Preventing Admission of Product Recall Evidence Against Your Medical Device Client

Marisa A. Trasatti[†]
Lydia S. Hu[‡]

I. INTRODUCTION

Toyota, Peanut Butter, Vioxx--You can probably guess what this car manufacturer, food, and pharmaceutical have in common – each has been the subject of a full scale product recall. In 2010, Toyota made headline news with its recall of several million vehicles due to faulty accelerators. Just a year earlier, peanut butter was in the hot seat when the Food and Drug Administration ("FDA") recalled thousands of peanut butter products due to salmonella concerns. Several years prior, in 2004, Vioxx was pulled from the shelves when the miracle arthritis drug was linked to elevated risks for heart attack and stroke.

Product recalls often affect the goods we rely upon in our daily lives; from our methods of transportation, to the foods we consume, and even the medications prescribed to relieve common aches and pains. For that reason, media channels and internet buzz tout the product recalls as the latest headline news story, leaving almost no member of the general public unaware. While the "real-time" broadcast of recent product recalls serves a purpose, i.e., warning consumers of product hazards, an unintended consequence is that it also taints jury pools.

Impaneling a jury that has been tainted by media and internet coverage complicates trial strategy. For example, medical device recalls are typically addressed to physicians, and the general public remains somewhat reliant on those learned intermediaries to convey any necessary warnings, etc. This does not mean that medical device recalls are not finding their way to the headlines and indeed, since at least 2007, there has been an uptick in the frequency at which such recalls are occurring. By way of illustration, in 2006, the FDA recalled eighteen (18) medical devices;[1] in 2007, the FDA recalled twenty-four (24) medical devices;[2] in 2008, the FDA

[†] Ms. Trasatti is a Principal at Semmes, Bowen, and Semmes in Baltimore, Maryland whose practice focuses on drug and medical device litigation.
[‡] Ms. Hu is an Associate at Semmes, Bowen, and Semmes in Baltimore, Maryland whose practice focuses on products liability.
[1] *See 2006 Medical Device Recalls*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm217449.htm (last visited July 22, 2011).
[2] *See 2007 Medical Device Recalls*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm217447.htm (last visited July 22, 2011).

recalled eighteen (18) medical devices;[3] in 2009, the FDA recalled thirty-one (31) medical devices;[4] and in 2010, the FDA recalled fifty-five (55) medical devices.[5]

This sets the stage for an uphill battle in preventing admission of this evidence at trial, for crafting limiting instructions when representing medical device clients, and for preventing mistrials associated with 20th century jurors who are savvier than the passive jurors of yesteryears.[6] This article addresses arguments litigators can make to prevent the jury from being further tainted by recall evidence. A seasoned litigator will presume that the jury has likely experienced or heard about a product recall in general, and is likely prejudiced. A shrewd plaintiffs' lawyer will use this juror suspicion tactically to curry sympathy for his or her "every man" client. Trial counsel has to understand how to adapt their approaches in light of juror sophistication, expectations, and perceptions, especially in product liability cases. This article aims to demystify the handling of recall evidence in product liability cases, explain the pitfalls of common objections to excluding the evidence, and map Plaintiff's typical strategy for gaining admission of the harmful evidence.

II.
OBJECTIONS

A. The Recall Evidence Is Inadmissible Hearsay.

The hearsay objection can be successfully implemented to exclude evidence of a recall against a product distributor, as opposed to a manufacturer. Distributor defendants should argue that the recall letters are out-of-court, written statements by the product manufacturers, and are thus, inadmissible hearsay.[7]

When the recall letter issued by the manufacturer is introduced by plaintiffs against a manufacturer defendant, however, several exceptions may thwart the application of the hearsay rule. First, the recall notices issued by your manufacturer client is a statement by a party-opponent.[8] Second, Plaintiff may argue, under Federal Rule of Evidence 804(b)(3),[9] that the

[3] *See 2008 Medical Device Recalls,* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *http*://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm217446.htm (last visited July 22, 2011).

[4] *See 2009 Medical Device Recalls,* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm217445.htm (last visited July 22, 2011).

[5] *See 2010 Medical Device Recalls,* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm238423.htm (last visited July 22, 2011).

