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## Disassembling Assembler Liability: Are OEMs Strictly Liable for PMA Parts in Aviation Cases?

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**DISASSEMBLING ASSEMBLER LIABILITY:  
ARE OEMS STRICTLY LIABLE FOR PMA PARTS IN  
AVIATION CASES?**

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I. INTRODUCTION

**I**MAGINE THAT A PLANE CRASHES and that the pilot and three passengers are tragically killed. An investigation reveals a potential problem with the “gadget,” a component part of the aircraft. Investigators find that the gadget, which is essential to the operation of the aircraft, had a design defect that probably caused the accident. The representatives of the estates of the deceased passengers sue the aircraft manufacturer asserting several causes of action, including strict liability based on an alleged design defect.<sup>1</sup> Under these facts, the aircraft manufacturer could be held strictly liable for the accident in virtually every jurisdiction under a doctrine commonly known as “assembler liability.” According to this doctrine, “a manufacturer/assembler who incorporates a defective component part into [its] finished product and places the finished product into the stream of commerce is liable in tort to one injured as a re-

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<sup>1</sup> Although this hypothetical specifically discusses a design defect, manufacturing-defect and failure-to-warn theories of strict liability are often pursued as well. This article does not address the standards applicable to negligence-based theories of product liability, which are distinct from, and typically harder to prove than, strict liability claims.

sult of a defect in the component part.”<sup>2</sup> This principle of liability applies notwithstanding the fact that the assembler did not design or manufacture the component part.<sup>3</sup>

But just how far does this liability extend? Imagine that the gadget was not the same gadget installed when the original manufacturer assembled and sold the aircraft, but rather an aftermarket replacement part. Under Federal Aviation Administration (FAA) regulations, third parties can manufacture and sell replacement parts under a process known as parts manufacturer approval (PMA), which requires the third-party manufacturer essentially to demonstrate equivalency between the original and replacement parts.<sup>4</sup> This article examines the relatively uncharted issue of an original equipment manufacturer’s (OEM) potential exposure to strict liability for a third-party supplier’s defective PMA replacement part.<sup>5</sup> Analogous issues have arisen in other product liability contexts, with most courts adopting a “bright-line” rule that the manufacturer of an assembled product cannot be held strictly liable for a design defect in a replacement component part that it did not manufacture, sell, or otherwise distribute, even where that replacement part was identical to the original.<sup>6</sup> However, recent decisions from the highest courts of Maryland, New York, and California have departed from that bright-line rule in asbestos cases, allowing a manufacturer to be held strictly liable for components it did not design, manufacture, or sell.<sup>7</sup> This emerging trend begs the question of whether the bright-line rule should continue to apply to other products cases, and for the reasons discussed below, this article concludes that it should apply to aviation cases.

Part II of this article provides an overview of the FAA regulations governing the production of aircraft and component parts. Part III discusses the judicial treatment of similar strict product liability questions in non-aviation cases, with Part IV specifically examining cases involving other heavily regulated products, such as pharmaceuticals. Part V argues that the majority, bright-

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<sup>2</sup> *Baughman v. Gen. Motors Corp.*, 627 F. Supp. 871, 873 (D.S.C. 1985), *aff’d*, 780 F.2d 1131 (4th Cir. 1986).

<sup>3</sup> *Id.*

<sup>4</sup> 14 C.F.R. § 21.33 (2016).

<sup>5</sup> To date, only one case has raised this issue, but no court has actually decided it. *See Sikkelee v. Precision Airmotive Corp.*, 876 F. Supp. 2d 479, 487 (M.D. Pa. 2012) (discussing whether an OEM can be considered a de facto manufacturer of the replacement part).

<sup>6</sup> *See infra* Part III.A.

<sup>7</sup> *See infra* Part III.B.

line rule that has emerged from such case law—namely, that assemblers are not strictly liable for defective components they did not design, manufacture, or distribute—should apply to OEMs in the aviation context as well. Part VI then discusses the emergence and growing use of additive manufacturing (or 3-D printing) in the aviation industry, explaining that, although the technology may well have the potential to revolutionize the production of aircraft component parts from a technical and cost perspective, nothing about this new technology justifies a departure from the bright-line rule.

## II. REGULATORY BACKGROUND

### A. ORIGINAL EQUIPMENT

The FAA is charged with promoting flight safety by establishing minimum standards for, *inter alia*, aircraft design and manufacturing.<sup>8</sup> To this end, it has established a multi-step process for certifying such design and production. Step one of the process is obtaining a “type certificate,” in which aircraft, engine, and propeller manufacturers must obtain approval from the FAA of any new designs.<sup>9</sup> This process requires the applicant to “make all inspections and tests necessary to determine . . . [t]hat [component] parts of the products conform to the drawings in the type design.”<sup>10</sup> Based on the engineering and testing data, the FAA determines the airworthiness of the manufacturer’s designs.<sup>11</sup> If the design complies with federal regulations, the FAA issues a type certificate.<sup>12</sup> Once a manufacturer has a type certificate, it can obtain a production certificate allowing it to manufacture and sell the type-certificated product.<sup>13</sup> Manufacture of the aircraft and component parts must be in strict accordance with the approved type-certificated design to ensure that the FAA will issue an airworthiness certificate for the product.<sup>14</sup> Unlike many other industries, therefore, the manufacturer of an aircraft and its component parts must obtain specific approval from the FAA of the design and manufacturing process.

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<sup>8</sup> See 49 U.S.C. § 44701(a) (2012).

<sup>9</sup> 14 C.F.R. §§ 21.21(b), 21.33(b), 21.35 (2016).

<sup>10</sup> *Id.* § 21.33(b)(3).

<sup>11</sup> *Id.* §§ 21.21(b), 21.33(b).

<sup>12</sup> 49 U.S.C. § 44704(a) (2012); 14 C.F.R. § 21.21(b).

<sup>13</sup> 14 C.F.R. § 21.132.

<sup>14</sup> *Id.* §§ 21.146, 21.183.

## B. PARTS MANUFACTURE APPROVAL

To avoid the monopolization of aircraft component parts, the FAA permits third parties to produce and sell replacement parts for a type-certificated product, provided that the third party complies with the PMA process.<sup>15</sup> Under the PMA process, applicants must provide to the FAA, among other things:

Test reports and computations necessary to show that the design of the article [for which a PMA is sought] meets the airworthiness requirements of this subchapter. The test reports and computations must be applicable to the product on which the article is to be installed, unless the applicant shows that the design of the article is identical to the design of [an] article that is covered under a type certificate. If the design of the article was obtained by a licensing agreement, the applicant must provide evidence of that agreement.<sup>16</sup>

This regulation provides two alternative means of obtaining a PMA. Under the first option, an applicant may rely on the so-called “test and computation” method of Section 21.303(a)(4), which “requires the PMA manufacturer to extensively test both the original and replacement parts to prove that they are equivalent.”<sup>17</sup> Applicants relying on this method generally “employ two strategies to show compliance with applicable airworthiness requirements for eligible products: general analysis and

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<sup>15</sup> *Id.* § 21.303(a)(4).

<sup>16</sup> *Id.*; *see also* Parts Manufacturer Approval Procedures, FAA Order No. 8110.42D, Table 1 (Mar. 21, 2014) (stating that an applicant’s obligation to obtain a PMA is to “[s]how that the design meets the applicable airworthiness standards by either of the following two ways: (1) Show that the PMA article’s design is identical to the design of an article that is covered under a type certificate (TC), or (2) Use test and computation that shows the PMA article’s design meets the airworthiness requirements that apply to the affected products”). This article does not reach the issue of whether strict liability should be imposed on OEMs for design defects in PMA parts manufactured under a licensing agreement. Licensing agreements are highly fact specific, posing unique challenges for the formulation of a general rule, and arguments in favor of strict liability in this distinct context have been successful where a licensing agreement vested exclusive design and manufacturing oversight in the OEM despite the fact that the article was manufactured under a PMA by a third-party manufacturer. *See Sikkelee v. Precision Airmotive Corp.*, 876 F. Supp. 2d 479, 487 (M.D. Pa. 2012) (denying summary judgment in a strict liability claim where, under the licensing agreement between the OEM and the PMA holder, the OEM “exclusively control[led] the design and manufacture of [the] replacement component part[ ] and mandate[d] the installation of said part[ ] during an overhaul of its engine”).

