THE POST SALE DUTIES TO WARN AND RECALL – ARE THEY PREEMPTED WHEN NHTSA OR THE CPSC OVERSEES THE MANUFACTURER'S CONDUCT?

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Introduction

A little over three years ago, the American Law Institute introduced the Restatement 3rd of Torts (the "Third Restatement"), which included, for the first time, sections proclaiming that sellers of commercial products had post-sale duties to consumers. Section 10 of the Third Restatement announces a manufacturer's post-sale duty to warn of product risks, whether or not the product was defective at the time sold.[1] Section 11 announces a manufacturer's duty to use reasonable care in conducting a voluntary or government ordered product recall.[2]

Because it seeks only to describe and influence the developments of state common law, the Third Restatement proclaims these post-sale duties without attempting

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[1] The Third Restatement §10 provides:

§ 10. Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Warn

(a) One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to provide a warning after the time of sale or distribution of a product if a reasonable person in the seller's position would provide such a warning.

(b) A reasonable person in the seller's position would provide a warning after the time of sale if:

(1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and

(2) those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and

(3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and

(4) the risk of harm is sufficiently great to justify the burden of providing a warning.

[2] The Third Restatement § 11 provides:

§ 11. Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Recall Product

One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to recall a product after the time of sale or distribution if:

(a)(1) a governmental directive issued pursuant to a statute or administrative regulation specifically requires the seller or distributor to recall the product; or

(2) the seller or distributor, in the absence of a recall requirement under Subsection (a)(1), undertakes to recall the product; and

(b) the seller or distributor fails to act as a reasonable person in recalling the product.

to determine whether they are preempted by federal law. The Third Restatement itself acknowledges this limitation in its scope:

> "The complex set of rules and standards for resolving questions of federal preemption are beyond the scope of this Restatement. However, when federal preemption is found, the legal effect is clear. Judicial deference to federal product safety statutes or regulations occurs not because the court concludes that compliance with the statute or regulation shows the product to be nondefective; the issue of defectiveness under state law is never reached. Rather, the court defers because, when a federal statute or regulation is preemptive, the Constitution mandates federal supremacy.

The Third Restatement §4(b), Comment e (1998).

Two federal laws, the National Traffic and Motor Vehicle Safety Act ("NTMVSA"), 49 USCA §30103, *et seq.* and the Consumer Product Safety Act (the "CPSA"), 15 U.S.C. §2051, *et seq*. (together the "National Acts"), vest control over post-sale warnings and recalls with the National Highway Traffic Safety Administration ("NHTSA") and the Consumer Product Safety Commission (the "CPSC") (together the "National Agencies"). Under the National Acts, manufacturers who learn of defects must notify the appropriate National Agency. 49 U.S.C. §30118(c);[3] 15 U.S.C. §2064(b).[4] The

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[3] The NTMVSA provides:

§30118. Notification of defects and noncompliance

(c) Notification by manufacturer. – A manufacturer of a motor vehicle or replacement equipment shall notify the Secretary by certified mail, and the owners, purchasers, and dealers of the vehicle or equipment as provided [i.e., according to the notice procedure] in section 30119(d) of this section if the manufacturer–

(1) Learns the vehicle or equipment contains a defect and decides in good faith that the defect is related to motor vehicle safety; or

(2) decides in good faith that the vehicle or equipment does not comply with an applicable motor vehicle safety standard prescribed under this chapter.

[4] The CPSA provides:

§2064(b) Noncompliance with applicable consumer product safety rules; product defects; notice to Commission by manufacturer, distributor, or retailer

Every manufacturer of a consumer product distributed in commerce, and every distributor and retailer of such product, who obtains information which reasonably supports the conclusion that such product–

(1) fails to comply with an applicable consumer product safety rule or with a voluntary standard upon which the Commission has relied under section 2058 of this title;

(2) contains a defect which could create a substantial product hazard described in subsection (a)(2) of this section; or

National Agency, in turn, determines whether and how the manufacturer must conduct a post-sale warning and/or recall campaign. 49 U.S.C. §§30119-301120[5]; 15 U.S.C. §2064(c)-(d).

This article seeks to accomplish two goals. First it reviews the cases which have considered adoption of the Third Restatement's pronouncement of these new post-sale duties since its enactment.[6] Second, it presents a defense argument[7] that state actions based upon these duties are implied preempted when the National Agencies oversee the manufacture's post-sale campaign.

II. Status of the Post Sale Duty to Warn and Recall

Since its enactment, surprisingly few published cases have directly considered adoption of the Third Restatement's pronouncement of post-sale duties to warn or recall.

One case has adopted the Third Restatement §10 in its entirety. *Lovick v. Wil-Rich,* 588 N.W.2d 688 (Ia. 1999). In *Lovick*, the Supreme Court of Iowa adopted the

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(3) creates an unreasonable risk of serious injury or death, shall immediately inform the Commission of such failure to comply, of such defect, or of such risk, unless such manufacturer, distributor or retailer has actual knowledge that the Commission has been adequately informed of such defect, failure to comply, or such risk.

[5] The NTMSA requires post-sale warning and recall of every defect, but allows NHTSA to exempt a manufacturer from the procedure. NTMVSA §§30119-301120.

