

Post-Market Warning Requirements for Devices and How They Impact Your Product Liability Case Medmarc Webinar Series

By Eric Larson Zalud
Benesch Friedlander Coplan & Aronoff LLP
200 Public Square, Suite 2300
Cleveland, Ohio 44114
(216) 363-4178 (Direct)
ezalud@beneschlaw.com

October 19, 2011

Cleveland | Columbus | Indianapolis | Philadelphia | Shanghai | White Plains | Wilmington

www.beneschlaw.com

 **BENESCH**
Attorneys at Law

Post-Market Warning Requirements for Devices and How They Impact Your Product Liability Case Medmarc Webinar Series

By Eric Larson Zalud
Benesch Friedlander Coplan & Aronoff LLP
200 Public Square, Suite 2300
Cleveland, Ohio 44114
(216) 363-4178 (Direct)
ezalud@beneschlaw.com

October 19, 2011

Cleveland | Columbus | Indianapolis | Philadelphia | Shanghai | White Plains | Wilmington

www.beneschlaw.com

 **BENESCH**
Attorneys at Law

The Genesis of the Obligation: Restatement (Third) Adds a Post-Sale Duty to Warn

- Section Ten of the Restatement (Third) of Torts Products Liability; “Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Warn” (1998)
- A Model for Many States
- There were sporadic cases before, dating from late 1950's.
- Liability for harm to persons or property caused by seller's failure to provide warning *after* time of sale or distribution of product *if reasonable person* in seller's position would provide such a warning—A negligence standard – Not strict liability! Was conduct reasonable?
- So, much room for subjectivity, and many litigation points

Four-part Restatement Test To Determine When Reasonable Person Would Provide The Warning

- (1) Seller knows or reasonably should know that the product poses substantial risk of harm to persons or property;
 - (2) Those to whom warning might be provided can be identified and can reasonably be assumed to be unaware of risk of harm;
 - (3) Warning can be effectively communicated to and acted upon by those to whom warning might be provided; and
 - (4) Risk of harm sufficiently great to justify burden of providing warning.
- * Important: All four must be present! If not, no duty. Authors of Restatement: Felt this limited this “monster duty”

Restatement Balancing and Checks and Balances

- § 10 balances risk of harm against burden of providing warning. Knowledge is a key issue. Sellers have duty *if they have knowledge* or if reasonable person in seller's position would have knowledge.
- If *buyer* can reasonably be assumed to *also* have knowledge, lessens seller's duty—So the Restatement balancing is infused with some learned intermediary principles

Restatement Balancing and Checks and Balances

§10 does *not* impose post-sale duty if seller cannot reasonably be expected to have knowledge of risk

- So, also infused with State of the Art principles
- Also no duty, if seller cannot reasonably be expected to be able to track down buyer. So, less knowledge, better (but don't be purposefully struthian)!
- Post-Sale duty is separate and independent of time of sale defect allegations

Restatement §10—The Nature of the Duty

- Affirmative duty of product suppliers to exercise reasonable care to learn of post sale problems with their products
- This general duty may require manufacturer to investigate when reasonable grounds exist for manufacturer/seller to suspect that previously unknown risk, now exists
- Restatement specifically *does not* call for: “constantly monitoring product performance in the field” because it “is usually too burdensome”
- Also, would the putative post sale warning effectively reduce risk inherent in original design

But Where Are They? Identifying the Users

- Under §10—Must be proof that actual end users, who would receive a putative post sale warning—can be identified
- Factors to consider:
 - ❖ Type of product
 - ❖ Number of units sold
 - ❖ Number of potential users
 - ❖ Availability of records
 - ❖ Available means of tracing product users

If no records available identifying end users—no post sale duty to warn! (Once again, don't intentionally *not* keep records)

Trigger Points of the Post Sale Duty

- Post Sale accidents, incidents, complaints and reports (balancing severity of incident with number of reports)
- Improvements/Changes in State of the Art
 - ❖ Particularly for ethical drug/device manufacturers



Restatement: Drug and Medical Device Specifics

- § 10 Comments: Specifically address medical device manufacturers: “With regard to one class of products, prescription drugs and devices, *courts traditionally impose a continuing duty of reasonable care to test and monitor after sale to discover product-related risks.*”
- Elaborating, “The drug manufacturer’s duty to warn is, therefore, commensurate not only with its actual knowledge gained from research and adverse reaction reports, but also with its constructive knowledge as measured by scientific literature and other available means of communication.”