<sup>17</sup> *Rolls-Royce Corp. v. Heros, Inc.*, No. 3:07-CV-0739-D, 2010 WL 184313, at \*1 (N.D. Tex. Jan. 14, 2010).

comparative analysis.”<sup>18</sup> “General tests and analyses show that an article directly complies with all airworthiness regulations applicable to the product affected by article installation.”<sup>19</sup> “Comparative tests and analyses substantiate that the PMA article is at least equal to the original article approved under a type certificate.”<sup>20</sup> Comparative testing generally requires “data from back-to-back comparisons of testing of [the PMA] article with an article from a type certificate.”<sup>21</sup>

Alternatively, an applicant may rely on the second part of Section 21.303(a)(4) to demonstrate that the “design of the article is identical to the design of [an] article that is covered under a type certificate.”<sup>22</sup> This so-called “identity” test

does not require that the specifications for a replacement part be exactly the same as those for the original part. Rather, identity requires only [ ] that the FAA has determined from a comparison of the two sets of data and drawings, and any other data it finds relevant, that the PMA part will be an adequate replacement for the original part as to fit, form, and function.<sup>23</sup>

To establish identity, an applicant may submit, as part of its application, “the original design drawing and related production specifications referenced within that drawing.”<sup>24</sup>

If the applicant does not possess the original design drawing for the OEM part, however, it can reverse engineer it. This process “entails disassembly, measurement of features, and material and functional analyses of an original article.”<sup>25</sup> The FAA has cautioned that “special care” must be taken “in evaluating identity based on reverse engineering” because “reverse engineering will not normally produce an identical design” and “[t]he applicant is unlikely to show that tolerances, processes, and manufacturing specifications are identical.”<sup>26</sup> Thus, in evaluating a PMA application, “sound engineering review and com-

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<sup>18</sup> Application for Parts Manufacturer Approval Via Tests and Computations or Identity, FAA Advisory Circular No. 21.303-4, § 7(d) (Mar. 21, 2014).

<sup>19</sup> *Id.* § 25(a).

<sup>20</sup> *Id.* § 25(b).

<sup>21</sup> *Id.*

<sup>22</sup> 14 C.F.R. § 21.303(a)(4) (2016).

<sup>23</sup> *United Techs. Corp. v. F.A.A.*, 102 F.3d 688, 689 (2d Cir. 1996).

<sup>24</sup> Parts Manufacturer Approval Procedures, FAA Order No. 8110.42D, § 2-7 (Mar. 21, 2014).

<sup>25</sup> *Id.* § 2-8(c).

<sup>26</sup> *Id.* § 2-7(a).

pliance determinations” must be submitted to demonstrate identity.<sup>27</sup>

If these standards are satisfied, the FAA will issue a PMA allowing manufacture and sale of parts in accordance with the approved design.<sup>28</sup> Subsequent design changes require FAA authorization prior to implementation.<sup>29</sup>

### III. ASSEMBLER LIABILITY

In the majority of jurisdictions in the United States, strict product liability for design defects is based on Section 402A of the Restatement (Second) of Torts:

One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

- (a) the seller is engaged in the business of selling such a product, and
- (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.<sup>30</sup>

A minority of jurisdictions has adopted Section 1 of the Restatement (Third) of Torts: Products Liability. Pertinent here, it similarly states: “One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.”<sup>31</sup>

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<sup>27</sup> *Id.* § 2-7.

<sup>28</sup> *See* 14 C.F.R. § 21.311 (2016).

<sup>29</sup> *See id.* § 21.319 (setting forth FAA approval requirements for minor and major design changes to a PMA article).

<sup>30</sup> RESTATEMENT (SECOND) OF TORTS § 402A(1) (AM. LAW INST. 1965); *Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 505–07 (Fla. 2015) (discussing whether to follow the majority of states in continuing to follow the Restatement (Second) or to join a minority of states following the Restatement (Third)).

<sup>31</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 (AM. LAW INST. 1998). Pursuant to the Third Restatement, a person is “engaged in the business of selling” a product when “in a commercial context, one transfers ownership thereto either for use or consumption or for resale leading to ultimate use or consumption. Commercial product sellers include, but are not limited to, manufacturers, wholesalers, and retailers.” *Id.* § 20(a). A person is “otherwise distributing products” when “in a commercial transaction other than a sale, one provides the product to another either for use or consumption or as a preliminary step leading to ultimate use or consumption. Commercial nonsale product distributors include, but are not limited to, lessors, bailors, and those who provide products to others as a means of promoting either the use or consumption of such products or some

The plain text of both versions of the Restatement militates against imposing strict liability on a product manufacturer that did not sell a component part later incorporated into the finished product. This circumstance falls outside the scope of the plain text because the manufacturer is not the “sell[er]” or “distribut[or]” of the defective component.<sup>32</sup> Accordingly, courts generally have been reluctant to hold assemblers strictly liable for defective aftermarket component parts when the assembler is not in the chain of distribution of those parts.<sup>33</sup> Thus, most have adopted a bright-line rule, categorically refusing to impose strict liability on entities for component parts they did not sell.

#### A. THE BRIGHT-LINE RULE

The majority, bright-line approach rejects the application of strict liability to the original manufacturer for defective aftermarket parts that the manufacturer did not sell, even if the parts are identical to the original components that the manufacturer incorporated into the original finished product that it did sell.<sup>34</sup> For example, in *Exxon Shipping Co. v. Pacific Resources, Inc.*, a ship broke free of its mooring and ran aground after a “chafe chain” used to hold the ship in place fractured.<sup>35</sup> The ship’s owner, Exxon Shipping, sued the owner and operator of the mooring facility, a joint venture between four companies referred to as “HIRI.” In turn, HIRI sued the chain’s designer, Sofec, seeking to hold it strictly liable for an alleged design defect.<sup>36</sup> Sofec argued that it could not be held strictly liable because, despite the fact that it had provided an identical chain made by the same supplier (Bridon) to HIRI when the facility was originally designed and built, it did not sell the specific chain that failed. Rather, HIRI subsequently had purchased the

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other commercial activity.” *Id.* § 20(b). Though not relevant for the purposes of this article, the principal difference between these versions of the Restatement with respect to strict liability is that the Restatement (Third) carves out specific rules for design-defect and failure-to-warn claims, whereas the Restatement (Second) addresses them under the same rubric as manufacturing-defect claims and subjects all of them to the same test for strict liability. The Restatement (Third) recognizes distinctions between these three theories of strict liability, addressing the unique policy rationales for each. *See, e.g., id.* § 2 cmt. a.

<sup>32</sup> *See id.* § 1; RESTATEMENT (SECOND) OF TORTS § 402A(1).

<sup>33</sup> *Exxon Shipping Co. v. Pac. Res., Inc.*, 789 F. Supp. 1521, 1528 (D. Haw. 1991).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 1522.

<sup>36</sup> *Id.* at 1523.

chain that failed directly from Bridon as a spare part. Sofec, therefore, was outside the chain of distribution.<sup>37</sup> Exxon and HIRI nonetheless argued that Sofec should be held strictly liable for the defect in the replacement chain sold by Bridon because the chain “was identical, in terms of make and manufacture, to the original component that was incorporated” into the design of the mooring facility.<sup>38</sup>

The court refused to hold Sofec strictly liable for a chain it did not sell because doing so would not further the policies underlying the doctrine of strict liability.<sup>39</sup> As the court explained:

Courts have articulated several justifications for holding suppliers, assemblers/manufacturers, and retailers strictly liable for defective component parts. As the Ninth Circuit explained in *Pan-Alaska*,<sup>40</sup> any integral part of the overall producing and marketing enterprise . . . should bear the cost of injuries resulting from . . . the product’s use. Second, some courts have reasoned that the assembler, among others, has a position in the marketing chain that allows it to exert pressure on the manufacturer of the component part to enhance the safety of the manufacturer’s product. . . . A third justification for imposing liability is that the public has a right to expect that a reputable seller will stand behind its goods, and the burden of accidental injuries is properly placed upon those who market the defective component.

For each of these theories, a position in the chain of title is a critical link for the imposition of liability. Because there is no evidence that Sofec ever held title to the fractured chain, Sofec cannot be held liable under strict liability. First, Sofec did not benefit financially or otherwise from HIRI’s direct purchase of the replacement chain from Bridon. . . . To require Sofec to absorb the social cost of a component part that it did not supply would undermine that economic result endorsed by the Ninth Circuit in *Pan-Alaska*.

Second, assuming that Sofec did not supply the fractured chain, there is no reason for Sofec to pressure Bridon for safer components other than the fact that Sofec is held liable. If the court were to endorse this reasoning, the court would be justified in imposing liability upon any company that does business with Bridon. . . . While [strict liability in tort] is meant to require manufacturers and sellers to bear much of the responsibility and cost of injures to consumers resulting from their defective products, it

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<sup>37</sup> *Id.* at 1525–29.