[6] For a discussion of cases adopting post-sale duties before publication of the Third Restatement, see the reporters notes after the individual sections, *See also,* Kenneth Ross, *Post-Sale Duty to Warn: A Critical Cause of Action*, 23 N.KY.L.REV. 573 (1999); Victor Schwartz, *The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to A Reasonable Doctrine*, 58 N.Y. LAW.REV. 892, 901 (1983).

[7] In presenting only the defense argument, this article does not seek to provide the perspective of the plaintiff. Indeed, the complexity of the subject matter at issue limits even the discussion of the defense argument and easily precludes, in the space taken here, a comprehensive discussion of the current state of the law, which is admittedly unsettled.

Third Restatement §10 as its jury instruction under Iowa Code §1668.12 (1987), an Iowa products-liability statute imposing a post-sale duty to warn.

Another case neither adopted nor rejected the Restatement Third §10, but relied upon it in rejecting a post-sale warning to second-hand owners under the facts of the specific case before it. *Lewis v. Ariens Co.*, 729 N.E.2d 323, 49 Mass.App.Ct. 301 (Mass.App.Ct. 2000). The *Lewis* court rejected "as a general rule, a requirement to update warnings to the owners of a product who has purchased it second-hand, third-hand, or fourth-hand. " *Id.* at 327, 49 Mass.App.Ct. at 306. However, the court left open the possibility that it would impose a post-sale duty to warn in a more extreme case. *Id. at* n. 10 ("One may imagine cases where the danger in a product is so urgent and would affect potentially such a large number of people that the manufacturer would have a duty to warn secondary buyers by recourse to the internet and advertisements through electronic and print media.")

By contrast, two cases appear to have rejected outright the Third Restatement §10 – at least in part. *DeSantis v. Frick Co.*, 745 A.2d 624 (Pa.Super.Ct 2000); and *Modelski v. Navistar International Transp. Corp.*, 302 Ill.App.3d 879, 707 N.E.2d 239 (1st Dist. 1999). Both cases rejected the Third Restatement Section 10 to the extent it imposes a post-sale duty to warn if no defect existed in the product at the time of sale.

In *DeSantis*, the plaintiff brought an action under Pennsylvania's wrongful death and survival acts against a manufacturer of industrial freezers. The plaintiff's traditional "point-of-sale" strict products-liability and negligence claims were barred by the statute of limitations. However, the plaintiff argued that its remaining claim – failure to issue post-sale warnings – did not accrue until much later, circumventing the statute's

application. Both the trial and appellate courts, however, found that no post-sale duty existed. *Id. at* 631 (stating that prior cases "persuade [the court] to decline to adopt Section 10"). The Pennsylvania Supreme Court accepted appeal on October 2, 2000.

In *Modelski,* the plaintiff alleged that a tractor manufacturer had a duty to warn of risks created if bolts securing a battery cover disengaged during operation. The plaintiff alleged that the manufacturer had a duty to warn at the time of sale and, in a separate allegation, asserted that the manufacturer had a post-sale duty to warn. The trial court struck the post-sale warning allegation and the appellate court affirmed. Rejecting the Third Restatement §10, the court found that if no duty to warn existed at the time of sale, then no duty existed after the sale. To the extent that a duty did exist at the time of sale, any post-sale duty was a continuation of the original duty and properly stricken as merely duplicative. Accordingly, the court held that the allegations should be dismissed in either event.

Modelski took a similar approach to post-sale duty to recall. The court held that any duty to retrofit was a continuation of the original duty to use reasonable care in the engineering and design of the product. Just as any post-sale duty to warn was duplicative of the duty to warn at the time of sale, so any duty to recall or retrofit was duplicative of the duty to properly design at the time of sale. As with warnings, no independent post-sale duty to retrofit was adopted. [8]

[8] Notably, although the *Modelski* court performed exactly the same analysis for both post-sale duties, the court's opinion clearly rejects the Third Restatement §10, but appears to adopt the Third Restatement §11. This is the natural result of the Third Restatement's different approaches to the two post-sale duties. *See* Part III (C) *infra*.

III. The Post-Sale Duties of the Third Restatement are Preempted by the National Acts and the Conduct of the National Agencies

Preemption arises as a necessary by-product of our dual state/federal systems of government. The Supremacy Clause of the United States Constitution provides that "the laws of the United States shall be the supreme Law of the Land; . . . anything in the Constitution or Laws of any State to the contrary notwithstanding." U.S. Constitution. Art. VI. When a state attempts to regulate an area already controlled at the federal level, federal law prevails, leaving the state law "without effect." *Cipollone v. Ligget Group, Inc.* 505 U.S. 504, 516, 120 L.Ed.2d 407 (1992) (citing *Maryland v. Louisiana*, 451 U.S. 725, 744-46, 68 L.Ed. 2d 576 (1981)).

Implied preemption[9] occurs in either of two ways: (1) when the federal scheme so extensively regulates an area that it occupies the regulatory field; and (2) when a state law claim actually conflicts with federal law. *Freightliner Corp. v. Myrick,* 514 U.S. 280, 287, 115 S.Ct. 1483, 1487 (1995); *Ray v. Atlantic Richfield Co.,* 435 U.S. 151, 158, 98 S.Ct. 988, 994 (1978). State law is in actual conflict with federal law where it is "impossible for a private party to comply with both state and federal requirements or when where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *Id.; See also Geier v. American Honda Motor Co., Inc.*, 120 S.Ct. 1913, 146 L.E.2d 914 (2000) (discussing conflict preemption).