[6] In recent years, a new term has entered the legal lexicon: The "Google mistrial" was coined to describe the mistrials declared because of jurors' use of the Internet to conduct research about the case whether that be product related, recall-related, etc. For example, in a 2009 Federal drug trial in Florida, nine of the twelve (12) jurors admitted to researching the case on the Internet. *See* Deirdra Funcheon, *Jurors and Prosecutors Sink a Federal Case Against Internet Pharmacies*, BROWARD PALM BEACH NEW TIMES (Apr. 23, 2009), http://www.browardpalmbeach.com/2009-04-23/news/jurors-and-prosecutors-sink-a-federal-case-against-internet-pharmacies/2/.

[7] *See* Higgins v. Gen. Motors Corp., 465 S.W.2d 898 (Ark. 1971) (holding that a recall letter issued by the manufacturer was inadmissible against the product dealer, but admissible as against the manufacturer).

[8] *See* FED. R. EVID. 801(d)(2); *Higgins,* 465 S.W.2d 898.

recall letters are "statements against interest" and as admission by the manufacturer that the product was defective. Under this rule, the unavailability of your designee to testify is irrelevant.[10] Third, opposing counsel may argue that records relating to the recall fall under the business records exception, provided by Rule 803(8),[11] allowing the court to admit evidence of the product recall.[12]

Aside from the various exceptions to the hearsay rule, plaintiffs' attorneys may also argue that an *involuntary* product recall, one conducted pursuant to statute or regulatory mandate, is not a statement. Some courts reason that a product recall conducted pursuant to statutory requirement, in contrast to a *voluntary* recall, is not a voluntary admission, thus falling outside the definition of a "statement"[13] for purposes of the hearsay rule.[14] As discussed below, admitting an involuntary recall will also preclude other avenues for exclusion, namely, the Subsequent Remedial Measures ("SRM") exclusion. Thus, careful consideration should be given at the recall stage so that the manufacturer understands the long-term litigation impact of a conducting a voluntary recall versus an involuntary recall.

B. The Recall Evidence Is Irrelevant.

Defendants can seek to exclude product recall evidence as not relevant under Federal Rules of Evidence 401[15] and 402.[16] The relevancy objections may stem from several aspects of the product recall evidence, as outlined below:

---

[9] "The following are not excluded by the hearsay rule if the declarant is unavailable as a witness: . . . (3) *Statement against interest.* A statement which is at the time of its making so far contrary to the declarant's pecuniary or proprietary interest, or so far tended to subject the declarant to civil or criminal liability, or to render invalid a claim by the declarant against another, that a reasonable person in the declarant's position would not have made the statement unless believing it to be true. A statement tending to expose the declarant to criminal liability and offered to exculpate the accused, is not admissible unless corroborating circumstances clearly indicate the trustworthiness of the statement." FED. R. EVID. 803(8).

[10] *See* Herndon v. Seven Bar Flying Serv., Inc., 716 F.2d 1322 (10th Cir. 1983); *see also* Farner v. Paccar, Inc. 562 F.2d 518 (8th Cir. 1977); Rozzler v. Ford Motor Co., 573 F.2d 1332 (5th Cir. 1978); Millette v. Radosta, 404 N.E.2d 823 (Ill. App. Ct. 1980).

[11] "Records, reports, statements, or data compilations, in any form, of public offices, 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 observed pursuant to duty imposed by law as to as to which matters there was a duty to report, excluding, however, in criminal cases matters observed by police officers and other law enforcement personnel, or (C) in civil actions and proceedings and against the Government in criminal cases, 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." FED. R. EVID. 803(8).

[12] *See generally In re* Multi-Piece Rims Prods. Liab. Litig., 545 F. Supp. 149 (W.D. Mo. 1982) (admitting a letter written by an employee based on product testing and suggesting that the manufacturer issue a product recall, pursuant to Federal Rule of Evidence 803(8), because the letter constituted factual findings resulting from an investigation pursuant to authority granted by law).

[13] "A 'statement' is (1) an oral or written assertion or (2) non-verbal conduct of a person, if it is intended by the person as an assertion." FED. R. EVID. 801(a).