Restatement: Drug and Medical Device Specifics

- So, if product is prescription drug or medical device, additional factor to be balanced. Enhances duty of manufacturer to provide post-sale warning. Obligation to warn doctors if harmful new side effects discovered—but not end users.
- Consistent with prior case law requiring drug and device manufacturers to keep informed of scientific developments and provide medical profession with information about risks of drugs already on market. See *Tinnerholm v. Parke Davis & Co.*, 285 F. Supp. 432, 451 (S.D.N.Y. 1968); *Baker v. St. Agnes Hosp.*, 421 N.Y.S. 2d 81,85 (N.Y. App. Div. 1979): Greater the drug's potential hazard, greater the obligation to inform medical profession; physician failure to search literature for hazards not intervening case.

Restatement: Drug and Medical Device Specifics: Antecedent Caselaw

- *Wooderson v. Ortho Pharm Corp.*, 681 P.2d 1038 (Kan. 1984): Drug manufacturer must warn medical profession of dangerous side effects “of which it knows, has reason to know, or should know, based upon its research, upon cases reported to it, and upon scientific development, research and publications in the field”, for as long as it markets the drug.
- *Borson v. E.R. Squibb & Sons, Inc.*, 682 P.2d 832 (Utah 1984); Pharmaceutical manufacturers are experts, held to “continuous duty” to keep abreast of scientific developments and warn accordingly post sale; FDA guidelines were “merely minimums” (this part is minority view)

Federal Regulations of Medical Devices Supplement the Post-Sale Duty to Warn, But Do Not Preempt It

- **FDA** has responsibility for ensuring that medical device manufacturers provide devices that are safe and effective for intended use.
- When FDA provides rules regulating medical device manufacturers, these rules may provide defense of preemption against common law claims.
- 21 C.F.R. § 803 regulates medical device reporting; requires manufacturers to report “Incidents in which a device may have caused or contributed to a death or serious injury” to FDA under Medical Device Reporting program (“MDR”)—Report to FDA, *not* end user.
- Also, reporting to FDA, *not* admission of fault, causation or liability (and, many MDR’s can be excluded)

Federal Regulations of Medical Devices Supplement Post-Sale Duty to Warn, But Do Not Preempt It

- 21 U.S.C. § 360i(e) imposes requirements that some medical device manufacturers have system in place for tracking class II and class III devices if:
 - * Failure reasonably likely to have serious adverse health consequences;
 - * Device is intended to be implanted in human body for more than two years; or
 - * It is life sustaining /supporting device

Federal Regulations of Medical Devices Supplement Post-Sale Duty to Warn, But Do Not Preempt It

- FDA—May also, if it determines that device “presents an unreasonable risk of substantial harm to the public health”, order manufacturer to:
 - * Notify affected persons
 - * Require repair of the device
 - * Require replacement of the device; or
 - * Order a labeling change to more adequately warn of danger presented by the device.

The Preemption Backdrop: Post-Sale Warning Claims Survive

- Prior to Supreme Court decision in *Reigel*, several Circuit Courts found post sale duty to warn claims preempted. See *McMullen v. Medtronic, Inc.* 421 F.3d 482 (7th Circ. 2005) (past sale warning, claim preempted since FDA requires continuous updates as part of PMA application and supplement process); *Kupek v. Medtronic, Inc.*, 405 F.3d 421. These cases apparently involve situations where manufacturers timely reported adverse events.
- *In re: Medtronic, Inc. Sprint Fidelis Leads Product Liability Litigation*, 592 F. Supp. 2d at 1159-1161: Rule 12(B)(6) dismissal founded upon implied preemption as to post sale duty to warn claims based on Medtronic's apparent violation of 21 CFR § 803.53 by failure to timely report in excess of 120 adverse event reports.

The Preemption Backdrop: Post-Sale Warning Claims Survive

- *Webster v. Pacemaker*, 259 F. Supp. 2d 27 (D.D.C. 2003): failure to warn based on untimely reporting of adverse events deemed preempted by *Buckman*.
- *Lake v. Kardjian*, 22 Misc. 3d 960, 874 N.Y.S. 2d 751 (2008): summary judgment in favor of manufacturer; action based on failure to report incidents deemed impliedly preempted.