The federal regulatory scheme arguably preempts state common law actions alleging negligent post-sale warning and recall campaigns because the National Acts and the oversight of the National Agencies occupy the entire regulatory field and because

[9] Express preemption, which this article does not explore, occurs when a federal intent to preempt is expressly stated.

state common law liability would thwart the purpose and objectives of the federal regulatory scheme.

A. Post-Sale Warning and Recall Campaigns Are National in Character

When engaging in an implied preemption analysis, courts should consider the unique federal character of post-sale warning and recall campaigns. *See U.S. v. Locke*, 529 U.S. 89, 120 S.Ct. 1135, 1152 (2000) (considering the 'federal interest' in regulating oil tankers as a factor in analyzing preemption of state standards). Such campaigns must be conducted on a national scale to be effective and have historically been administered at the federal level.

The federal government has been actively involved in post-sale warning and recall campaigns for decades. The NTMVSA and the CPSA were passed in 1966 and 1972 respectively. Since the passage of these acts, the National Agencies have overseen tens of thousands of post-sale warning and recall campaigns involving millions of products.[10] When the National Acts were passed, state involvement in post-sale warning and recall campaigns was virtually nonexistent. Even to this day, individual states have rarely (if ever) overseen post-sale warning or recall campaigns. Generally, the only state involvement in such campaigns starts after the campaign is over – when a plaintiff attempts through hindsight to second-guess the campaign and impose common law

[10] In addition to these agencies, the Food and Drug Administration, the Federal Aviation Administration, and the Environmental Protection Agency also have oversight of post-sale warning and recall campaigns.

liability. Even this involvement by the states, however, appears to be very recent.[11] Third Restatement §10 *comment a*.

The national character of post-sale warning and recall campaigns makes state oversight of them difficult or impossible. In rejecting the possibility of a state law recall, one U.S. District Court stated:

> ... Not surprisingly, state law simply does not provide a basis for worldwide recalls.
>
> At the outset I note, as has defendant, that the prospect of a state-based recall action raises a significant choice of law problem, as well as a jurisdictional problem. It is difficult to understand where a court applying Massachusetts law, for example, would get the authority to order a worldwide recall of a product manufactured in another state or states. Yet, even if there were answers to these questions, there remain more fundamental problems.
>
> No court has ever ordered a notification and recall campaign on the basis of state law.

National Women's Health Network, Inc. v. A.H. Robins Company, Inc., 545 F.Supp. 1177, 1179 (D.Mass. 1982) (finding plaintiff's request for injunctive order for a recall preempted by the FFDCA); *See also, Walsh v. Ford Motor Co.*, 130 F.R.D. 260 (D.D.C. 1990) (noting the difficulties of court ordered recalls).

B. The Intent of Either Congress or the National Agencies may Preempt State Law

Preemption is a question of intent – specifically, whether the federal government intended to displace state law. In determining whether the regulatory oversight of the

[11] Plaintiffs will undoubtedly argue that post-sale duties to warn and recall products are within the 'historic police power' of the states and, therefore, that a presumption against preemption should be applied. As discussed in the text, the police power was not 'historically' exercised by the states. Regardless, the presumption does not exist in an implied preemption analysis in any event. *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 769 (C.A. 11 (Ga.) 1998); *Geier v. American Honda Motor Co., Inc.* 120 S.Ct. 1913, 1920, 146 L.Ed.2d 914 (2000).

National Agencies preempts state review of post-sale warning and recall campaigns, we consider both the intent of Congress and also the intent of the National Agencies.

Where Congress grants broad authority to a federal administrative agency, a "narrow focus [solely] on Congress' intent to supersede state law is misdirected." *City of New York v. Federal Communications Comm'n*, 486 U.S. 57, 64 (1988); *Fidelity Federal Savings & Loan Assn. v. de la Cuesta*, 458 U.S. 141, 154 (1982). "The correct focus is [also] on the federal agency that seeks to displace state law and on the proper bounds of its lawful authority to undertake such action." *City of New York, supra,* at 64.

> [M]any of the responsibilities conferred on federal agencies involve a broad grant of authority to reconcile conflicting policies. Where this is true, the Court has cautioned that even in the area of preemption, if the agency's choice to pre-empt "represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned."

City of New York, 486 U.S. at 64, 108 S.Ct. 1637, quoting *United States v. Shimer*, 367 U.S. 374, 383, 81 S.Ct. 1554, 6 L.Ed.2d 908 (1961); *See also Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta,* 458 U.S. 141, 154, 102 S.Ct. 3014, 73 L.Ed.2d 664 (1982).