<sup>38</sup> *Id.* at 1526.

<sup>39</sup> *Id.* at 1526–27.

<sup>40</sup> *Pan-Alaska Fisheries v. Marine Constr. & Design*, 565 F.2d 1129, 1135 (9th Cir. 1977).

is not meant to impose upon each manufacturer and seller an absolute liability as insurer for all injuries to consumers, regardless of the relation of plaintiff's injuries to the particular defendant's product. Although the doctrine of strict liability departs from general principles of fault, the doctrine, if it is to have any limits, must be bounded by general principles of responsibility.

Third, it appears that Sofec never represented itself to be the supplier of the HIRI chain. To the contrary, HIRI purchased the replacement chain directly from Bridon, intentionally bypassing Sofec in the chain of supply. Even if Sofec had implicitly endorsed Bridon as an appropriate supplier, the need to preserve a bright line in the law of strict products liability (that is, a chain of title rule) is evident.<sup>41</sup>

The court went on to express particular concern over the last point of its analysis—namely, the complications that could result from extending liability to the original manufacturer under a theory of implicit endorsement—refusing to conduct a mini-trial on the issue:

[I]f an assembler were strictly liable for an “identical” replacement part purchased from a third party, the court would be forced to conduct an inquiry into whether the original and the replacement parts were manufactured by the same company. If so, whether the original and the replacement parts were sufficiently similar? If so, whether the original and replacement parts were manufactured utilizing a similar process and similar materials? If so, at what point [in] time did the endorsement by the assembler of the component manufacturer come to an end, if ever? Each of these questions would have to be answered in order to support liability under an “endorsement” theory, notwithstanding the other justifications for strict liability.<sup>42</sup>

Most other courts who have examined the issue have agreed.<sup>43</sup> However, a minority of courts, principally in California, Mary-

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<sup>41</sup> *Exxon Shipping*, 789 F. Supp. at 1527 (some internal citations and quotation marks omitted).

<sup>42</sup> *Id.* at 1527–28 (internal citations omitted).

<sup>43</sup> *See, e.g.*, *Baughman v. Gen. Motors Corp.*, 780 F.2d 1131, 1132–33 (4th Cir. 1986) (no strict liability for spare component parts sold by a third party because the original “manufacturer has not had an opportunity to test, evaluate, and inspect the component; it has derived no benefit from its sale; and it has not represented to the public that the component part is its own”); *Newman v. Gen. Motors Corp.*, 524 So. 2d 207, 209 (La. Ct. App. 1988) (“A manufacturer can not be liable in a product liability claim where it shows that it did not manufacture or install the component of the product alleged to be defective.”); *Ford Motor Co. v. Wood*, 703 A.2d 1315, 1331 (Md. Ct. Spec. App. 1998) (collecting cases applying the majority view and noting these courts’ holdings that the policy ratio-

land, and New York, have begun to abandon the bright-line approach.

### B. ABANDONING THE BRIGHT-LINE RULE

In asbestos litigation, a trend away from the bright-line rule may be emerging with recent high court cases in California, Maryland, and New York holding that an original manufacturer may be held strictly liable for defective aftermarket replacement components, where such components were necessary for the proper functioning of the product into which they were incorporated.<sup>44</sup>

The California Supreme Court first considered this exception in *O'Neil v. Crane Co.*, a wrongful death action arising from the use of asbestos-containing gaskets and insulation on World War II naval warships.<sup>45</sup> A naval officer died from mesothelioma years after serving on an affected aircraft carrier.<sup>46</sup> His family sued two manufacturers of asbestos-containing valves and pumps—Crane Co. and Warren Pumps LLC—for negligence, negligent failure to warn, strict liability for failure to warn, and strict liability for design defect.<sup>47</sup> However, the asbestos-contain-

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nale for strict liability is “not advanced by making a manufacturer liable for component parts that it did not market or place into the stream of commerce”), *abrogated on other grounds* by *John Crane, Inc. v. Scribner*, 800 A.2d 727 (Md. 2002); *cf.* *May v. Air & Liquid Sys. Corp.*, 129 A.3d 984, 1000 (Md. 2015) (distinguishing *Wood* and recognizing that “a manufacturer is generally not strictly liable for products it has not manufactured or placed into the stream of commerce,” but also recognizing “narrow circumstances” where strict liability is proper because “the ultimate product sold . . . cannot function properly without the expendable and noxious component”).

<sup>44</sup> *See, e.g.*, *Kochera v. Foster Wheeler, LLC*, No. 14-CV-29-SMY-SCW, 2015 WL 5584749, at \*4 (S.D. Ill. Sept. 23, 2015) (denying summary judgment for a manufacturer whose turbines required insulation that contained asbestos because the court was “not convinced that a manufacturer should avoid liability on a failure to warn theory where it designed its products to be used with asbestos-containing materials”); *Spychalla v. Boeing Aerospace Operations, Inc.*, No. 11-CV-497, 2015 WL 3504927, at \*6 (E.D. Wis. June 3, 2015) (denying summary judgment to defendant manufacturer in a strict liability claim because the manufacturer specified the use of an asbestos part in its service manuals); *Quirin v. Lorillard Tobacco Co.*, 17 F. Supp. 3d 760, 769–70 (N.D. Ill. 2014) (holding that “a duty may attach where the defendant manufactured a product that, by necessity, contained asbestos components, where the asbestos-containing material was essential to the proper functioning of the defendant’s product, and where the asbestos-containing material would necessarily be replaced by other asbestos-containing material, whether supplied by the original manufacturer or someone else”).

<sup>45</sup> *O'Neil v. Crane Co.*, 266 P.3d 987, 991 (Cal. 2012).

<sup>46</sup> *Id.* at 993.

<sup>47</sup> *Id.* at 991.

ing components the naval officer encountered were not manufactured and sold by the defendants, but by third parties on the aftermarket.<sup>48</sup> The plaintiff argued that the defendants should be held strictly liable as well as negligent because the original valves and pumps were designed to be used with asbestos-containing components.<sup>49</sup> According to the plaintiffs, “it was foreseeable workers would be exposed to and harmed by the asbestos in replacement parts” used with the original manufacturers’ valves and pumps.<sup>50</sup>

The plaintiffs prevailed on this theory in the California Court of Appeal. According to the Court of Appeal, “these replacement parts were ‘no different’ from the asbestos-containing components originally included in defendants’ products. . . . ‘If [the defendants] had warned the hypothetical original user, or protected that person by avoiding defective design, subsequent users, too, would have been protected.’”<sup>51</sup>

The California Supreme Court reversed, reaffirming the longstanding and fundamental principle that “strict products liability should be imposed only on those entities responsible for placing a defective product into the stream of commerce.”<sup>52</sup> The Court noted that strict liability had never been extended to “harm from entirely distinct products that the consumer can be expected to use with, or in, the defendant’s nondefective product,” and it emphasized that “the basis for [strict] liability remains that [the manufacturer] has marketed or distributed a defective product.”<sup>53</sup> On the record before it, the Court therefore concluded:

[I]t is undisputed that O’Neil was exposed to *no* asbestos from a product made by defendants. Although he was exposed to potentially high levels of asbestos dust released from insulation the Navy had applied to the exterior of the pumps and valves, [the defendants] did not manufacture or sell this external insulation. They did not mandate or advise that it be used with their products. O’Neil was also exposed to asbestos from the replacement gaskets and packing inside the pumps and valves. Yet, uncontroverted evidence established that these internal components were not the original parts supplied by [the defendants]. They were

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<sup>48</sup> *Id.*

<sup>49</sup> *Id.* at 996.

<sup>50</sup> *Id.* at 991.

<sup>51</sup> *Id.* at 994.

<sup>52</sup> *Id.* at 995.