[14] *See* Vockie v. Gen. Motors Corp., Chevrolet Div., 66 F.R.D. 57 (D. Pa. 1975), *aff'd*, 523 F.2d 1052 (3d Cir. 1975) (holding that the manufacturer should not be penalized for issuing a product recall to comply with the Federal National Traffic and Motor Vehicle Safety Act).

[15] "'Relevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." FED. R. EVID. 401.

a) Not the Same Product.

Defendant should object when the product recall evidence relates to a product that is not *identical* to the product at issue in the litigation.[17] *Similar* products are not the *same* products. Even small variations in products implicate design differences.

b) No Evidence That the Product At Issue Was Defective.

A few bad apples should not spoil the whole bunch. Often times, a product recall will capture all units manufactured although only a small percentage is actually defective. Do not let this fact be left unheard by the judge, especially if the specific product at issue in your case has been spoliated. Differences in lots, manufacturing plants and protocols, and batches matter.

Moreover, product recall evidence "cannot be used to make the transition from the general to the particular" to prove that the particular product at issue in the litigation contained the defect to which the product recall related.[18] In *Vockie*, Plaintiffs alleged that a 1965 Pontiac contained a defective brake hose and sought to introduce evidence of Pontiac's recall for the same defect. Not all vehicles recalled actually had the defect, however. The court excluded the recall evidence because there was no evidence that a particular vehicle at issue in the case had the defective part. Thus, Plaintiff's attempt to prove the defect by moving from the general product recall to the specific product at issue, without any evidence that the specific product was defective, was rejected by the court.[19]

This factual background also lends itself to an objection, based on Federal Rule of Evidence 403,[20] that the probative value of the evidence far outweighs its prejudicial value.[21]

c) Not the Same Defect.

---

[16] "All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible." FED. R. EVID. 402.

[17] *See* Jordan v. Gen. Motors Corp., 624 F. Supp. 72 (E.D. La. 1985) (excluding evidence of a product recall for the 1986 model, when the vehicle at issue was the 1987 model).

[18] *See Vockie*, 66 F.R.D. at 61.

[19] *See id.*; *see also* Calhoun v. Honda Motor Co., 738 F.2d 126 (6th Cir. 1984); Harley-Davidson Motor Co. v. Daniel, 260 S.E.2d 20 (Ga. 1979); Holmquist v. Volkswagon of Amer., Inc., 261 N.W.2d 516 (Iowa 1977); Glynn Plymouth, Inc. v. Davis, 170 S.E.2d 848 (Ga. Ct. App. 1969) (excluding evidence of the product recall because the recall applied to all vehicles while indicating only a small number of vehicles would be affected; and, it could not be assumed that the vehicle at issue "was one of the small percentage" to have the defective part without some evidence of it).

[20] "Although relevant evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." FED. R. EVID. 403.

[21] *See* Bizzle v. McKesson, 961 F.2d 719 (8th Cir. 1992) (holding that the recall evidence's minimal probative value was outweighed by dangers of unfair prejudice to defendant because of possibility that particular product was not subject to the recall).

Evidence of other product recalls relating to the same product, but *different* defects and/or different mechanisms of failure should prompt relevancy objections.[22]

d) Not the Proximate Cause of the Accident.

After establishing that the defect for which the recall was implemented *was* present in the specific product, the plaintiff must establish the defect was the proximate cause of the injury. If plaintiff is unable to establish the proximate cause connection, then evidence of the recall should be excluded on relevancy grounds.

C. The Subsequent Remedial Measures Rule Excludes The Recall Evidence.[23]

The SRM rule excludes evidence of a party's corrective action following the discovery of a failure and/or injury. The rule is found at Federal Rule of Evidence 407, and it provides:

> 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. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.

Evidence of a SRM is excluded for public policy reasons. The first is that "the conduct is not in fact an admission."[24] Second, manufacturers should be encouraged in, or at least not discouraged from, taking steps that further public safety.[25] By excluding the evidence, manufacturers are incentivized to promptly correct a defect or hazard without fear of fall-out that the corrective actions taken will somehow be used against the manufacturer in a subsequent personal injury action.[26]

A remedial measure is an action that, had it been taken earlier, would have made the injury less likely to occur.[27] Product recalls fall within this definition of remedial measures because had the recalls been activated sooner, then injury allegedly caused by the product would