Congress gave the National Agencies[12] very broad authority to reconcile the competing policies of public safety, national uniformity, and the burden of regulation on manufacturers. 49 U.S.C. §130101 (safety purpose of NTMVSA); S. Rep. No. 89-1301 (1966) (stating NTMVSA policy that regulation be "uniform throughout the country"); 15 U.S.C. §12051 (same policies under CPSA). Among other things, Congress gave the National Agencies the power:

[12] Technically, the NTMVSA actually grants authority to the Secretary of Transportation. However, the Secretary of Transportation delegated the authority to NHTSA. 49 CFR §1.50(a). Accordingly, the distinction between the Secretary of Transportation and NHTSA is unimportant for purposes of preemption.

- to mandate exclusive federal regulatory safety standards for design, testing, and performance, 49 U.S.C. §30111; 15 U.S.C. §2056;

- to demand product labels contain specific information; 49 U.S.C. §30111; 15 U.S.C. §2063;

- to independently test products for safety; 49 U.S.C. §30111(e); 15 U.S.C. §2054(b);

- to conduct research studies or hearings for any purpose related to their responsibilities, 49 U.S.C. §30168; 15 U.S.C. §2054(b), §2076; and

- to collect, analyze, and investigate accidents involving products under their jurisdiction, 49 U.S.C. §30166; 15 U.S.C. §2054(a).

Most importantly for this article, in reconciling the policies charged to their discretion, the National Agencies have broad authority over a manufacturer's post-sale notice or recall campaign. 49 U.S.C. §30118; 15 U.S.C. §2064. Accordingly, the National Agencies — by manifesting their own preemptive intent — can preempt state law.

C. The National Agencies Should Receive the Same Deference in Preempting Either the Post-Sale Duty to Warn or Recall.

The Third Restatement instructs courts to give great deference to the National Agencies on issues of recalls. Because the same rationales apply when a National Agency oversees a post-sale warning campaign, the same deference should be given.

The Third Restatement §11 and the cases on which it was based recognize the importance of letting the National Agencies determine whether and to what extent post-sale recall activities should be taken by manufacturers. The Third Restatement states:

> If every improvement in product safety were to trigger a common-law duty to recall, manufacturers would face incalculable costs every time they sought to make their product lines better and safer. Even when a product is defective within the meaning of §2, §3, or §4 [i.e., defective in design, manufacture, or from lack of warnings at the time of sale] an involuntary duty to recall should be imposed

> on the seller only by a governmental directive issued pursuant to statute or regulation. Issues relating to product recalls are best evaluated by governmental agencies capable of gathering adequate data regarding the ramifications of such undertakings.

Third Restatement §11, *comment a*.

Gregory v. Cincinnati, Inc. 538 N.W.2d 325, 450 Mich 1 (1995), which the reporters notes of the Third Restatement §11 calls the "most significant recent case supporting" the section, provides more detail. *Gregory* sets forth the following reasons for relying on the National Agencies to decide whether and how a manufacturer should perform a post-sale recall of a product:

1. "Focusing on post-manufacturer conduct in a negligent design case improperly shifts the focus from point-of-manufacture conduct and considers post-manufacture conduct and technology that accordingly has the potential to taint a jury's verdict regarding a defect."

2. "[T]he duty to repair or recall is more properly a consideration for administrative agencies and the Legislature who are better able to weigh the benefits and costs involved in locating, recalling, and retrofitting products, as well as other economic factors affecting businesses and consumers. Courts have traditionally not been suited to consider the economic effect of such repair or recall campaigns.

3. "[A] continuing duty instruction adds nothing to plaintiff's case but potential confusion.

4. "[W]hen appropriate, i.e., when the protection of vital interests was deemed necessary, policymakers have explicitly delegated such authority to administrative agencies.

Id. at 333-34, 450 Mich. at 22.

All of the same rationales apply equally well to a post-sale warning campaign under the jurisdiction of the National Agencies. In a post-sale warning case, evidence improperly focuses a jury on information available to a manufacturer only after the sale of the product – tainting the jury's perception of forseeability of the risk. The National

Agencies are better able to weigh the benefits and costs of a post-sale warning campaign. When the plaintiff claims that the manufacturer should have warned at the time of sale, a post-sale warning instruction can add nothing to plaintiff's case but confusion. *See Modelski, supra*. (finding a post-sale warning instruction duplicative of a point-of-sale instruction). Finally, when appropriate, policymakers have explicitly delegated authority over post-sale warnings to the National Agencies.

D. The Federal Government So Extensive Regulates Post-Sale Warning and Recall Campaigns that it Occupies the Regulatory Field

The federal regulatory scheme vests such extensive regulatory authority over post-sale warning and recall campaigns in the National Agencies that they arguably occupy the entire field of regulation.

When the National Agencies asserts their authority over a safety issue, Congress expects them to take over – i.e., to occupy the regulatory field for that risk. Congress wanted NHTSA to take "primary responsibility for regulating the national automotive manufacturing industry" and for individual states to be relegated to only a "consultative role." S. Rep. No. 89-1301 (1966), reprinted in 1996 U.S.C.C.A.N. 2709, 2712. The legislative history of the CPSA is even more explicit, stating:

> It is intended that Federal authority – once exercised – occupy the field and broadly preempt State authority to regulate the same product hazards.

House Committee on Interstate and Foreign Commerce, Report No. 92-1153, p. 49.