<sup>53</sup> *Id.*

replacement parts the Navy had purchased from other sources. . . . Although the internal gaskets and packing originally supplied with defendants' products contained asbestos, none of these original parts remained on board the [ship] by the time O'Neil arrived decades later. Accordingly, even assuming the inclusion of asbestos makes a product defective, no defect inherent in defendants' pump and valve products caused O'Neil's disease.<sup>54</sup>

This holding of *O'Neil* is thus consistent with the bright-line rule applied in most other jurisdictions. However, the California Supreme Court went on to note other scenarios that might warrant a deviation from the bright-line approach:

A stronger argument for liability might be made in the case of a product that *required* the use of a defective part in order to operate. In such a case, the finished product would inevitably incorporate a defect. One could argue that replacement of the original defective part with an identically defective one supplied by another manufacturer would not break the chain of causation. Similarly, if the product manufacturer specified or required the use of a defective replacement part, a stronger case could be made that the manufacturer's failure to warn was a proximate cause of resulting injury. In both contexts, however, the policy rationales against imposing liability on a manufacturer for a defective part it did not produce or supply would remain. These difficult questions are not presented in the case before us, and we express no opinion on their appropriate resolution.<sup>55</sup>

Even though this footnote correctly has been construed as "merely dicta [that] does not reflect California law,"<sup>56</sup> some subsequent California lower court decisions have cited it to justify denying the dismissal of a complaint alleging strict liability on the grounds that a manufacturer designed its product to be used with a potentially defective product sold by another party.<sup>57</sup>

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<sup>54</sup> *Id.* at 996.

<sup>55</sup> *Id.* at 996 n.6 (citation omitted).

<sup>56</sup> *McNaughton v. Gen. Elec. Co.*, No. 2:11-63943-ER, 2012 WL 5395008, at \*1 n.1 (E.D. Pa. Aug. 9, 2012); *see also* *Floyd v. Air & Liquid Sys. Corp.*, No. 2:10-CV-69379-ER, 2012 WL 975684, at \*1 n.1 (E.D. Pa. Feb. 9, 2012) ("The Court has considered Plaintiffs' argument . . . that Defendant is liable for asbestos-containing component parts that were used with its pumps but that it did not manufacture or supply because its pumps required (or 'called for') the use of defective (i.e., asbestos-containing) component parts in order to operate. However, the Court rejects this argument because California law does not provide for such liability, and notes that footnote 6 of *O'Neil* is dictum.").

<sup>57</sup> *See, e.g.,* *Hetzel v. Hennessy Indus., Inc.*, 202 Cal. Rptr. 3d 310, 317 (Cal. Ct. App. 2016) (defendant manufacturer could be held liable for replacement brake

Few of these cases, however, also have cited the California Supreme Court's additional word of caution that, even if "required use" might justify imposing strict liability on a manufacturer outside the stream of commerce, "the policy rationales against imposing liability on a manufacturer for a defective part it did not produce or supply would remain."<sup>58</sup>

Notwithstanding this observation, a recent decision from Maryland's highest court, under facts similar to *Crane*, applied strict liability to a company that did not manufacture or place the component part at issue into the stream of commerce.<sup>59</sup> In *May v. Air & Liquid Systems Corp.*, a majority of the court held that, even if a manufacturer does not actually produce or sell the specific asbestos-containing component at issue, it nonetheless

will have a duty to warn under negligence and strict liability when (1) its product contains asbestos components, and no safer material is available; (2) asbestos is a critical part of the pump sold by the manufacturer; (3) periodic maintenance involving handling asbestos gaskets and packing is required; and (4) the manufacturer knows or should know the risks from exposure to asbestos.<sup>60</sup>

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linings that contained asbestos when "virtually all brake linings during the relevant time period contained asbestos which resulted in [the defendant's] machines being used 90 to 95 percent of the time to grind brakes producing asbestos dust," and therefore the "'normal operation' of the grinders inevitably caused the release of asbestos dust"); *Olivares v. Morehouse-Cowles*, No. B245407, 2014 WL 1571766, at \*8 (Cal. Ct. App. Apr. 21, 2014) (cause of action for strict liability adequately pled where "the complaint alleges defendants' product was specifically 'intended to be used with another product' (chemical ingredients used to manufacture electrical insulation) 'for the very activity that created a hazardous situation' (mixing the chemical ingredients together, causing the release of toxic particles)"); *Shields v. Hennessy Indus., Inc.*, 140 Cal. Rptr. 3d 268, 281 (Cal. Ct. App. 2012) ("Taken as true, the causes of action contend that Hennessy distributed a machine directly to consumers designed only to grind asbestos-containing brake linings, a machine that was defective because its intended operation necessarily released asbestos fibers into the air and was not a machine manufactured for use as a component in another finished product. . . . [T]he alleged sole and intended use of the brake arcing machine resulted in the release of contained asbestos particles. These allegations satisfy the circumscribed parameters of liability articulated by the Court of Appeal in *Tellez-Cordova* and approved by the Supreme Court in *O'Neil*").

<sup>58</sup> See *O'Neil*, 266 P.3d at 996 n.6. In addition, the Washington State Supreme Court has rejected the California courts' expanded view of strict liability on policy grounds. *Simonetta v. Viad Corp.*, 197 P.3d 127, 135 (Wash. 2008).

<sup>59</sup> *May v. Air & Liquid Sys. Corp.*, 129 A.3d 984, 1000 (Md. 2015).

<sup>60</sup> *Id.*

The majority acknowledged the refusal by other courts (including the California Supreme Court in *Crane*) to hold original manufacturers liable for replacement asbestos components, but it ultimately opined that the particular facts of this case presented one of the “narrow circumstances” in which a manufacturer could be held strictly liable because “the pump contained asbestos, and . . . the asbestos was essential to its operation, needed periodic replacement, and was dangerous.”<sup>61</sup> The dissent, however, emphasized that the majority’s holding “impermissibly expand[ed] strict liability in all products liability cases—not just those involving asbestos products—and blur[red] beyond recognition the existing bright line that, to be strictly liable, the defendant must have either manufactured or sold the injury-causing product.”<sup>62</sup>

Consistent with the majority view in *May*, the New York Court of Appeals also recently held in *In re New York City Asbestos Litigation* that “the manufacturer of a product has a duty to warn of the danger arising from the known and reasonably foreseeable use of its product in combination with a third-party product which, as a matter of design, mechanics or economic necessity, is necessary to enable the manufacturer’s product to function as intended.”<sup>63</sup> The Court of Appeals relied in part on its view that the original product manufacturer is in a superior position, as compared to the third-party component manufacturer, to know of and warn against the hazards of using the product with another company’s component part.<sup>64</sup> As the court explained:

[W]here one manufacturer’s product is a durable item designed for continuous use with the other manufacturer’s fungible product, which by contrast deteriorates relatively quickly and is designed to be replaced, the manufacturer of the durable product typically is in the best position to guarantee that those who use the two products together will receive a warning; the end user is more likely to interact with the durable product over an extended period of time, and hence he or she is more likely to

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

<sup>62</sup> *Id.* at 1004–05 (Watts, J., dissenting).

<sup>63</sup> *In re N.Y.C. Asbestos Litig.*, 59 N.E.3d 458, 463 (N.Y. 2016). In the process, the court blurred the line between strict liability and negligence almost completely. *See id.* at 469 (“While claims based on . . . a lack of adequate warnings[ ] can be framed in terms of strict liability or negligence, failure-to-warn claims grounded in strict liability and negligence are functionally equivalent, as both forms of a failure-to-warn claim depend on the principles of reasonableness and public policy at the heart of any traditional negligence action.”).

<sup>64</sup> *Id.* at 471–72.

inspect warnings on that item or in associated documentation than to review warnings supplied by the maker of the “wear item.”<sup>65</sup>

The Court of Appeals also addressed the policy argument underlying strict liability, that the original product seller gains no economic advantage from the sale of the necessary component replacement part, as follows:

[W]here a manufacturer creates a product that cannot be used without another product as a result of the design of the product, the mechanics of the product or the absence of economically feasible alternative means of enabling the product to function as intended, the manufacturer has a substantial, albeit indirect, role in placing the third-party product in the stream of commerce. Specifically, when the manufacturer produces a product that requires another product to function, the manufacturer naturally opens up a profitable market for that essential component, thereby encouraging the other company to make that related product and place it in the stream of commerce. The manufacturer also derives a benefit from the sale of the essential third-party product, as the manufacturer is able to sell its own product to customers precisely because the third party has sold to those customers another item that is essential to the product’s function.<sup>66</sup>

Echoing *May*’s dissent, a concurring opinion in *In re New York City Asbestos Litigation* expressed concern that the majority’s “functional necessity” test “opens too broad an avenue of potential liability,” and stated that to properly follow precedent, a standard “must focus on the affirmative action taken by the manufacturer in placing the harmful product containing asbestos into the stream of commerce.”<sup>67</sup>

What remains to be seen is whether this emerging departure from the “bright-line rule” of strict liability specifically in the asbestos context foreshadows a similar departure more broadly in other product liability cases, as feared by the dissenting and concurring opinions in *May* and *In re New York City Asbestos Litigation*.