The Preemption Backdrop: Post-Sale Warning Claims Survive

- In *Reigel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), Supreme Court held that state common-law duties do impose requirements that are “with respect to” PMA medical devices, but only those state common-law duties that impose requirements that are “different from or in addition to” requirements imposed by FDA are expressly preempted.
- Court noted that FDA regulations do not “prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations.”
- Injured party could bring failure to warn claim premised on reporting and tracking requirements imposed by FDA regulations.

The Preemption Backdrop: Post-Sale Warning Claims Survive

If failure to report timely adverse events per requirement of 21 CFR § 803.1(A) and § 803.53. Under *Reigel*, would probably lead to different result *i.e.*, not preempted.

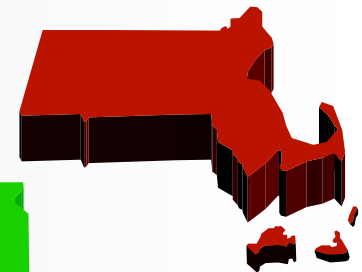
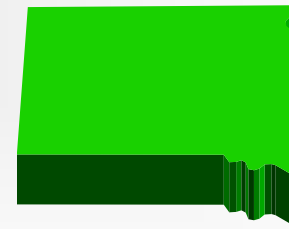
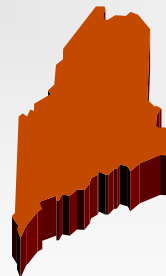
E.g., Heisner v. Genzyme Corp., 2008 WL 2940811 (N.D.L. 2008): recognizing unpreempted viability of post sale duty to warn theory and negligence *per se* claim, yet Rule 12(B)(6) Motion granted but with leave for plaintiff to amend Complaint.

So, courts free to impose post-sale duty to warn on medical device manufacturers, and claims based on this probably duty *not* preempted (PMA: probably: 510(k) definitely)

A State Smorgasbord: Some states have expressly adopted Restatement (Third).

- Diverse treatment across the jurisdictions
- Can't choose forum – *lex loci delicti*
- Some states simply adopted post-sale duty to warn when appropriate case presented itself.
- States that have expressly adopted § 10 of the Restatement (Third) through case law:

- Florida
- Iowa
- Maine
- Massachusetts
- New York
- South Dakota



Express Restatement Adoption Through Case Law

- *Example: Lewis v. Ariens Co.*, 751 N.E.2d 862 (Mass. 2001); Plaintiff brought claim against Ariens after being injured by impellers of snow blower.
- Bought the snow blower from sister of a friend—so, attenuated purchase sequence; bought used
- Theory of claim based upon notion that manufacturer had breached duty to warn plaintiff of product defects or dangers discovered *after* snow blower entered stream of commerce.
- Second hand purchasers—generally too diffuse a universe to impose this duty

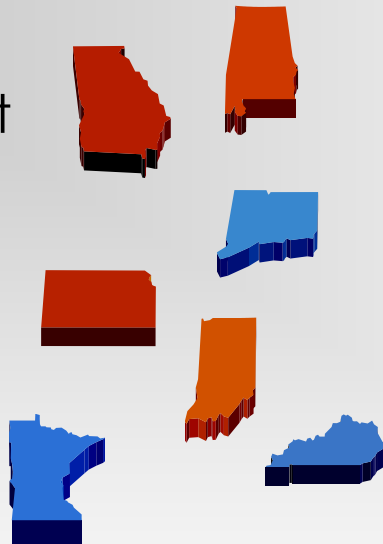
Express Restatement Adoption Through Case Law

- Although court did not find duty to warn on the facts of *that case*, court stated, “We take this occasion to adopt the principles set forth in the Restatement (Third) ... regarding a manufacturer’s continuing duty to warn users of substantial product risks or dangers discovered post-sale.”
- *Another Example: Lovick v. Wil-Rich*, 588 N.W.2d 688,694 (Iowa 1999), Iowa court simply quoted Restatement (Third) and enumerated reasonableness test, and stated its agreement.
- Other states have adopted the Restatement (Third) in similar ways.

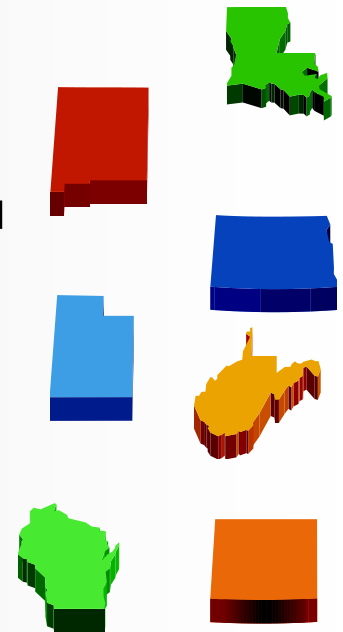
The Smorgasbord: Some states recognize post-sale duty to warn, but do not expressly mention Restatement (Third).