One of the areas Congress expected the National Agencies to 'exercise Federal authority' over was post-sale warning and recall campaigns. The legislative history bluntly calls National Agency oversight of post-sale warning and recall campaigns

"essential" to the goals of each of the National Acts. S. Rep. No. 89-1301 (1966), reprinted in 1996 U.S.C.C.A.N. 2709, 2710 ("Federal oversight of defect notification and correction is essential"); *House Committee on Interstate and Foreign Commerce*, Report No. 92-1153, p. 26.

National Agency control over post-sale activities starts before a defect is even identified. Manufacturers have a responsibility to report defects, 49 U.S.C. §30118(c); 15 U.S.C. §2064(b), and to report certain incidents involving their products even if no defect is identified, 49 U.S.C. §130166;[13] 15 U.S.C. § 2084. Moreover, the National Agencies do not sit back and wait for manufacturers to find defects. The National Agencies actively look for defects. They audit manufacturers' records. 49 U.S.C. §130166; 15 U.S.C. §2065. They purchase and test products independently of the manufacturers. 49 U.S.C. §30168; 15 U.S.C. §2076. In addition, they have access to many sources of information that the manufacturer does not. They have access to confidential information submitted from other manufacturers, 49 U.S.C. §30167 (limiting disclosure of such information by the National Agencies); 15 U.S.C. §2055 (same), to information from other government agencies, 49 U.S.C. §30166; 15 U.S.C. §2054, and to national accident and injury information databases. 49 U.S.C. §30168,[14] 15 U.S.C. §2078.

[13] In 2000, the NTMVSA was amended by the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act, P.L. 106-414, which expanded NHTSA's authority to require what the TREAD Act called 'early warning' information from manufacturers. Under the provisions of the TREAD Act, NHTSA is to finalize rulemaking setting forth a manufacturer's additional reporting requirements no later than June, 2002.

[14] The national Center for Statistics and Analysis ("NCSA") provides NHTSA with access to several databases, including the Fatality Analysis Reporting Systems (FARS), the National Automotive Sampling System (NASS), the Crashworthiness Data System (CDS) and the General Estimates System (GES). For more in depth description of these systems, visit NHTSA's web site, www.NHTSA.gov.

Because the National Agencies often have more information than the manufacturer, it is often the National Agencies who are first able to identify a potential defect.

Whether it is the manufacturer or the National Agency that first identifies the defect, once a potential defect is identified, the National Agencies assert control at every stage of the post-sale process. The National Agency generally requires the manufacturer to file a report on nearly every conceivable piece of information about the defect and the product, including:

- a detailed description of the product and the defect; 49 CFR §573.5(c)(2); 16 CFR §115.13(d)(1)-(5);
- a chronology of the manufacturer's investigation, 49 CFR §573.5(c)(6); 16 CFR §115.13(d)(6);
- the number and percentage of products on the market that may have the defect, 16 CFR §115.13(d)(7)-(9);
- the manufacturer's basis for believing the defect does not exist in similar products;
- the results of all testing performed by the manufacturer on the product; 49 CFR §573.5(c)(7);

With this information in hand the National Agency reviews what post-sale action must be taken. Generally, the manufacturer voluntarily proposes a post-sale warning and/or recall plan for the product. 49 U.S.C. §130118 and 49 CFR §573.5(b), §573.5(c)(8); 15 U.S.C. §2064(c) and 16 CFR §115.20. Ultimately, however, the National Agencies are charged with determining whether the proposal adequately protects the public. The National Agencies approve or reject the repair (or 'fix') based on its determination of whether the repair adequately addresses the risk to the public. 49 U.S.C. §30120(e); 16 CFR §1115.20(3). The National Agencies approve the time frame for the recall. 49 U.S.C. §30120(c)(3) and 49 CFR §573(c)(8); 16 C.F.R. §1115.20(3). If the product is being returned, the National Agencies approve the amount of the refund the consumer will receive and the method by which the consumer must prove ownership of the product.

The National Agencies also approve the publication and content of post-sale warning or recall notices. The National Agencies approve the content of all notices sent out by the manufacturer to consumers. 49 CFR §573.5(c)(10), §573.8; 16 CFR §115.13(d)(11), §115.20(a)(ii). They review and approve letters to retailers and any point of purchase posters. 49 CFR §573.5(c)(10); 16 CFR §115.13(d)(11). They issue joint press releases with the manufacturer announcing the recall, approve which magazines, newspapers, radio and television stations should be contacted, and, where appropriate, insist on a video news release for television. The National Agencies also disseminate the recall announcement directly. They share recall information through sharing agreements with various state agencies, maintain recall e-mail and fax services, and publish internet web sites containing recall announcements and details.

The National Agencies also continue to monitor the recall after it begins. They require the manufacturer to report on which media outlets published the recall announcement, on how many consumer inquiries were received, and how many actual products were returned or repaired. 49 CFR §573.6(b). In some instances, they conduct recall audits, at times visiting individual retail stores to ensure that the product has been pulled from the shelves and that point-of-purchase posters are properly displayed. They have even been known to call the manufacturer, pretending to be consumers, to verify that the manufacturer's consumer service department was providing adequate recall information to callers. If the National Agency is satisfied with the results of the recall, it closes its file. If not, it demands additional efforts by the manufacturer.