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<sup>65</sup> *Id.* at 472.

<sup>66</sup> *Id.* at 474 (internal citation omitted).

<sup>67</sup> *Id.* at 483.

## IV. OTHER HEAVILY REGULATED INDUSTRIES

In many industries, such as those at issue in the cases described above, the government does not regulate a manufacturer's design, manufacture, and sale of products or component parts. But the aviation industry is heavily regulated by the FAA under the Federal Aviation Regulations (FARs) which, among other things, set out a particular procedure, discussed above, that must be followed before a party may lawfully manufacture and sell certain aviation products or replacement parts.<sup>68</sup> As foreshadowed by *O'Neil*, should it make a difference that the applicable regulations *require* the replacement parts to be substantially identical to their original counterparts? To answer that question, it is instructive to examine other heavily regulated products, such as pharmaceuticals.

In the pharmaceutical industry, manufacturers must apply to the Food and Drug Administration (FDA) for approval to market a new drug.<sup>69</sup> The drug's manufacturer must prove to the FDA that there is enough evidence on the drug's safety and effectiveness to meet the FDA's requirements for marketing approval.<sup>70</sup> A new drug application (NDA) must contain, *inter alia*, a summary of the pharmacologic class of the drug, its scientific rationale, its intended use, and its potential clinical benefits.<sup>71</sup> It must also contain technical sections with "data and information in sufficient detail to permit the agency to make a knowledgeable judgment about whether to approve the [application]."<sup>72</sup> Among other things, these technical sections must include (1) a description of the "composition, manufacture, and specification of the drug substance . . . including its physical and chemical characteristics and stability"; (2) the method of its synthesis; "the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance"; and (3) preclinical (animal) and clinical (human) testing data establishing safety and effectiveness.<sup>73</sup> "The process of submitting an NDA," therefore, is "both onerous and lengthy."<sup>74</sup>

However, manufacturers of generic versions of innovator (or name-brand) drugs that the FDA already has approved can cir-

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<sup>68</sup> See *supra* Part II.

<sup>69</sup> See generally 21 C.F.R. §§ 314.1–314.170 (2016).

<sup>70</sup> *Id.* § 314.105(c).

<sup>71</sup> *Id.* § 314.50(c)(2).

<sup>72</sup> *Id.* § 314.50(d).

<sup>73</sup> *Id.*

<sup>74</sup> *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013).

cumvent the onerous and lengthy NDA process by submitting an abbreviated new drug application (ANDA).<sup>75</sup> Under this process:

[A] generic drug may be approved without the same level of clinical testing required for approval of a new brand-name drug, provided the generic drug is identical to the already-approved brand-name drug in several key respects. First, the proposed generic drug must be chemically equivalent to the approved brand-name drug: it must have the same “active ingredient” or “active ingredients,” “route of administration,” “dosage form,” and “strength” as its brand-name counterpart. Second, a proposed generic must be “bioequivalent” to an approved brand-name drug. That is, it must have the same “rate and extent of absorption” as the brand-name drug. Third, the generic drug manufacturer must show that “the labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug.” Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the “qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.” Generic manufacturers are also prohibited from making any unilateral changes to a drug’s label.<sup>76</sup>

An ANDA generally does not need to provide the results of clinical studies to establish safety and effectiveness; rather, the applicant must prove that the generic drug is “bioequivalent” to the innovator drug—that is, that it performs in the same manner.<sup>77</sup> The abbreviated new drug application requires the applicant to show bioequivalence by one of two methods. The applicant can provide “[e]vidence demonstrating that the drug product . . . is bioequivalent to the reference listed drug,” such as a report of the results of bioequivalence studies.<sup>78</sup> Alternatively, the applicant can provide “[i]nformation to show that the drug product is bioequivalent to the reference-listed drug which would permit FDA to waive the submission of evidence demonstrating in vivo bioequivalence.”<sup>79</sup> Bioequivalence may be “self-evident” if, for example, the generic is administered in a particular way and “[c]ontains an active drug ingredient in the same concentration and dosage form as a drug product that is the

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<sup>75</sup> See 21 C.F.R. § 314.92(a).

<sup>76</sup> *Bartlett*, 133 S. Ct. at 2471 (citations omitted).

<sup>77</sup> 21 C.F.R. § 314.94(a)(7) (2016).

<sup>78</sup> *Id.* § 320.21(b)(1).

<sup>79</sup> *Id.* § 320.21(b)(2).

subject of an approved full new drug application or abbreviated new drug application” and “[c]ontains no inactive ingredient or other change in formulation from the [approved drug] that may significantly affect” the functioning of the generic.<sup>80</sup> Generally, the generic drug’s “[l]abeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug.”<sup>81</sup>

Plaintiffs who have taken generic drugs have sued the innovator drug manufacturers, arguing that the manufacturers of name-brand drugs should be subject to strict liability for the defects of the generic versions. In nearly all of these cases, the courts have held that a name-brand drug manufacturer cannot be held liable under a strict liability theory where the plaintiff took the generic equivalent.<sup>82</sup> “[E]very federal circuit court to consider the issue . . . has reached a similar conclusion, applying the law of several states.”<sup>83</sup> In at least twenty-two states, “it is well-settled law that the ‘threshold requirement of any products-liability claim is that the plaintiff assert that the defendant’s product caused the plaintiff’s injury.’”<sup>84</sup> Thus, even in the heavily regulated drug context, where generic drug manufacturers are required to strictly adhere to the design of the innovator drug, courts have followed the “bedrock principles of tort law,” immunizing from strict liability manufacturers who “do not have any relationship” with the plaintiff who ingested the generic drug, thus refusing to “make brand manufacturers the de facto insurers for competing generic manufacturers.”<sup>85</sup>

Only one state court has deviated from this bright-line rule, and its legislature swiftly overruled it. In *Wyeth, Inc. v. Weeks*, the Alabama Supreme Court became the first state supreme court to recognize strict liability for brand-name manufacturers in a failure-to-warn case brought by a patient who claimed he was in-

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<sup>80</sup> *Id.* § 320.22(b)(3)(ii)–(iii).

<sup>81</sup> *Id.* § 314.94(a)(8)(iv).

<sup>82</sup> *See, e.g.,* *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476–77 (5th Cir. 2014) (“[C]laims against brand manufacturers are foreclosed by [the plaintiffs’] respective states’ product liability laws . . . which shield the companies from liability for products they did not create” because such manufacturers “are not ‘manufacturers or sellers’” of the product at issue.).

<sup>83</sup> *McNair v. Johnson & Johnson*, No. 2:14-17463, 2015 WL 3935787, at \*5 (S.D. W. Va. June 26, 2015) (collecting cases).

<sup>84</sup> *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 938 & n.7 (6th Cir. 2014) (collecting cases).

<sup>85</sup> *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 379–80 (Iowa 2014).

jured after taking the generic version of a brand-name drug.<sup>86</sup> Plaintiffs argued that the name-brand manufacturer's duty to warn of its drug's side effects—and to refrain from making related fraudulent misrepresentations—extended to the generic version manufactured and sold by a third party.<sup>87</sup> The court agreed, recognizing that the claims were, “in essence, ‘products-liability’ claims.”<sup>88</sup> It emphasized that prescription drugs, “unlike other consumer products, are highly regulated by the FDA,” and that because of the labeling duties imposed by law on name-brand and generic drug manufacturers, “it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce” because a name-brand manufacturer could foresee harm to a patient taking the generic caused by inadequate labeling.<sup>89</sup>

However, the Alabama state legislature abrogated the holding by enacting a statute restricting liability for product liability claims, including design defect claims, to the actual manufacturer of the article that injured the plaintiff. “Designers, manufacturers, sellers, or lessors of products not identified as having been used, ingested, or encountered by an allegedly injured party may not be held liable for any alleged injury . . . even if [a third party's] use of the [original manufacturer's] design is foreseeable.”<sup>90</sup>

As these precedents make abundantly clear, courts—and legislatures—have overwhelmingly applied the traditional, bright-

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<sup>86</sup> See *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676 (Ala. 2014).

<sup>87</sup> *Id.* at 655.

<sup>88</sup> *Id.* at 656.

