

# **The Evidentiary Impact of Regulatory Action on Product Litigation in the United States**

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Manufacturers of regulated products have increasingly found themselves targeted by a strong, organized plaintiff bar pursuing mass tort and class action litigation. Because the stakes can be enormous, both sides have sought to ally themselves with the actions of relevant federal agencies such as the Food and Drug Administration ("FDA"), the National Highway Traffic Safety Administration ("NHTSA") and the Consumer Products Safety Commission ("CPSC"). As a result, agency activities -- pre-market, post-sale, or recall-related -- have become increasing sources of evidence and evidentiary disputes in product litigation.

## **Accessibility of Information Regarding Agency Activity.**

An important reason why agency activity is taking center stage in product liability litigation is the sheer accessibility of the agencies themselves. Information about what a governmental agency is doing or has done with respect to a product is becoming more and more accessible to the public – including plaintiffs' counsel. For example:

- The FDA website<sup>1</sup> has a searchable databases of warning letters and responses,<sup>2</sup> transcripts of advisory committee meetings,<sup>3</sup> FDA talk papers and press releases, recall and market withdrawal information, and safety alert archives. The FDA also provides a

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<sup>1</sup><http://www.fda.gov>

<sup>2</sup><http://www.fda.gov/foi/warning.htm>

<sup>3</sup>See <http://www.fda.gov/oc/advisory/default.htm>  
<http://www.fda.gov/cder/audiences/acspage/acslst1.htm>

searchable database for Medwatch reports<sup>4</sup> which are a common target for plaintiffs' attorneys.<sup>5</sup>

- NHTSA's Office of Defects Investigation provides a searchable, on-line database for all complaints, defect investigations, safety recalls, service bulletins, and foreign campaigns.<sup>6</sup> It allows users to search current and past NHTSA investigations of vehicles, tires and equipment by year, make or model. NHTSA's site also includes the Office of Vehicle Safety Compliance database<sup>7</sup> in which users can find pass/fail marks on compliance tests for certain vehicle models.
- The CPSC homepage links to its "Recalls and Product Safety News" site, which provides a recall database searchable by date, product type, product description, product category, or by the name of the company involved in the recall.<sup>8</sup>

Another resource for consumers is recall.gov,<sup>9</sup> a self-described "one stop shop" organized by the CPSC, concerning recalls from six different federal regulatory agencies. The easy public access to these materials, coupled with FOIA and other discovery devices, provides ready opportunities for both plaintiffs and defendants to obtain information about regulatory policies, procedures and activities.

### **Types of Agency Activity Implicated in Product Litigation.**

Evidence about all phases of regulatory activities may be sought in product litigation. While recall-related information is perhaps the most commonly sought, a post-market recall is just one aspect of regulatory activity that can come into play.

**Pre-market.** Some federal agencies begin their regulation well before the product ever makes it to the market. Perhaps the best example of a hands-on approach by an

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<sup>4</sup><http://www.fda.gov/medwatch/index.html>

<sup>5</sup>Other FDA searchable safety databases include (1) the Vaccine Adverse Event Reporting System (<http://www.vaers.org/>), and (2) the Manufacturer and User Facility Device Experience Database (<http://www.fda.gov/cdrh/maude.html>) containing all voluntary reports since June, 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August, 1996.

<sup>6</sup><http://www-odi.nhtsa.dot.gov/cars/problems/tsb/tsbsearch.cfm>

<sup>7</sup><http://www.nhtsa.dot.gov/cars/problems/comply/>

<sup>8</sup><http://www.cpsc.gov/cpscpub/prerel/prerel.html>

<sup>9</sup><http://www.recalls.gov/>. This site links to CPSC, FDA, and NHTSA websites, as well as the Environmental Protection Agency, the United States Department of Agriculture, and the United States Coast Guard.