In short, from the adequacy of the recall 'fix' to the format of the envelopes enclosing a post-sale warning to consumers, the National Agencies exercise authority

over every aspect of a post-sale warning or recall campaign. Their broad oversight makes a strong argument that the National Agencies occupy the entire field of regulation, leaving no room for state court litigation.

E. A State Common Law Action for Negligence in a Post-Sale Warning or Recall Campaign Directly Conflicts with Approval of the Campaign by the Appropriate National Agency

State common law actions alleging negligent post-sale warnings or recalls conflict with the approval already given by the National Agencies. As described above, the National Agencies review the appropriateness of post-sale recall campaigns as they occur. After considering the specific facts and circumstances of the product, the potential risk, and the specific post-sale actions taken, the National Agencies approve the manufacturer post-sale warning and recall campaign only if it is reasonable and appears adequate to protect the public. Because state court review of the campaign could only conflict with the authorization given by the National Agencies, it should be preempted. *See Irving v. Mazda Motor Corp.,* 136 F.3d 764, 769 (11th Cir. 1998) (citing *Taylor v. General Motors Corp.*, 875 F.2d 816, 827 (11th Cir. 1989).

Assume, as an example, that a state court claim alleges a manufacturer negligently worded a post-sale warning. If the National Agency approved the form of the warning sent to the consumers as part of the post-sale warning campaign under its jurisdiction, see, 49 CFR §573.5(c)(10), §573.8; 16 CFR §115.13(d)(11), §115.20(a)(ii), it has already determined that the wording is reasonable. Under these circumstances, there is nothing left for the state court to litigate. *See Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.,* 450 U.S. 311, 318, 101 S.Ct. 1124, 1131, 67 L.E.2d 258 (1981).

In *Kalo,* the U.S. Supreme Court held that the Interstate Commerce Commission's approval of an application for abandonment preempted state common law liability. The Court explained:

> [W]e need not decide whether a state-court suit is barred when the Commission is empowered to rule on the underlying issues, because here the Commission has actually addressed the matters respondent wishes to raise in state court. . .. These findings by the Commission, made pursuant to the authority delegated by Congress, simply leave no room for further litigation over the matters respondent seeks to raise in state court. Consequently, we hold that on the facts of this case, the Interstate Commerce Act also preempts Iowa's common law causes of action for damages stemming from a carrier's negligence and tort when the judgments of fact and of reasonableness necessary to the decision have already been made by the Commission.

Id. at 327, 101 S.Ct. at 1135.

Notably, the issue is not whether the National Agency made the best decision. If the National Agency made a decision that the conduct should be allowed, the state court cannot second-guess it. *Geier, supra; Taylor v. General Motors Corp.,* 875 F.2d 816, 827 (11th Cir. 1989) (finding that "a state cannot impose common law damages on individuals for doing what a federal act or regulation 'authorized them to do"'). In *Geier*, a NHTSA safety standard giving manufacturers the option of installing either an airbag or an alternative passive restraint system[15] preempted a state common law action alleging that a reasonable manufacturer would have chosen the airbag. The Supreme Court held that NHTSA's decision to specifically allow the manufacturer to choose the alternative systems preempted state attempts to prohibit them from doing so.

[15] *See* 49 C.F.R. §208.

Similarly, in our example, the National Agency decided to specifically allow the manufacturer to use the notice. The state cannot impose liability on the manufacturer for doing so.[16]

E. State Liability Under the Third Restatement's Pronouncement of Post-Sale Duties Thwarts the Purpose of the National Acts

The National Acts were passed to promote safety, to create national uniformity, and to promote research into safety issues. 49 U.S.C. §130101; 15 U.S.C. §2051. State post-sale warning and recall claims should be preempted because they thwart these purposes.

Allowing state post-sale warning and recall litigation shifts the oversight of post-sale activities away from the National Agencies who are best equipped to assess their costs and benefits. *See Third Restatement §11, comment a;* Victor Schwartz, *The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to A Reasonable Doctrine*, 58 N.Y. LAW. REV. 892, 901 (1983).[17] Although the plaintiff's bar will argue vehemently to the contrary, this shift thwarts the purpose of safety. First, allowing such actions

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[16] *Geier* spends a good deal of time discussing the flexibility intended by NHTSA in providing the options to the manufacturer. Notably, the same flexibility was intended by the National Acts in allowing the manufacturer to propose post-sale warning and recall plans.

[17] Professor Schwarts describes the inherent limitations of the courts in assessing recalls:

> Product recalls . . . are properly the province of administrative agencies as the federal statutes that expressly delegate recall authority to the various agencies suggest. As Congress has recognized, administrative agencies have the institutional resources to make fully informed assessments of the marginal benefits of recalling a specific product. Because the cost of locating, recalling, and replacing mass-marketed products can be enormous and will likely be passed on to consumers in the form of higher prices, the recall power should not be exercised without extensive consideration of its economic impact. Courts, however, are constituted to define individual cases, and their inquiries are confined to the particular facts and arguments in the cases before them. Decisions to expand a manufacturer's post-sale duty beyond making reasonable efforts to warn product users about newly discovered dangers should be left to administrative agencies, which are better able to weigh the costs and benefits of such action.
>
> *Id.*

disregards the decision of the post-sale warning and recall experts – the National Agencies. The National Agencies have decades of experience, including publication of thousands of warnings and recalls of millions of products. They have conducted repeated studies of recall and warnings effectiveness. They have more experience with post-sale campaigns than any company or consultant.