[22] *See* Olson v. Ford Motor Co., 410 F. Supp. 2d 869 (D. ND. 2006) (the trial court granted defendant's motion *in limine* to preclude the introduction of four Ford Motor product recalls, none of which related to alleged failure of the speed control cable involved in the underlying action).
[23] While this objection is not always available, the reasons for which are discussed *infra*, defense attorneys should be well-versed in the subsequent remedial measures doctrine, especially in medical device cases.
[24] *See* FED. R. EVID. 407 advisory committee's note.
[25] *Id.*
[26] This is akin to the rationale for protecting medical review committee actions taken with respect to medical professionals. *See* St. Joseph Md. Ctr., Inc. v. Cardiac Surgery Assocs., P.A., 896 A.2d 304, 314–315 (2006).
[27] *See* FED. R. EVID. 407; Rocky Mountain Helicopters, Inc. v. Bell Helicopters Textron, 805 F.2d 907, 918 (10th Cir. 1986).

have been less likely to occur.[28] Although a general removal of a product from the marketplace is sufficient to provide grounds for subsequent remedial measure protection, even a partial removal may afford the manufacturer defendant protection.[29]

Not all records relating to product recalls are excluded by Rule 407, however. *Federal Register* published settlements, recall letters, and press releases are not admissible to prove negligence, culpable conduct, a defect in a product, a defect in the product's design, or a need for warnings.[30] By contrast, post-accident studies, tests, and reports may fall outside of the exclusionary power of Rule 407, even if these documents later lead to a recall campaign. The studies, tests, and reports, taken alone, would not have made the injury less likely to occur, and thus, the public policy argument no longer applies.[31]

The application of Rule 407 is somewhat narrow. Already mentioned is the requirement that the remedial measure must actually be one that makes the injury less likely to have occurred. Defense attorneys should be prepared to confront the following plaintiff arguments that, if successful, will circumvent the SRM exclusion of recall evidence:

SRM Does Not Apply When The Recall Is Involuntary: SRM actions must be voluntary actions taken by the party in order to be excludable. As previously mentioned, mandatory, or involuntary, recall campaigns are not "remedial measures" for the purpose of Rule 407. Plaintiff will bear the burden of proving that the recall was involuntary to overcome the subsequent remedial measure exclusion.

In *HDM Flugservice GmbH v. Parker Hannifin Corp.*, Plaintiff sued for damage to his helicopter when landing gear allegedly failed to operate properly.[32] Plaintiff sought to introduce evidence that Defendant modified its safety manual shortly after the incident to require more thorough equipment inspections. Plaintiff argued that the modification was a mandatory response pursuant to a federal regulatory agency's directive, which fell outside the exclusionary power of Rule 407. The Court agreed that Rule 407 only applies to voluntary recalls, but disagreed that the Defendant's actions were required by the agency such that they were involuntary. The Court found that the Defendant's initial communication and continued cooperation with the federal agency demonstrated voluntary participation and action.

Proving that a recall campaign is involuntarily conducted requires more than a mere showing that a federal agency is involved. Still, however, it remains unclear what level of

---

[28] *Compare* Chase v. Gen. Motors Corp., 856 F.2d 17 (4th Cir. 1988), *and* Vockie v. Gen. Motors Corp., Chevrolet Div., 66 F.R.D. 57 (D. Pa. 1975), *aff'd*, 523 F.2d 1052 (3d Cir. 1975), *and* Fields v. Volkswagen of Am., Inc., 555 P.2d 48 (Okla. 1976), *and* Landry v. Adam, 282 So.2d 590 (La. Ct. App. 1973), *and* Gauche v. Ford Motor Co., 226 So.2d 198 (La. Ct. App. 1969), *with* Barry v. Manglass, 389 N.Y.S.2d 870 (1976).

[29] *See In re* Propulsid Prods. Liab. Litig., No. 00-2577, 2003 U.S. Dis. LEXIS 3824 (E.D. La. March 11, 2003) (holding that defendant's implementation of a restricted-availability program for a prescription drug, instead of a full-scale removal, qualified for subsequent remedial measure protection and exclusion from trial because the defendant's actions would have made the injury less likely to occur).

[30] *See Vockie*, 66 F.R.D. 57.