agency prior to a the first sale of the product is the FDA, which becomes involved with products at the very initial stages of development and throughout the phases of animal and clinical testing. For prescription drugs, the FDA approves or recommends test protocols, reviews data from animal research and clinical trials, and approves labeling information, all before a prescription drug ever reaches the ultimate user. In the medical device arena, the FDA engages in an "indisputably thorough, rigorous, and costly pre-market review" of the product before it is approved for marketing. *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (describing a FDA review of a Class III medical device involving "some 1,200 FDA man-hours at hundreds of thousands of dollars in cost"). Plaintiffs, and in some instances defendants, may try to use pre-market regulatory information for various reasons, for example to prove prior knowledge of a defect, causation, or defensively to show compliance with regulatory standards.<sup>10</sup>

Although documents provided to and created by regulatory agencies on the pre-market approval process are a ready target for litigators, another attempted avenue to introduce purported regulatory evidence is through expert testimony. The better decisions bar such testimony. For example, in *In re Rezulin Products Liability Litigation*, 2004 WL 540477 (S.D.N.Y. March 17, 2004), the court granted defendants' motion in limine to bar plaintiffs' experts from testifying about the FDA's procedures and regulations for approving a new drug or

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<sup>10</sup>See, e.g., *Anderson v. Department of Health and Human Services*, 907 F.2d 936 (10<sup>th</sup> Cir. 1990) (FOIA dispute over 16,000 pages of documents submitted by manufacturer to FDA concerning product still in the testing phase and for which FDA approval was still being sought); *Sterling Drug Inc. v. Harris*, 488 F. Supp. 1019 (D.C.N.Y. 1980) (FOIA action to compel production of documents relating to the FDA's proposal to withdraw approval of new drug application for plaintiffs' prescription drug).

the FDA's motivation in making decisions in approving or removing drugs from the market. *Id.* at \*1.<sup>11</sup>

**Post-sale.** Agency review, investigation, or industry-type studies performed while a product is on the market is another potential evidentiary source for litigators in product liability lawsuits. For example, the FDA may recommend changes to the labeling of a drug based on post-market experience reports or conduct advisory committee meetings to discuss the risks and benefits of a drug while it's still on the market. Often, plaintiffs will attempt to use evidence relating to these activities to prove knowledge or causation. In *Gonzales v. Surgidev Corp.*, 899 P.2d 576, 584-86 (N.M. 1995), the plaintiff was allowed to introduce transcripts of FDA expert advisory panel hearings on risks associated with intraocular lenses in a product liability lawsuit. Similarly, in *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 138 (3<sup>rd</sup> Cir. 1973) the court allowed evidence on the manufacturer's failure to submit a FDA-mandated "New Drug Application" before recommending to physicians that a currently marketed drug be used for treatment of a different illness.<sup>12</sup>

Actions by other governmental agencies can give rise to the same types of evidentiary inquiries. In *General Motors Corp. v. Moseley*, 447 S.E.2d 302 (Ga. Ct. App. 1994), NHTSA had initiated an investigation to verify that GM had complied with federal standards on side impact collisions. Though still ongoing at the time of trial, the trial court nevertheless allowed evidence of the pending investigation to be offered into evidence during plaintiff's cross-examination of the manufacturer's chief design engineer. *Id.* at 310. The Court of Appeals

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<sup>11</sup>*Accord, In re Diet Drug, No. MDL 1203*, 2001 WL 454586, \*2 (E.D. Pa. Feb. 1, 2001) (barring expert testimony regarding "what beliefs of FDA officials were on matters upon which they spoke or acted.").

<sup>12</sup>*See also, Stanton by Brooks v. Astra Pharm. Prod. Inc.*, 718 F.2d 553, 564 (3<sup>rd</sup> Cir. 1983) (manufacturer's failure to forward 200 adverse events to FDA as required by statute deemed negligent per se).

later held this to be error, since the NHTSA investigation had not been completed nor had any conclusions been reached at the time of trial. *Id.*