By disregarding the decisions of the experts, state courts increase the risk to consumers. As an example, assume the National Agency overseeing a recall approved a recall poster with a color photograph of the product. Months later, an injured plaintiff convinces a jury that she never learned about the recall because the color photograph led her to believe the poster was an advertisement. In fact, however, the National Agency – the expert in recalls – may have concluded any one of the following:

- that a color photograph was necessary for proper recognition of the product;
- that a color photograph was more likely to catch the eyes of consumers in a shopping area; or
- that consumers correlated the expense of the poster with the seriousness of the safety hazard and were more likely to respond to a color photograph.

In short, state law claims would allow the jury to create a common law standard, which – because it differed from the standard created by the National Agency – decreases the effectiveness of the recall.

Plaintiffs will argue that, because their lawsuit would impose a higher duty than the National Agency has imposed on the manufacturer, they are increasing safety. A state's power to second-guess the adequacy of the federal regulatory scheme cannot depend on the state's own determination of adequacy. Indeed, "the issue is not adequate

regulation but political responsibility" and "a state law is not to be declared a help because it attempts to go farther than Congress has seen fit to go." *U.S. v. Locke,* 529 U.S. 89, 120 S.Ct. 1135, 1152 (2000) (preempting state standards for oil tankers).

Furthermore, even when the state court attempts to set a 'higher' post-sale standard, it increases the risk of injury to consumers. Assume an injured plaintiff did not hear about a recall. Based on the low participation rate of the recall generally, the plaintiff argues that a reasonable manufacturer would have purchased paid advertising to further publicize the recall. The plaintiff argues that such additional notice could never be detrimental to safety, but she is mistaken.

The National Agencies are charged with promoting the safety of <u>all</u> of the products in their jurisdiction. They do not (and should not) consider a single product or a single recall in a vacuum. They consider each recall on a case-by-case basis, viewing it in the context of the overall scheme of consumer protection. Thus, in the example, the National Agency may have concluded that too few products were involved in the recall to justify paid advertising. They may have deliberately chosen <u>not</u> to dilute the publicity of other recalls through over-publication of this one. They may further have concluded that, for this individual recall, advertising was unlikely to be an effective method of obtaining recall participation. In short, they may have determined that additional publication was a bad idea – not necessarily for this individual recall – but for the promotion of overall public safety.

The above example would not be the first time that the National Agencies were concerned about state requirements diluting their message to consumers. *Beverly v. Ford Motor Co,* 224 F.3d 570 (6th Cir. 2000). While *Beverly* involved pre-sale rather than

post-sale warning, it otherwise addressed the exact problem presented by our example. *Beverly* considered the preemptive effect of the airbag warning label requirements of FMVSS 208. The plaintiff argued that, in addition to the warning mandated by NHTSA, that Ford had a state common law obligation to place additional warnings inside the car. The Sixth Circuit, citing to NHTSA's concerns about 'information overload,' held the common law claim was preempted. The court stated:

> NHTSA thought of its warning language as not simply a minimum, but as the sole language it wanted on the subject. NHTSA feared "information overload," i.e., that additional warnings would distract from the warnings it had determined were critical, leading consumers not to focus properly on the latter. It was also concerned that additional warnings might simply lead people to pay no attention to any of them. *See* Rules and Regulations, Department of Transportation, National Highway Traffic Safety Administration: Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 58 FR 46551, 46554 (Sept. 2 1993) ("additional statements ... would contribute to an 'information overload,' thereby diluting the impact of the most important information.").

Id. at 574.

The CPSC has expressed similar concerns about diluting post-sale publications of warnings and recalls. Recall studies published by the CPSC have concluded that demanding 'state of the art' recalls from every manufacturer in every situation would be harmful to product safety. *Report of Recall Effectiveness Task Force of the Consumer Product Safety Commission,* August 25, 1980, Tab E p.1 ("we cannot, and should not promote each of our corrective actions with equal effort"). They have found that aggressive promotion of every recall diminishes overall public attention to product announcements. *Id. at* Tab E (describing "consumer boredom").[18]

[18] Notably, these same studies also conclude that increased consumer participation is not necessarily directly related to the degree of publication, *Id. at* Tab A, p. 15, and that recall return rates are not an accurate measure of recall effectiveness. *Id. at* Tab B; Tab C. The fact that these findings are not obvious simply emphasizes the need for deference to the expertise of the National Agencies.

Allowing state court juries to second-guess the National Agencies also increases the risk of injuries to consumers by substantially slowing the recall process. The CPSC has concluded that a procedure allowing manufacturers the flexibility to prepare their own recall plans can increase safety by speeding up the initiation of recalls. *See* N. J. Scheers, Ph.D. CPSC Office of Planning and Evaluation, *Evaluation of the Fast-Track Product Recall Program of the U.S. Consumer Product Safety Commission* (October 13, 1998). Manufacturers cannot initiate recalls quickly if they must research the standards of various common law decisions for guidance.