These states impose post-sale duty to warn and cite to the reasonable person standard:

- Alabama
- Connecticut
- Georgia
- Indiana
- Kansas
- Kentucky
- Minnesota



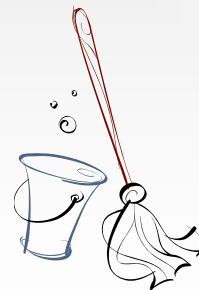
- Louisiana
- New Mexico
- North Carolina
- North Dakota
- Utah
- West Virginia
- Wisconsin
- Wyoming



Clearly impose post-sale duty to warn through case law, but do not expressly mention Restatement (Third).

The Post Sale Reasonable Person Test in the Case Law

- In Georgia, in *Smith v. Ontario Sewing Machine Co.*, 249 Ga. App. 364 (Ga. App. 2001) plaintiff brought suit after being injured by defective part on mop assembly machine that caused machine to activate on its own.
- Manufacturer was in negotiation with *plaintiff's employer* regarding defect at time of plaintiff's injury, but *plaintiff* had no awareness of problem.
- In discussing whether manufacturer owed plaintiff any duty to warn, court stated, "Georgia law imposes on the manufacturer of personal property the duty to exercise ordinary care to warn users of a known or reasonably foreseeable risk of injury or death after a product's sale, because the manufacturer's duty does not cease upon sale."



The Post Sale Reasonable Person Test in the Case Law

- Court went on to clarify factors it relied upon to make determination:
 - * Manufacturer's knowledge of foreseeable danger arising from reasonable use for which product is intended;
 - * Lack of adequate and specific post-sale warning;
 - * Failure to notify third parties who were in immediate danger from the defect of whom manufacturer had knowledge;
 - * The failure to make reasonable efforts to specifically determine identity of third parties who were in immediate danger;
 - * Similar to the reasonable person test enumerated in the Restatement (Third), but no reference to it.

The Post Sale Reasonable Person Test in the Case Law

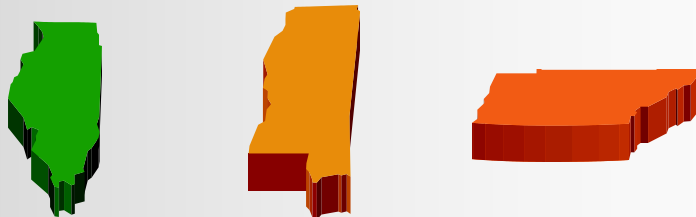
Similarly, *Patton v. Hutchinson Wil-Rich Mfg. Co.*, 861 P.2d 1299, 1314-15 (Kan. 1993), adopted 8 Point Reasonableness Test:

1. The nature of the harm that may result from use without notice,
2. The likelihood that harm will occur
3. How many persons are affected,
4. The economic burden on the manufacturer of identifying and contacting current product users,
5. The nature of the industry,
6. The type of product involved,
7. The number of units manufactured or sold, and
8. Steps taken other than giving of notice to correct the problem.

Just Say No! Some states expressly reject Restatement's adoption of post-sale duty to warn.

- Not all states have imposed a post-sale duty to warn. These states expressly reject Restatement (Third)'s adoption of a post-sale duty to warn:

- * Illinois
- * Mississippi
- * Tennessee



- In Mississippi, in *Palmer v. Volkswagen of America, Inc.*, 905 So. 2d 564 (Miss. App. 2003), plaintiffs brought an action against Volkswagen of America, Inc. when their ten-year old daughter was killed in automobile accident sustained from front-passenger airbag.
- One of theories was post-sale duty to warn, citing to Restatement (Third).

Just Say No! Some states expressly reject Restatement's adoption of post-sale duty to warn.

- Mississippi Court rejected claim and the post-sale duty:
- “This Court is not prepared to recognize a post-sale warning duty at this time and in the absence of legislative action.”
- Court examined Mississippi's Product Liability Act and stated that the plain meaning of the: “language is that the statute imposes liability on the manufacturer or seller for warnings that were inadequate at the time of sale, not for warnings that became inadequate at some later time.”