Defendants also have reason in some cases to introduce evidence of post-sale regulatory activity. In *Rodriguez v. Suzuki Motor Corp.*, 996 S.W.2d 47 (Mo. banc 1999), the court held that the trial court committed reversible error in barring manufacturers from admitting evidence of NHTSA reports that critiqued the crash test methodology used by plaintiff's experts. *Id.* at 56-57. The court observed that NHTSA, when presented with a consumer's defect petition as it had in this case, was required to conduct a technical review of the petition and the agency's subsequent decision not to grant a recall petition was then required to be published in the Federal Registrar. Under Missouri's rules of evidence, these reports met the public records exception and should have been admitted. *Id.* at 56. Similarly, in *Browning v. Paccar, Inc.*, 448 S.E.2d 260, 264 (Ga. Ct. App. 1994) the court held that the trial court properly admitted the manufacturer's evidence that plaintiff's model of truck had never been subject to recall or regulatory action. "The absence of a recall is not irrelevant where, as here, the manufacturer is engaged in mass production of a vehicle over a period of many years and the claim is that each vehicle suffered from the same design defect." *Id.* at 264.<sup>13</sup>

**Recall.** Product recalls are often instigated, directly or implicitly, by federal regulatory agencies. The CPSC, for example, has statutory authority to order a manufacturer, distributor, or retailer to notify the public of a "substantial product hazard."<sup>14</sup> The Motor Vehicle Safety Act<sup>15</sup> provides NHTSA with the authority to investigate whether a defect or noncompliance exists in the manufacturer of cars and car equipment. If a evidence of a defect or

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<sup>13</sup>See also, *Olson v. Snap Products, Inc.*, 29 F. Supp. 2d 1027, 1038 (D. Minn. 1998) (manufacturer allowed to offer evidence that label complied with CPSC regulations, however this was insufficient to preclude an instruction on punitive damages).

<sup>14</sup>15 U.S.C.A. § 2064(a), (c).

<sup>15</sup>49 U.S.C.A. §§ 30101, 30103(d), 30166 (1994)

noncompliance with a safety standard is found, NHTSA may issue a recall order requiring the manufacturer to notify consumers and remedy the problem.<sup>16</sup> Similarly, the FDA is empowered to recall medical devices that pose an "unreasonable risk of substantial harm to the public health."<sup>17</sup> The FDA can also urge food and pharmaceutical manufacturers to voluntarily as an alternative to a FDA-initiated court action to compel the removal of a dangerous product.<sup>18</sup>

When a consumer good is recalled from the market – be it voluntarily or mandatory – there will almost certainly follow a fight over the admissibility of agency or manufacturer documents relating to that recall. While courts will look at the proffered evidence to determine admissibility, generally if the evidence directly relates to a recall of the specific product at issue in the litigation it will be considered relevant.<sup>19</sup> As discussed further, the harder evidentiary questions arise when the recall happens after the alleged injury, involves a similar product rather than the product at issue, or involves a defect that is not necessarily implicated in the litigation. Additional concerns arise over the purpose for which the evidence is being proffered, for example to prove causation, ownership or control, feasibility of alternative designs, or the manufacturer's knowledge of a defect. Although less common, there are also a number of cases where the manufacturer attempts to provide evidence that an agency declined to issue a recall notice.

### **Admissibility of Regulatory Evidence in Product Litigation.**

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<sup>16</sup>See *United States v. Chrysler Corp.*, 158 F.3d 1350, 1354 (D.C. Cir. 1998) ("NHTSA may seek a recall of a motor vehicle . . . when a vehicle does not comply with an applicable motor vehicle safety standard . . . . An allegation of noncompliance may or may not include a charge that a vehicle has a safety defect").

<sup>17</sup>21 U.S.C.A. § 360h. Note, however, that the FDA defines recall as "a firm's removal or correction of a marketed product that the Food and Drug Administration of the laws it administers and against which the agency would initiate legal action, e.g., seizure. 'Recall' does not include a market withdrawal or a stock recovery." 15 U.S.C.A. § 2064(d).

<sup>18</sup>Other agencies vested with recall power are the U.S. Coast Guard, 46 U.S.C.A. § 1464 (recreational boats with safety defects), and the Department of Health and Human Services, 21 U.S.C. § 360ll(f) (electronic products emitting unsafe radiation).

<sup>19</sup>See generally, *Firestone Tire & Rubber Co. v Adams*, 541 A. 2d 567 (Del. 1988).