[31] *See* Benetiz-Allende v. Alcan Aluminio do Brasil, 857 F.2d 26, 33 (1st Cir. 1988); *Rocky Mountain Helicopters, Inc.*, 805 F.2d at 918.

[32] *See* 332 F.3d 1025 (6th Cir. 2002).

government involvement is required to warrant a determination that the recall campaign is involuntary. In the context of medical devices, involuntary and mandatory recalls are rare. The FDA posted the following on its website:

> In most cases, a company (manufacturer, distributor, or other responsible party) recalls a medical device on its own (voluntarily). When a company learns that it has a product that violates FDA law, it does two things:
>
> - Recalls the device (through correction or removal)
> - Notifies the FDA.
>
> Legally, FDA can require a company to recall a device. This could happen if a company refuses to recall a device that is associated with significant health problems or death. However, in practice, FDA has rarely needed to require a medical device recall.[33]

Therefore, this exception to the SRM exclusionary rule is rarely seen in medical device cases to introduce evidence of product recalls.

Recall Evidence Is Admissible To Show Control: Rule 407 carves out an exception that allows evidence of a subsequent remedial measure to show control or ownership of the defective product.[34] The idea is that if a defendant denies control or ownership of the product, after having recalled the product, the plaintiff can introduce evidence of the recall campaign to prove control and ownership. Depending upon the product identification related facts of each case, defendants are likely better served to admit ownership and control to avoid introduction of the recall evidence.

Recall Evidence Admissible To Show Feasibility Of A Precautionary Measure/Alternative Design: Plaintiff may introduce evidence of a product recall when the feasibility of an alternative design is controverted.[35] Feasibility means the possibility of an alternative design, the costs and conveniences associated with it, and the ultimate utility and success of its performance.[36] In *Anderson v. Malloy*, the Court of Appeals for the Eighth Circuit reversed the trial court based, in part, on its exclusion of evidence of subsequent remedial measures when defendant contravened the feasibility of other safety measures. Plaintiff was assaulted while staying in defendant's hotel room when an unidentified assailant broke and entered. Defendant denied that the hotel room could have been made any safer and testified that even a door chain and peep holes would have provided only a false sense of security, thereby implying that those devices were not feasible alternative designs.[37] The appellate court held that such testimony "opened the door" to plaintiff's evidence that defendant installed door chains and peep holes shortly after the assault.

---

[33] *See Medical Device Recalls*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/default.htm (last visited July 1, 2011).
[34] *See* FED. R. EVID. 407; Clausen v. Sea-3, Inc., 21 F.3d 1181 (1st Cir. 1994).
[35] *See* FED. R. EVID. 407.
[36] *See* Anderson v. Malloy, 700 F.2d 1208, 1213 (8th Cir. 1983) (reversing the trial court's exclusion of subsequent remedial measures when defendant controverted the effectiveness of door chains and peep holes to make a hotel room safer).
[37] *Id.* at 1214.

This exception is likely to come into play in design defect cases. If the defendant claims that the plaintiff's suggested alternative design was not feasible, including the costs and utility, then plaintiff may introduce evidence of a product recall.

However, if the defendant elects to concede feasibility of an alternative design, then RULE 407 will apply to preclude evidence of the product recall because feasibility is not controverted.

In cases where the defendant is silent on the issue of feasibility, federal circuits are divided as to the effect of Rule 407. A minority of jurisdictions holds that silence on the issue of feasibility still allows the plaintiff to introduce evidence of the product recall; in other words, silence on feasibility means feasibility is controverted.[38] The majority presumes feasibility is admitted unless a defendant affirmatively controverts it and therefore, the SRM evidence is not admissible.[39]

Product Recall Evidence Admissible For Impeachment: Evidence of a product recall is admissible for the purpose of impeachment.[40] "Impeachment" is limited to situations where the recall evidence will directly and significantly contradict a witness' earlier testimony.[41] Testimony that embellishes or uses superlatives, such as "the best" or "the highest quality," to describe the product at issue may be impeached through product recall evidence.[42]

Non-Party Controlled Recall Admissible: Evidence of SRM actions taken by a non-party is not excluded by Rule 407. With the exception of the U.S. Court of Appeals for the Sixth Circuit, all federal circuits have held that Rule 407 does not require the exclusion of subsequent remedial measures taken by a non-party.[43] "The admission of remedial measures by a non-party necessarily will not expose that non-party to liability, and therefore will not discourage the non-party from taking the remedial measures in the first place."[44]

---

[38] *See* Meller v. Heil Co., 745 F.2d 1297 (10th Cir. 1984); Ross v. Black & Decker, Inc., 977 F.2d 1178 (7th Cir. 1992).