<sup>89</sup> *Id.* at 676–77. The court identified two other decisions recognizing the possibility of brand-name manufacturer liability. However, neither case involved strict liability. See *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 703–09 (D. Vt. 2010) (applying Vermont law and denying summary judgment on negligence and fraud claims against a brand-name manufacturer); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 311, 318 (Cal. Ct. App. 2008) (applying California law, denying summary judgment on intentional and negligent misrepresentation claims against a brand-name manufacturer, and specifically noting that strict liability could not be applied because the plaintiff did not take the brand-name drug). Another court similarly denied summary judgment in favor of a brand-name manufacturer sued in negligence by a patient who took a generic equivalent, but also refused to hold the brand-name manufacturer strictly liable for defects in the generic version of the drug because “the public policy rationale that justifies burdening the seller with the cost of injury rather than the consumer does not merit placing liability on an entity [the brand-name manufacturer] whose benefit from the sale is so remote, and whose ability to account for the cost is so limited.” *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 720–24 (N.D. Ill. 2014).

<sup>90</sup> ALA. CODE § 6-5-530(a) (LexisNexis Supp. 2016).

line refusal to apply strict liability to manufacturers who are not in the chain of distribution of an allegedly defective product, even in industries as heavily regulated as aviation.

## V. A BRIGHT-LINE RULE FOR AVIATION

Returning to the gadget hypothesized at the outset, imagine that the defective component was a PMA replacement part, not the same gadget that was on the aircraft when the OEM sold it. Should the OEM, who holds the type certificate for the aircraft, be held strictly liable for the defective PMA part?

One might argue that the OEM should be held liable for the defective PMA part because the PMA part was identical to the original gadget incorporated into the OEM's type-certificated aircraft, thus rendering the harm foreseeable to the OEM. This argument has superficial appeal. As the holder of the type certificate, the OEM is responsible for the airworthiness of the aircraft, and the type certificate issued includes all the components on the aircraft and, at least for major components, usually specifies them by manufacturer and part number. The PMA process is specifically designed to ensure that replacement parts for these components are equally as airworthy as the OEM's original parts by directly comparing them to the components on the OEM's type-certificated product. Therefore, the argument goes, the PMA design can be traced back to the OEM's design, and the OEM can and should be held accountable for it.

Such reasoning, however, ignores the critical policy considerations justifying strict liability in the first place. Specifically, three longstanding tort principles that influence the imposition of strict liability—(1) allocating the risk of loss to the manufacturer; (2) exerting pressure on manufacturers to police the safety of their products; and (3) managing complexity—do not justify the expansion of strict liability under these circumstances.

### A. POLICY JUSTIFICATIONS

#### 1. *Risk Allocation*

As noted earlier, courts have justified the imposition of strict liability on assemblers on the grounds that “any integral part of the ‘overall producing and marketing enterprise . . . should bear the cost of injuries resulting from’ . . . the product’s use.”<sup>91</sup> Lia-

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<sup>91</sup> *Exxon Shipping Co. v. Pac. Res., Inc.*, 789 F. Supp. 1521, 1527 (D. Haw. 1991).

bility properly attaches to the “defendant who, by manufacturing, selling, or marketing a product, is in the best position to know of the dangerous aspects of the product and to translate that knowledge into a cost of production against which liability insurance can be obtained.”<sup>92</sup>

Nothing in the FARs, type-certification procedures, or PMA process supports allocating the risk of loss from defective PMA parts to the OEM. As in other industries, if the OEM does not sell the replacement part, it does not profit from the sale, and it is in no position to incorporate into the price of the part the risks associated with its use, or to obtain applicable liability insurance. At best, the OEM can only incorporate such risks into the cost of producing its own product. Expecting the OEM nonetheless somehow also to take into account the risk associated with the use of a spare part that it did not make or sell would effectively transform the OEM into an insurer of the PMA manufacturer—a result courts squarely and consistently have rejected.<sup>93</sup>

## 2. *Pressure on Manufacturers to Maintain Safety*

It could be argued that the OEM, upon whose design the PMA part is necessarily based, has the ability to “exert pressure” on the PMA manufacturer to “enhance the safety” of its product by enhancing the original, underlying design.<sup>94</sup> However, the OEM plays no role in the PMA application process, assisting neither the FAA nor the applicant. The OEM does not review the PMA manufacturer’s design for the replacement component; it quite obviously plays no part in reverse engineering its own design; and it conducts no tests on the PMA design to ensure its airworthiness. The ultimate decision of whether to grant the PMA is reposed exclusively with the FAA and is based on data provided by the PMA applicant alone. Often, the OEM is not even privy to the fact that a PMA application has been sub-

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<sup>92</sup> *Simonetta v. Viad Corp.*, 197 P.3d 127, 134 (Wash. 2008).

<sup>93</sup> *See Exxon Shipping*, 789 F. Supp. at 1527 (“While [strict liability in tort] is meant to require manufacturers and sellers to bear much of the responsibility and cost of injuries to consumers resulting from their defective products, it is not meant to impose upon each manufacturer and seller an absolute liability as insurer for all injuries to consumers, regardless of the relation of plaintiff’s injuries to the particular defendant’s product.”) (quoting *Southwire Co. v. Beloit E. Corp.*, 370 F. Supp. 842, 848 (E.D. Pa. 1974)).

<sup>94</sup> *See id.*

mitted.<sup>95</sup> From the outset, therefore, an OEM has no meaningful influence over the PMA process.<sup>96</sup>

Nor does an OEM have a significant opportunity to influence a PMA manufacturer after the FAA grants the PMA. The OEM plays no role in the manufacturing or quality control processes employed by the PMA manufacturer. The OEM has no “opportunity to test, evaluate, and inspect the component”<sup>97</sup> as it comes off the PMA manufacturer’s assembly line. The OEM thus has no ability to influence the safety of the PMA part at this stage of the process either.

The same is true later, after the PMA part is being sold on the market. If the OEM were to determine that the PMA design is defective, then perhaps the OEM could “exert pressure” on the PMA supplier indirectly by changing the design of its own type-certificated product.<sup>98</sup> Given that PMA approval is contingent on proof that the PMA part is functionally equivalent to the OEM component, it could be argued that a path to “exerting pressure” on the PMA manufacturer is changing the OEM design.<sup>99</sup> The flaw in this logic, however, is that there may not be anything wrong with the OEM design that would compel a change. It is entirely consistent with the FARs for an OEM to recognize the adequacy of its own design yet disagree with the FAA’s determination of airworthiness for the PMA part.<sup>100</sup> Under such circumstances, a design change to the OEM’s product would not be warranted.

One could also argue that the OEM might exert pressure on a PMA manufacturer by reporting potential safety problems with the PMA part to the FAA. However, the FARs do not require OEMs to investigate or report an issue with a PMA part to the

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<sup>95</sup> See *United Techs. Corp. v. F.A.A.*, 102 F.3d 688, 691 (2d Cir. 1996).

<sup>96</sup> See *In re Deep Vein Thrombosis*, 356 F. Supp. 2d 1055, 1067 (N.D. Cal. 2005) (holding that, as a matter of law, “Boeing was under no duty to ‘exert pressure’ or ‘reward’” third-party airlines and seat manufacturers “to design safer seats and seating configurations”).

<sup>97</sup> *Baughman v. Gen. Motors Corp.*, 780 F.2d 1131, 1133 (4th Cir. 1986).

<sup>98</sup> See *Exxon Shipping*, 789 F. Supp. at 1527.

<sup>99</sup> Section 21.319 of the FARs creates a parallel procedure for instituting design changes to a PMA part that corresponds to the procedure for instituting design changes to a type-certificated component. See *Production and Airworthiness Approvals, Part Marking, and Miscellaneous Proposals*, 71 Fed. Reg. 58914 (proposed Oct. 5, 2006) (codified at 14 C.F.R. pts. 1, 21, 43, 45) (discussing 14 C.F.R. § 21.319, pertaining to design changes to PMA parts, and “add[ing] requirements for classifying and approving PMA design changes”).

<sup>100</sup> See *United Techs.*, 102 F.3d at 689.

FAA. The FARs require a type certificate holder or a PMA, under certain enumerated circumstances, to report “any failure, malfunction, or defect in any product or article *manufactured by it*.”<sup>101</sup> The law thus places the reporting responsibility on the party that holds either the type certificate or PMA *and* manufactured the part—which, in the case of PMA parts, is not the OEM.<sup>102</sup>

Practically speaking, the lack of a legal obligation does not mean that the OEM is not permitted to make such reports. Indeed, the FARs contemplate that someone other than the OEM or PMA manufacturer may report defective product issues to the FAA.<sup>103</sup> An OEM thus could report PMA product defects to the FAA. But regardless of the source of the report, it is ultimately the FAA’s prerogative to take the action it deems appropriate, which could include, for example, revocation of the PMA,<sup>104</sup> issuance of an airworthiness directive,<sup>105</sup> or nothing at all. Even assuming an OEM were somehow aware of issues with a PMA part, and reported those issues to the FAA, the OEM would still be unable to exert any direct, meaningful pressure on the PMA manufacturer with regard to safety. At best, an OEM has the same ability to exert indirect pressure on the PMA manufacturer as any other person making a report to the FAA.<sup>106</sup> If such indirect and attenuated pressure were enough to warrant strict lia-

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<sup>101</sup> 14 C.F.R. § 21.3(a) (2016) (emphasis added).