As the internet has made government fact-finding documents more accessible, parties have increased their attempts to use this information in product liability litigation. Both plaintiffs and defendants have made arguments for and against the introduction of regulatory evidence at summary judgment or trial when offered as proof of causation, prior knowledge of a specific defect, ownership or control of the product at issue, duty to warn or the adequacy of a warning, or to support or refute expert testimony. In turn, courts are increasingly tasked with determining the admissibility of the proffered regulatory evidence that was acquired from third-party agencies. As with most types of evidence, there is no bright line rule for when regulatory evidence will be admissible in summary judgment or trial. Hurdles such as the hearsay doctrine, subsequent remedial measures, and relevance often hinder a party's ability to use documents acquired through a regulatory agency. Generally speaking, however, the purpose for which the evidence is being offered will have a considerable impact on whether or not a court will find the evidence admissible.

### **Hearsay and the Public Records Exception.**

Perhaps the most commonly fought battle over the admissibility of regulatory evidence is the application of the hearsay doctrine. The focus of this debate generally centers on whether the document falls under the "public records" exception to the hearsay rule. Under the Federal Rule of Evidence 803(8), the hearsay exclusion does not apply to: "records, reports, statements, or data compilations, in any form, of public offices or agencies, setting forth (A) the activities of the office or agency, or (B) matters observed pursuant to duty imposed by law as to which matters there was a duty to report . . . or (C) . . . factual findings resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness." With the plethora of different types of

documents, reports, and even testimony available to parties, courts have been unable to formulate hard line rules governing when a document will meet the public records exception. Importantly, however, the burden of proving untrustworthiness of regulatory material is on the party opposing admission of the evidence. *Kehm v. Procter & Gamble Manufacturing Co.*, 724 F.2d 613, 618 (8th Cir. 1983).

Though couched in different challenges under the exception, the determinative factor over whether or not a document will be admissible as a public record is whether the offered government documents are sufficiently reliable to qualify as a public record. In *Kehm*, *supra*, the court noted that the public records exception rests on "the assumption that a public official will perform his duty properly and the unlikelihood that he will remember details independently of the record." The rule "assumes admissibility in the first instance but with ample provision for escape if sufficient negative factors are present." *Id.* at 618 (admitting Center for Disease Control evaluation of toxic shock syndrome based on doctor and patient questionnaires). For example, in *Figueroa v. Boston Scientific Corp.*, 2003 WL 21488012 (S.D.N.Y., June 27, 2003), the court, ruling on the manufacturer's motion in limine to exclude evidence, held that a FDA report setting forth risks associated with the use of a medical device was admissible hearsay. The court determined that the document at issue "was a 'report' or 'statement' of a public agency, the FDA, setting forth 'matters observed pursuant to duty imposed by law as to which matters there was a duty to report,' namely, health risks presented by use of a medical device." *Id.* at \*3.<sup>20</sup> In *Gonzales v. Surgidev Corp.*, 899 P.2d 576, 584-86 (N.M. 1995),

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<sup>20</sup>See also, *Thirsk v. Ethicon, Inc.*, 687 P. 2d 1315, 1318 (Colo. Ct. App. 1983) (FDA reports admissible); *Pine St. Trading Corp. v. Farrel Lines, Inc.*, 364 A.2d 1103, 1110-11 (Md. 1976) (admitting FDA analyses of condemned goods as proof of damages in claim over contamination of goods); *Becker v. National Health Products, Inc.*, 896 F. Supp. 100, 104

plaintiff was allowed to introduce transcripts of FDA expert panel hearings on intraocular lenses in a product liability lawsuit. The court noted that the "Panel was under a duty to hold hearings and make findings concerning the safety and efficacy of the Style 10 lens," and further reasoned that the manufacturer had representatives present at the panel hearing and could have corrected any factual mistakes, the panel consisted of well qualified experts, and there was no evidence of bias. *Id.*, at 585-586.<sup>21</sup> In *Guild v. General Motors Corp.*, 53 F. Supp. 2d 363 (W.D.N.Y. 1999) the manufacturer successfully argued for the admission of a NHTSA study under the public record exception to show proof of non-defect. The court held that even though the report contained conclusions as well as factual findings, the conclusions were "factually based and thus reliable." *Id.* at 366. Similarly, in *In re Multi-Piece Rims Products Liability Litigation*, 545 F. Supp. 149 (W.D. Mo. 1982) the court held that correspondence from NHTSA urging manufacturers to initiate a voluntary recall campaign of their products to obviate the necessity of further Agency investigative efforts was admissible under the public records exception to the hearsay rule.