[39] *See* Grenada Steel Indus. v. Alabama Oxygen Co., 695 F.2d 883, 888 (5th Cir. 1983); Werner v. Upjohn Co., 628 F.2d 848, 855 (4th Cir. 1980) ("feasibility is not in issue unless controverted by the defendant.").

[40] FED. R. EVID. 407.

[41] *See* Petree v. Victor Fluid Power, Inc., 831 F.2d 1191 (3d Cir. 1987) (allowing evidence of product recall when defense expert witness testified that any possibility of danger had been engineered out of the product, that there was no need to modify the product's design, and a warning would serve no purpose); Flaminio v. Honda Motor Co., 733 F.2d 463, 468 (7th Cir. 1984) (explaining that evidence of a subsequent design change does not impeach a defendant's testimony that it used due care, but that evidence of a design change would impeach a defendant's testimony that it never would have made the design changes).

[42] *See* Wood v. Mobark Indus., 70 F.3d 1201, 1208 (11th Cir. 1995) (allowing evidence of a design change to impeach testimony offered by the president of a corporate defendant that the wood chipper chute was the safest length possible); Muzyka v. Remington Arms Co. Inc., 774 F.2d 1309, 1313 (5th Cir. 1985) (allowing evidence of a design change to impeach testimony that the rifle was the best and safest of its kind on the market).

[43] Bowling v. Scott Cnty., Tenn., **Error! Main Document Only.**No. 3:04-CV-554, 2006 WL 2336333, at *5 (D. Tenn. 2006) (stating that the U.S. Court of Appeals for the Sixth Circuit has never specifically addressed the issue). *See also* Younglove Constr.v. PSD Dev., **Error! Main Document Only.**No. 3:08CV1447, 2011 WL 1933755, *1 (D. Ohio 2011).

[44] *Id.* (internal citations and quotations omitted).

