federal products liability reform policy requiring state courts to enforce federal procedures. While Congress may permissibly engage in this type of tort law reform, Congress should be reluctant to further expand federal tort reform policy.