Not all agency documents will pass muster under the public records exception to the hearsay rule. In *Smith v. Isuzu Motors*, 137 F.3d 859, 862 (5<sup>th</sup> Cir. 1998), the court held that internal memoranda prepared by NHTSA staff were not public records and did not qualify as a hearsay exception under Rule 803(8). In reaching its conclusion, the court observed that the documents contained preliminary or interim opinions about research on safety of particular types of vehicles and did not reflect factual findings. Similarly, in *Henkel v. R and S Bottling Co.*, 323 N.W.2d 185, 192-93 (Iowa 1981), the Iowa Supreme Court affirmed the trial court's exclusion of

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(N.D.N.Y. 1995) (holding that FDA "complaint/injury reports" were admissible under the public records exceptions to show the manufacturer's notice of a defect).

<sup>21</sup> *Cf. Baker v. Firestone Tire & Rubber Co.*, 793 F.2d 1196 (11<sup>th</sup> Cir. 1986) (finding politically-motivated congressional committee report inadmissible).

evidence of a CPSC "hazard analysis". The court concluded that the CPSC report, containing information from largely unverifiable sources such as un-investigated consumer complaints, lacked the indicia of trustworthiness necessary for admissibility under the public records exception and that the report was therefore inadmissible.<sup>22</sup>

To the extent a party wants to keep out evidence under the hearsay doctrine, it is important to keep in mind the possibility that the document, report or testimony could still be used for impeachment purposes. For example, in *Gamblin v. Ford Motor Co.*, 513 S.E.2d 467 (W. Va. 1998), the West Virginia Supreme Court upheld the trial court's determination that a letter from a NHTSA official to a manufacturer was inadmissible hearsay under the public records exception, however the court reversed the defense verdict on the grounds that the plaintiff should have been able to use the same document to impeach the manufacturer's witness. The court reasoned that the letter should have been available to the plaintiff for cross-examination purposes after a former executive of the manufacturer testified that the company had submitted all documentation requested by NHTSA, yet the letter from the agency indicated that certain materials had not been provided. *Id.*, at 467.

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<sup>22</sup>See also, *Swallow v. Emergency Medicine of Idaho, P.A.*, 67 P.3d 68, 73 (Idaho 2003) (trial court properly excluded FDA adverse event reports showing 10 patients taking Cipro suffered myocardial infarction. Evidence was not reliable because there was no information in these reports to show what percentage of drug recipients experienced this reaction or whether such a percentage would be statistically significant); *Toole v. McClintock*, 999 F.2d 1430, 1433-35 (11th Cir. 1993) (trial court erred in admitting FDA report of "proposed findings" regarding risks associated with silicone breast implants under the public records exception). *Volkswagen of America, Inc. v. Gentry et al.*, 564 S.E.2d 733 (Ga. App. 2002) (Letter written by NHTSA director was inadmissible hearsay); *McKinnon v. Skil Corp.*, 638 F.2d 270, 278-80 (1st Cir.1981) (proffered CPSC reports contained multiple levels of hearsay and were thus deemed unreliable and properly excluded by the trial court).

### **Admissibility of Recall Letters.**

When a product is recalled from the market – be it a voluntary or mandatory recall – there will almost certainly follow a fight over the admissibility of agency or manufacturer documents relating to that recall. The threshold question is whether the proffered document or testimony is relevant to the instant litigation. Close on the heels of that issue, however, is whether the evidence should be excluded as a subsequent remedial measure.

**Relevancy.** While courts will look at the proffered evidence, generally if the evidence directly relates to a recall of the specific product at issue in the litigation it will be considered relevant.<sup>23</sup> More troubling to the courts are cases where plaintiffs attempt to introduce evidence of a recall of either a different product, or of a different defect, than those at issue in the instant litigation.