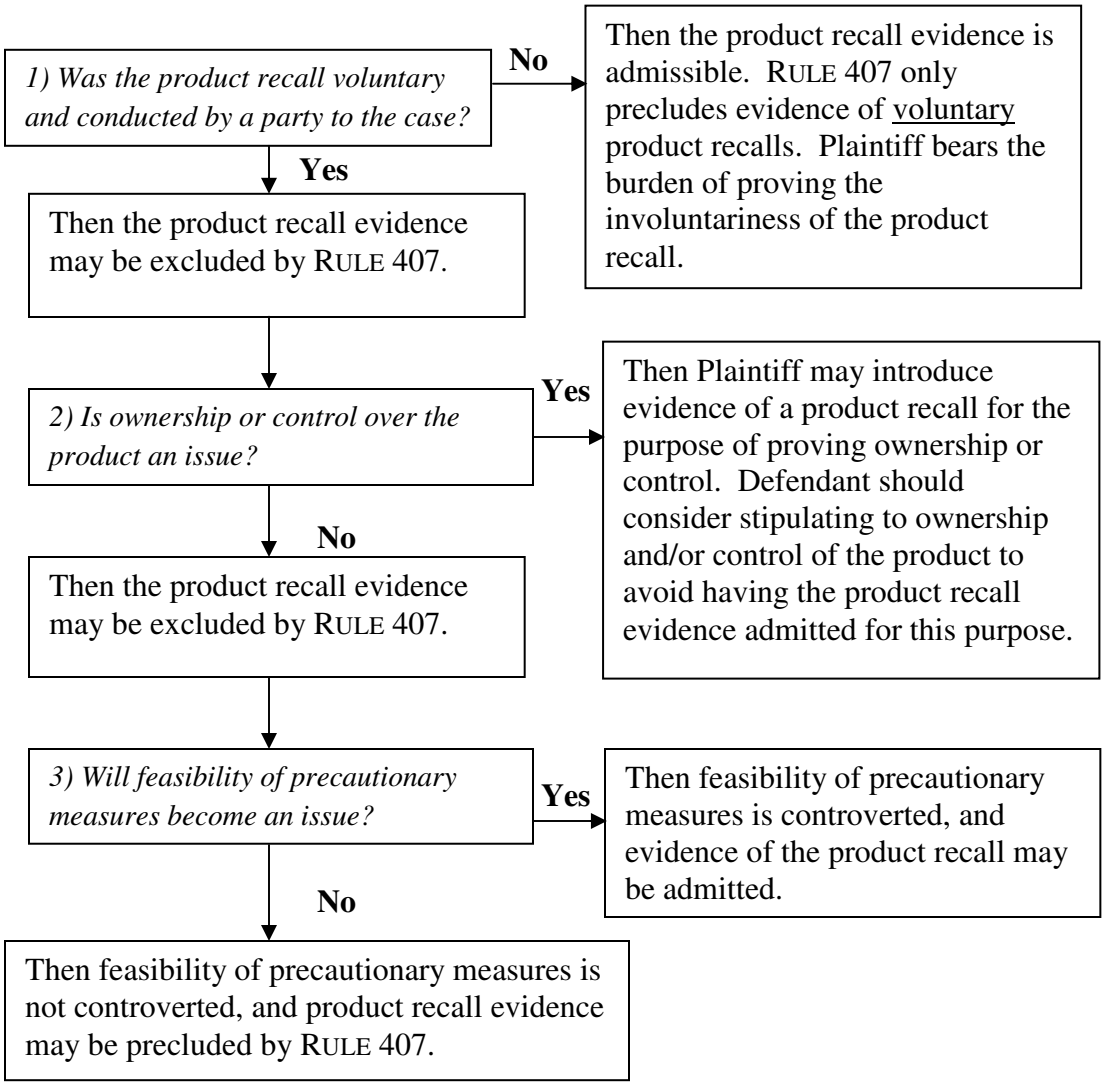
Accordingly, a product recall conducted by a non-party actor is not excluded by Rule 407 and may be admissible evidence relating to a defendant's liability.[45] When involved in a case where the plaintiff has not sued the manufacturer of the device and there was a product recall, be advised that Rule 407 will not preclude the admission of the recall evidence as a subsequent remedial measure. If the Complaint is amended or if a third-party action is filed against the manufacturer, then the newly added manufacturer defendant can move to exclude the evidence on behalf of all defendants.

[45] Diehl v. Blaw-knox, 360 F.3d 426 (3d Cir. 2004) (holding that evidence of the defendant's employer's post-accident modifications to the product were not excluded by Rule 407).

III.
CONCLUSION

The likelihood of success of excluding evidence of a product recall is influenced, in part, by the facts of individual cases. Remember the following checklist of possible objections:

1) Hearsay Objections:
   a) Statement by manufacturer defendant;
   b) Statement by non-party distributor against manufacturer defendant.
2) Relevancy Objections:
   a) not the same product;
   b) not the same defect;
   c) no evidence that the product was defective; and
   d) no evidence that the defect was the proximate cause of the injury.
3) Subsequent Remedial Measures:
   a) The dichotomous key below is helpful to our analysis:



There is no silver bullet, unfortunately, when it comes to excluding product recall evidence. In fact, some medical device defendants may be best-served by embracing the evidence of the recall as a demonstration to the jury of their corporate accountability and responsibility. Under this strategy, defense attorneys can then emphasize self-corrective behavior.

The more common strategy, however, is to keep the product recall evidence away from the jury because overcoming juror prejudice associated with headline product recalls is a feat. In these cases, the goal is to use the evidentiary tools discussed in this article to keep the evidence out and convince the jury that they are smarter than the Plaintiff. Inevitably, jurors will ask themselves, "Could this happen to me?" You want the answer to be, "No." If jurors believe that the plaintiff made a mistake or acted with disregard to a warning, then they would decide the accident was Plaintiff's, or Plaintiff's physician's fault.

With medical device recalls on the rise in recent years, defense attorneys are well-advised to anticipate plaintiffs' attempting to introduce product recall evidence at trial. Preparation, i.e., knowing the rules of evidence, is the only antidote. Hopefully, this article will serve as a helpful resource in this regard.