In addition to thwarting safety, allowing state law claims thwarts uniformity – another purpose of the National Acts. The National Acts seek to promote national uniformity and to reduce the burden of conflicting state laws on manufacturers. S. Rep. No. 89-1301 (1966), reprinted in 1996 U.S.C.C.A.N. 2709, 2716 (stating "uniform notification" of defects as a goal under the NTMVSA); 15 U.S.C.A. §2051(a)(4), (b)(3). ("The purposes of this chapter are . . . to develop uniform safety standards for consumer products and to minimize conflicting state and local regulations."); *Moe v. MTD Products, Inc.*, 73 F.3d 179, 183 (8th Cir. 1995) (finding that the goal of national uniformity must be considered in determining the preemptive scope of CPSA). Imposing state common law post-sale duties subjects manufacturers to a myriad of state standards. A jury in one state could conclude that reasonable manufacturers issuing post-sale warnings would put the name of the product in big bold letters. A jury in another state could find that bold letters identifying the product detract from the word "Warning." The National Agency, disagreeing with both states, may insist that the two appear in the same

size. These conflicting state standards may be impossible to comply with. Even when they are not, they thwart uniformity – one of the objectives behind the National Acts.

III. Other Considerations

The scope of this article was to present a single defense argument that the post-sale duties are preempted by the National Acts. It does not attempt to present all of the arguments available. However, I find the following of particular interest because of their interrelationship with this article:

1. *Does the Post-Sale Duty Exist?*

Many states are considering whether to impose these new post-sale duties for the first time. Whether a new cause of action is recognized often turns on a variety of factors, including the previous existence of an adequate remedy. Even if a new post-sale duty is not recognized, a plaintiff is not without recourse to seek additional post-sale actions. Under both the National Acts, any interested person may bring her comments, criticisms and suggestions to the National Agency. 49 U.S.C. §30162; 15 U.S.C.A. §2058(i). If meritorious, the National Agency may integrate such suggestions into its general procedures or mandate the additional action be taken in a specific post-sale campaign.

2. *Does Preemption Apply even When No Post-Sale Action has been Taken?*

While this article focuses on preemption when a National Agency has overseen a post-sale campaign, manufacturers should not give up hope on the argument of preemption simply because no post-sale action has been taken. If the National Agencies made a

conscious decision that no post-sale warning or recall campaign was required, the decision "may imply an authoritative federal determination that the area is best left unregulated, and have as much pre-emptive force as a decision to regulate." *See Gracia v. Volvo Europa Truck, N.V.,* 112 F.3d 291, 296 (7th Cir. 1997) (finding NHTSA's exclusion of specific vehicles from windshield retention standards preempted state common law actions).

Courts have consistently found preemption of post-sale warning and recall claims under the similar provisions of the Federal Food Drug and Cosmetic Act (the "FFDCA") even when no post-sale campaign was ordered. As with the National Acts, the FFDCA requires that manufacturers who discover a defect in their products notify a federal agency (the FDA), vested with the power to control post-sale warnings and recalls. Courts have held that such notice to the FDA is the only post-sale warning required and that it preempts common law duties to warn consumers directly.

> The defendant maintains that federal regulations impose a duty on the manufacturer to give information to the FDA regarding any problems with [the product at issue], but do not impose a duty on the manufacturer to give information to the patients. In addition, federal regulations also impose a duty on the FDA to recall [the product] or to notify patients upon discovery of a defect. Therefore, the defendant argues, any state law requiring the manufacturer to provide information to the patient would be different from or in addition to federal regulations and thus preempted. ...
>
> This Court holds that state law claims for failure to warn are preempted by federal law. The Court bases its decision on the existence of federal regulations, such as those cited by defendant, which govern the manufacturers' obligations to inform of any problems with [the product].

Lewis v. Intermedics Intraacular, Inc., 1993 WL 533976, *7-8 (E.D.La. 1993); *Caronia v. Intermedics Intraocular, Inc.*, 1993 WL 533981 (E.D.La. 1993); *Angelle v. Intermedics Intraocular, Inc.*, 1993 WL 533983 (E.D.La. 1993); *Hamilton v. Surgidev Corp.*, 1993

WL 533994 (E.D.La. 1993); *Hunsaker v. Surgidev Corporation*, 818 F.Supp. 744 (M.D. Pa. 1992).

3. *Who Determines the Standard in Post-Sale Actions?*

The preemption defense, even if unsuccessful, dovetails nicely into a summary judgment argument that the standard of care has been met. Preemption highlights the expertise of the National Agency which, as a practical matter, sets the post-sale warning and recall standard of care. If a manufacturer has met the standard of care demanded by the National Agency and gained its approval, the manufacturer can argue that it has met its standard of care as a matter of law.

When the National Agencies orders a recall, the Third Restatement appears to limit the manufacturer's duty to compliance with the order of the National Agency. Third Restatement §11. A related but similar argument can be made when a post-sale warning or recall campaign is done voluntarily. The Third Restatement proclaims that a manufacturer who voluntarily undertakes to perform a recall, must perform that voluntary undertaking with due care. *See* Third Restatement §11. Arguably, because a manufacturer only volunteers to perform the recall as proposed to the National Agency, the scope of the manufacturer's duty is limited to that proposal.