<sup>102</sup> See *Dalrymple v. Fairchild Aircraft Inc.*, 575 F. Supp. 2d 790, 797 (S.D. Tex. 2008) (“By its plain terms, § 21.3(a) applies only to a type certificate holder that *also* manufactured the subject product or part that is determined to be defective. Although Defendant held the type certificate for the SA 226-AT at the time of the accident, it is undisputed that Swearingen, not Defendant, manufactured the aircraft. The reporting requirement in § 21.3(a) does not apply to a non-manufacturer such as Defendant.”).

<sup>103</sup> See 14 C.F.R. § 21.3(d)(1)(ii) (carving out of Section 21.3’s reporting obligations for “[f]ailures, malfunctions, or defects” that “[w]ere reported to the FAA by another person”).

<sup>104</sup> See 14 C.F.R. § 21.313 (2016).

<sup>105</sup> See *id.* § 39.5 (2016).

<sup>106</sup> It could be argued that the OEM could exert pressure on the PMA manufacturer by surrendering its type certificate completely. See *id.* § 21.51 (“A type certificate is effective until surrendered, suspended, revoked, or a termination date is otherwise established by the FAA.”). This would be a drastic step that would have little, if any, effect on PMA manufacturers. Surrender of a type certificate would cause all production of the type-certificated product to stop, but it would not necessarily result in a revocation of airworthiness certificates from existing products already on the market, nor would it prevent PMA holders from continuing to manufacture parts. See *Type Certification*, FAA Order No. 8110.4C, § 3-2 (Dec. 20, 2011).

bility against the OEM with respect to PMA parts, it is difficult to see any limit to the OEM's potential liability.

In the absence of a right to intervene or appeal from the FAA's grant of PMA approval to a third party, an OEM simply does not have any meaningful influence over a PMA manufacturer's production and sale of spare parts.

### 3. *Managing Complexity*

Courts often refuse to extend strict liability based on the need to avoid injecting unnecessary complication into already complex product liability cases. As the court in *Exxon Shipping* noted:

[T]he need to preserve a bright line in the law of strict products liability (that is, a chain of title rule) is evident. For example, if an assembler were strictly liable for an "identical" replacement part purchased from a third party, the court would be forced to conduct an inquiry into whether the original and the replacement parts were manufactured by the same company. . . . If so, whether the original and the replacement parts were sufficiently similar? . . . If so, whether the original and replacement parts were manufactured utilizing a similar process and similar materials? If so, at what point [in] time did the endorsement by the assembler of the component manufacturer come to an end, if ever? Each of these questions would have to be answered in order to support liability . . . notwithstanding the other justifications for strict liability.<sup>107</sup>

These concerns are especially compelling in the aviation context.

One could argue that the PMA regulatory approval process largely alleviates such concerns—after all, the FAA already has determined identity or, at least, functional equivalence and already has approved of the manufacturing and quality control processes. However, this argument assumes that a court and the parties are necessarily bound by the FAA's determinations. Given the OEM's absence from the PMA process, and the fact-intensive nature of these issues, a court is unlikely to impose the FAA's determinations on the OEM without at least giving it an opportunity to rebut them. Indeed, due process would compel it to do so.<sup>108</sup> Consequently, the existence and possible use of the

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<sup>107</sup> *Exxon Shipping Co. v. Pac. Res., Inc.*, 789 F. Supp. 1521, 1527–28 (D. Haw. 1991).

<sup>108</sup> Moreover, although the FAA's determinations may be presumed admissible as public records, it is not a given that they would be admitted into evidence, let alone given conclusive weight. For example, courts have refused to admit both

FAA's PMA determinations ultimately would not avoid, and may even exacerbate, the complicated nature of these already-complex cases.

#### B. ABANDONING THE BRIGHT-LINE RULE, REVISITED

As discussed above, in some asbestos cases, a minority of jurisdictions have considered and recently adopted an exception to the bright-line rule against imposing strict liability on original manufacturers for products manufactured and sold by a third party. According to the California Supreme Court, for example, a "stronger case" for strict liability can be made if the OEM's product "required the use of a defective part in order to operate."<sup>109</sup> In most PMA cases, this exception would seem to have little effect on the outcome of the case—after all, an OEM usually does not design its product to require a PMA replacement part. There is one potential scenario, though, that warrants a closer look. What if, instead of a PMA gadget, the part at issue was the same model and part number gadget used on the OEM's product, but was simply purchased directly from the OEM's supplier? Couldn't this be one of the "narrow circumstances"<sup>110</sup> contemplated by *May* or *O'Neil* in which strict liability could apply because the type-certificated product was designed specifically to operate with that part?

This was the precise fact pattern in the *Exxon Shipping* case—a case in which the court rejected the imposition of strict liability under such circumstances, given the policies underlying assembler liability.<sup>111</sup> Cases such as *May* and *In re New York City Asbestos Litigation* rejected, either expressly or implicitly, the holdings in cases like *Crane* and *Exxon Shipping*, but failed to meaningfully address the policy justifications for the bright-line rule—a flaw in the majority's reasoning that the dissenting and concurring

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National Transportation Safety Board staff factual reports and FAA airworthiness directives under Federal Rule of Evidence 803(8)(C), where circumstances suggest that they are untrustworthy. See generally William D. Janicki, *Aircraft Accident Reports and Other Government Documents: Evidentiary Use in International Air Crash Litigation in the United States*, 74 J. AIR L. & COM. 801 (2009) (examining the evidentiary use of civil and military accident reports and other government documents in plane accident litigation).

<sup>109</sup> *O'Neil v. Crane Co.*, 266 P.3d 987, 996 n.6 (Cal. 2012).

<sup>110</sup> *May v. Air & Liquid Sys. Corp.*, 129 A.3d 984, 995 (Md. 2015); see also *O'Neil*, 266 P.3d at 998 n.7.

<sup>111</sup> *Exxon Shipping*, 789 F. Supp. at 1526–27.

opinions in both cases emphasized.<sup>112</sup> While *May* never reaches these questions, *In re New York City Asbestos Litigation* flips the policy consideration on its head, opining that an original product manufacturer “benefit[s] from the sale of the essential third-party product, as the manufacturer is able to sell its own product to customers [precisely] because the third party has sold to those customers another item that is essential to the product’s function.”<sup>113</sup> However, the logic is precisely backwards. The market for the component manufacturer’s replacement part is created by the sale of the original product, not the other way around. The asbestos cases give the other most basic principles of strict liability short shrift, leaving their justification for expanding strict liability—especially outside the asbestos context—wanting. For the reasons discussed above, the policy rationales underlying strict liability apply with equal force in aviation cases and counsel against expanding the doctrine to parts not manufactured or sold by the OEM.

## VI. NEW TECHNOLOGY, NEW RULE?

An emerging technology known as additive manufacturing (or 3-D printing) “seems poised to transform the goods we buy,

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<sup>112</sup> *In re N.Y.C. Asbestos Litig.*, 59 N.E.3d 458, 484 (N.Y. 2016) (“Rather than basing liability on the defendant’s actions here, the majority, in my view, focuses on forces acting upon the product downstream from the manufacturer. While ‘design’ does suggest some affirmative step, under the majority’s test liability may also be premised, in the alternative, on ‘mechanics’—undefined—or, most troubling, ‘economic necessity.’ What level of necessity is required and when it may arise, or what ‘mechanics’ means in this context, will assuredly become questions for future juries in an expanding pool of litigation.”); *May*, 129 A.3d at 1005 (Watts, J., dissenting) (“Indeed, to adopt Petitioner’s view would lead to numerous questions and analyses that would further complicate an already complex litigation process, including inquiry as to whether the original and replacement parts are sufficiently similar, whether they are manufactured in a similar fashion with similar materials, whether the manufacturer knew of or anticipated the use of replacement parts, whether the replacement parts were integral to the product’s operation, and whether any other types of suitable replacement parts were available. . . . As a matter of public policy, a defendant who neither manufactures, sells, nor otherwise places a product into the stream of commerce generally is not in a ‘position to take precautions and protect against the defect.’ Nor is such a defendant able to ‘stand behind’ a good that it did not manufacture or sell. In other words, the justifications supporting imposition of strict liability—or liability for negligence, for that matter—on a seller or manufacturer of an injury-causing product in a failure-to-warn case are absent where the defendant is neither the seller nor the manufacturer of the product.”) (internal citations omitted).