Courts do not always require that both the product and defect at issue in the recall match that at issue in the lawsuit. For example, in *Hessen v. Jaguar Cars, Inc.*, 915 F.2d 641, 648-49 (11th Cir. 1990) it was held that the trial court properly admitted evidence of a recall campaign even though the vehicle at issue in the litigation was not included in recall. The court determined that the plaintiff could show that alleged defect in vehicle was the same as defect involved in recall, and therefore the evidence was relevant.

**Subsequent remedial measures.** Courts have long recognized the doctrine of excluding evidence of subsequent remedial measures.<sup>24</sup> Federal Rule of Evidence 407 has expressly adopted this exclusion, reading in part:

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<sup>23</sup>See generally, *Firestone Tire & Rubber Co. v Adams*, 541 A2d 567 (Del. 1988); *Gordon Harper Harley-Davidson Sales, Inc. v Cutchin*, 350 S.E.2d 609 (Va. 1986).

<sup>24</sup>See *Columbia & Puget Sound Railroad Co. v Hawthorne*, 144 U.S. 202, 207 (1892) ("[E]vidence [of subsequent remedial measures] is incompetent, because the taking of such

When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design or a need for a warning or instruction.

Generally, Rule 407 excludes evidence of subsequent remedial measures as proof of an admission of fault, to encourage remedial steps to improve products in the future by holding such evidence inadmissible in the past except in some limited circumstances. *See generally Bauman v. Volkswagenwerk Aktiengesellschaft*, 621 F.2d 230, 233 (6th Cir. 1980).

Despite the subsequent remedial measures doctrine, plaintiffs are often successful in introducing evidence of recall evidence in product liability cases.<sup>25</sup> One explanation for this is the inherent limit in applicability of the doctrine, which only bars evidence of subsequent remedial measures to prove negligence. As an initial matter, courts are split as to whether the rule applies to strict liability claims.<sup>26</sup> Further, Rule 407 expressly allows for the introduction of evidence of subsequent measures "when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment." Fed. R. Evid. R. 407. So, for example, in *Manieri v. Volkswagenwerk A.G.*, 376 A.2d 1317, 1323 (N.J. Super. Ct. App. Div. 1977) the court found that recall letters were inadmissible to establish

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precautions against the future is not to be construed as an admission of responsibility for the past.").

<sup>25</sup>The rules against admitting evidence of subsequent remedial measures arises in other contexts involving agency activity. For example, in *Werner v. Upjohn Co., Inc.*, 628 F.2d 848, 853 (4<sup>th</sup> Cir. 1980) *cert. denied* 101 S.Ct. 862, 449 U.S. 1080, 66 L.Ed.2d 804 (1981), the court found that the trial judge committed reversible error in allowing evidence of change in drug labeling after the time plaintiff was injured. Although the trial judge instructed the jury that it was only on the issue of feasibility that they should consider the manufacturer's subsequent, revised warning as to the drug's side effects, it was clear that such warning was used by plaintiff to prove negligence, and should have been barred under the doctrine of subsequent remedial measures.

<sup>26</sup>*See generally*, Brian C. McManus, *Admissibility of Evidence of Subsequent Remedial Measures in Strict Liability*, 70 Def. Couns. J. 240 (April 2003).

defendant's negligence or culpable conduct because they were evidence of subsequent remedial measures, the evidence was admissible to prove that the alleged defect originated while in manufacturer's control. In *Gordon Harper Harley-Davidson Sales, Inc. v Cutchin*, 350 S.E.2d 609 (Va. 1986), the court found that such evidence is uniquely relevant as proof of the manufacturer's knowledge of the potential danger and violation of its duty to warn. In addition, courts have allowed recall evidence when offered to corroborate other evidence of the existence of a defect. See *Gauche v. Ford Motor Co.*, 226 So. 2d 198 (La. Ct. App. 4<sup>th</sup> Cir. 1969). In considering whether any of the exceptions apply, the critical question is the purpose for which the evidence is offered.<sup>27</sup>

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<sup>27</sup>In products liability actions, the admissibility of recall letters to prove ownership and control does not often arise because the product at issue is usually owned or controlled by the plaintiff or a third party and not the manufacturing defendant.