<sup>113</sup> *In re N.Y.C. Asbestos Litig.*, 59 N.E.3d at 474.

the products we use, and the world we inhabit.”<sup>114</sup> This technology already has been used by, among others, the entertainment industry to create props and set pieces for movies, and the medical industry to create medical implants for patient use.<sup>115</sup> The technology even has found its way onto the International Space Station as a means of manufacturing tools and spare parts on site.<sup>116</sup> The emergence of this revolutionary technology, and its particular appeal to manufacturers in the aviation industry, begs the question of whether its use in aviation manufacturing should change the foregoing analysis.

By way of background, additive manufacturing is “a process of joining materials to make objects from 3-D model data, usually layer upon layer.”<sup>117</sup> It allows for the “rapid production of three-dimensional parts directly from computer models.”<sup>118</sup> A 3-D printer follows the computer-model blueprint to thinly layer materials, such as powders, to create a three-dimensional object.<sup>119</sup> Due to its versatility, as noted above, 3-D printing is gaining ground in several industries, including health care, firearms, clothing, consumer electronics, music, food, and aviation.<sup>120</sup> Indeed, for some time, the aviation industry has been using the technology to print prototype parts, and some manufacturers now are shifting to “live” commercial production.<sup>121</sup> Conse-

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<sup>114</sup> Nora Freeman Engstrom, *3-D Printing and Product Liability: Identifying the Obstacles*, 162 U. PA. L. REV. ONLINE 35, 36 (2013).

<sup>115</sup> Nicole D. Berkowitz, Note, *Strict Liability for Individuals? The Impact of 3-D Printing on Products Liability Law*, 92 WASH. U. L. REV. 1019, 1019 (2015).

<sup>116</sup> *Id.* at 1019–20.

<sup>117</sup> Jeffrey T. Leslie, Comment, *The Internet and Its Discontents: 3-D Printing, the Commerce Clause, and a Possible Solution to an Inevitable Problem*, 17 SMU SCI. & TECH. L. REV. 195, 197 (2014) (internal quotation marks omitted).

<sup>118</sup> *Id.* (quoting Emanuel Sachs et al., *Three Dimensional Printing: Rapid Tooling and Prototypes Directly from CAD Representation*, 39 CIRP ANNALS - MANUFACTURING TECH. 27, 28 (1990)).

<sup>119</sup> *Id.*

<sup>120</sup> Anne Lewis, *The Legality of 3D Printing: How Technology Is Moving Faster Than the Law*, 17 TUL. J. TECH. & INTELL. PROP. 303, 304 (2014).

<sup>121</sup> Niclas Rolander, *3-D Printed Plane Parts Help Sweden’s Arcam to Take Off*, BLOOMBERG TECHNOLOGY (Oct. 12, 2015, 2:30 AM), <http://www.bloomberg.com/news/articles/2015-10-12/3-d-printed-plane-parts-help-sweden-s-arcam-to-take-off> [https://perma.cc/E8L6-8FWP]; see also Brett Lyons, *Additive Manufacturing in Aerospace: Examples and Research Outlook*, 42 THE BRIDGE 13, 13–19 (2012) (discussing the additive manufacturing technologies being used for the production of aircraft components); *3D Printing: A Potential Game Changer for Aerospace and Defense*, 7 GAINING ALTITUDE, May 2013, <http://www.pwc.com/us/en/industrial-products/publications/assets/pwc-gaining-altitude-issue-7-3d-printing.pdf> [https://perma.cc/8NRB-7Y64] (discussing current and future applications of 3-D printing).

quently, OEMs and PMAs alike are having to establish protocols and carry out tests to prove to the FAA that 3-D printed parts are airworthy.

Outside the aviation industry, commentators have noted that 3-D printing carries with it the potential to expand strict liability beyond sophisticated corporate manufacturers. Additive manufacturing “empowers ordinary Americans to become countertop creators—and not merely of jam and lemonade, but of material that’s complicated, sophisticated, and potentially dangerous.”<sup>122</sup> Thus, a potentially broader pool of product sellers may be created and subject to strict liability.<sup>123</sup> Whether the policy rationale for strict liability applies in the case of these homegrown manufacturers or whether existing state product liability law is equipped to handle strict liability claims arising from small-scale 3-D printing has been debated in the literature. For example, some have argued that traditional justifications for strict liability do not apply in the context of home-based 3-D printing because such small sellers are “on relatively equal footing with buyers in their ability to bear the risk” of a product defect.<sup>124</sup> Others have argued that existing state laws may have trouble encompassing small-scale 3-D printing operations because so-called “hobbyist inventors” may fall outside the type and scope of commercial activity that traditionally has justified the imposition of strict liability.<sup>125</sup> Although these issues undoubtedly will need to be addressed as 3-D printing becomes more common, they will not likely affect the strict liability analysis in the aviation industry.

Despite the potential of additive manufacturing to revolutionize the production of aircraft parts, nothing about the use of the technology itself in the aviation industry weakens the policy justifications for the bright-line rule discussed above. An OEM earns no more profit on a PMA part made by a 3-D printer than it does on one manufactured using traditional methods. Likewise, an OEM plays no greater role in the design process and has no more influence over a 3-D printing manufacturer to improve the safety of the PMA component part.

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<sup>122</sup> Engstrom, *supra* note 117, at 41.

<sup>123</sup> Berkowitz, *supra* note 118, at 1039–40.

<sup>124</sup> *Id.* at 1042.

<sup>125</sup> Engstrom, *supra* note 117, at 37–38 (noting that while “someone who starts as a 3-D hobbyist could become so wrapped up in her product’s creation and distribution that she could morph into a commercial seller[,] . . . if the hobbyist forswears advertising, keeps volumes low, and limits her product’s distribution, this ‘commercial seller’ requirement . . . will limit liability”).

And the need for a bright-line rule in the context of a 3-D printed part may be even more compelling. As discussed above, courts have favored a bright-line rule for purposes of avoiding mini-trials concerning questions of identity and the sufficiency of the manufacturing process.<sup>126</sup> PMA parts manufactured by 3-D printing present all the same questions compounded by additional, new questions concerning the scanning and printing process itself. For example, if reverse-engineered from an existing part, was the scanner operating correctly? Did the printer correctly interpret the data from the scan to create a sufficiently identical model? Did the printer's software code sufficiently render the part consistent with the design? Such questions would need to be answered in determining whether the manufacturing process itself was sufficient and/or whether the finished product was substantially identical to the OEM's design.

Moreover, the process of obtaining a type certificate or a PMA is complex and requires resources and a level of aviation engineering sophistication and expertise not likely to be present in many smaller 3-D printing operations. The regulatory environment for aviation components, therefore, makes it unlikely that homegrown or small-scale 3-D printing manufacturers will undertake the approval process necessary to enter the market in the first place. Thus, the potential for the expansion of strict liability to such manufacturers in the aviation industry is limited.

At bottom, the question of strict liability discussed here turns not on *what* technology is being used to produce the part in question, but rather *who* is using the technology. And for all the reasons discussed above, only the actual manufacturer or seller of parts produced through additive manufacturing should be held strictly liable for any defects in such parts.

## VII. CONCLUSION

"Strict liability is a harsh rule and should be applied only in very limited situations."<sup>127</sup> While policy considerations may support placing the risk of harm caused by a defective product on its manufacturer through the imposition of strict liability, those same considerations counsel against extending such liability to

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<sup>126</sup> See, e.g., *Exxon Shipping Co. v. Pac. Res., Inc.*, 789 F. Supp. 1521, 1527–28 (D. Haw. 1991).

<sup>127</sup> *Carroll-Boone Water Dist. v. M. & P. Equip. Co.*, 661 S.W.2d 345, 351 (Ark. 1983).

OEMs for PMA parts that the OEM did not produce or sell. Regardless of the FAA's regulatory regime, an OEM that does not profit from the sale of a PMA component part and has no direct or otherwise meaningful control over the design or manufacturing processes involved in making the part should not be subject to strict liability for injuries arising from a defect in the part. Put simply, an OEM of an aviation product should have no greater risk of strict liability than any other product manufacturer.