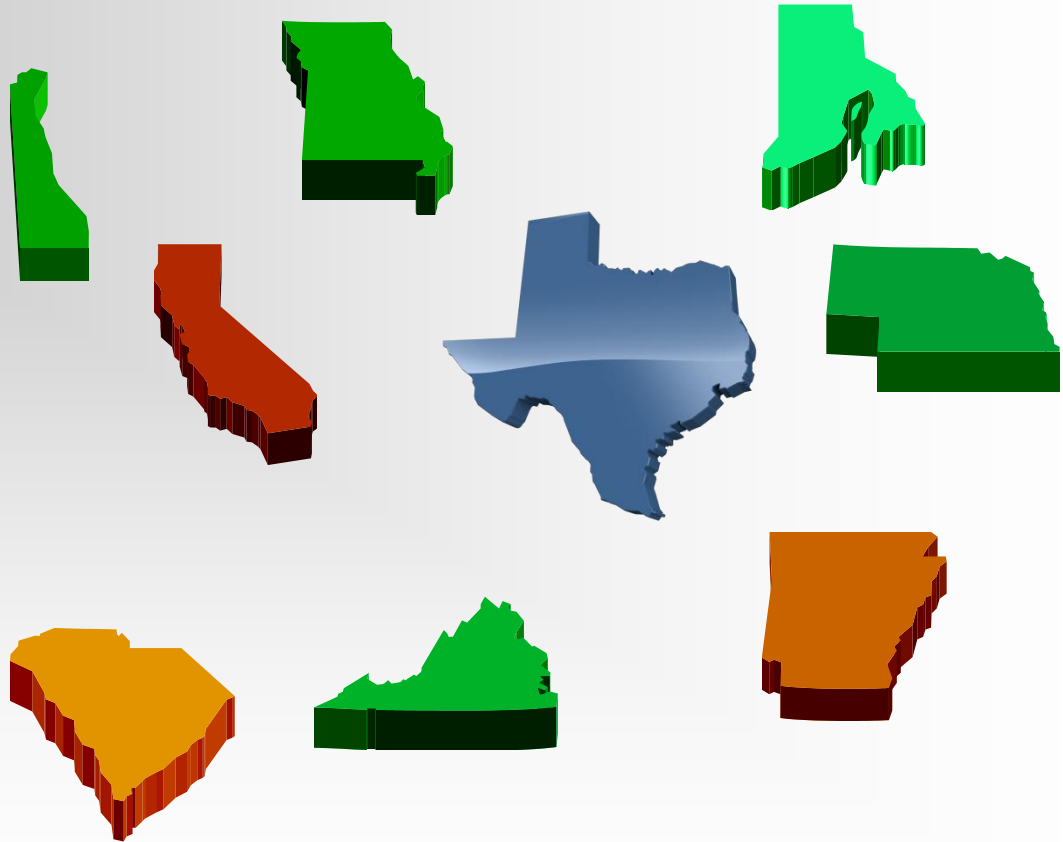
Just Say No! Some states expressly reject Restatement's adoption of post-sale duty to warn.

- In states that expressly reject position of § 10, court must pose question of whether manufacturer or seller had knowledge of defect at time of sale.
- If not, or if no defect existed at that time, then no post-sale duty to warn.
- Expressly rejecting post-sale duty to warn does not clarify whether there is no post-sale duty at all or only duty to warn for latent risks.
- These states might adopt post-sale duty to warn if appropriate case arises.

Just Say No! Some states expressly reject Restatement's adoption of post-sale duty to warn.

These states do not recognize any post-sale duty to warn:

- Arkansas,
- California,
- Delaware,
- Missouri,
- Nebraska,
- Rhode Island,
- South Carolina,
- Texas, and
- Virginia



Just Say No! Some states expressly reject Restatement's adoption of post-sale duty to warn.

- In Texas, in *Bryant v. Giacomini, S.p.A.*, 391 F. Supp. 2d 495 (2005), plaintiffs brought action based on product liability and post-sale duty to warn.
- Plaintiffs were inside their trailer home when it caught fire.
- Plaintiffs alleged that they had removed space heater from trailer although propane gas supply for heater was left connected. Gas valve cut off residence from propane gas supply.
- Plaintiffs' four-year old child was able to turn on valve as result, gas spread throughout trailer and ignited when one of the plaintiffs lit a cigarette lighter.
- Issues on appeal: Whether the state recognized post-sale duty to warn.



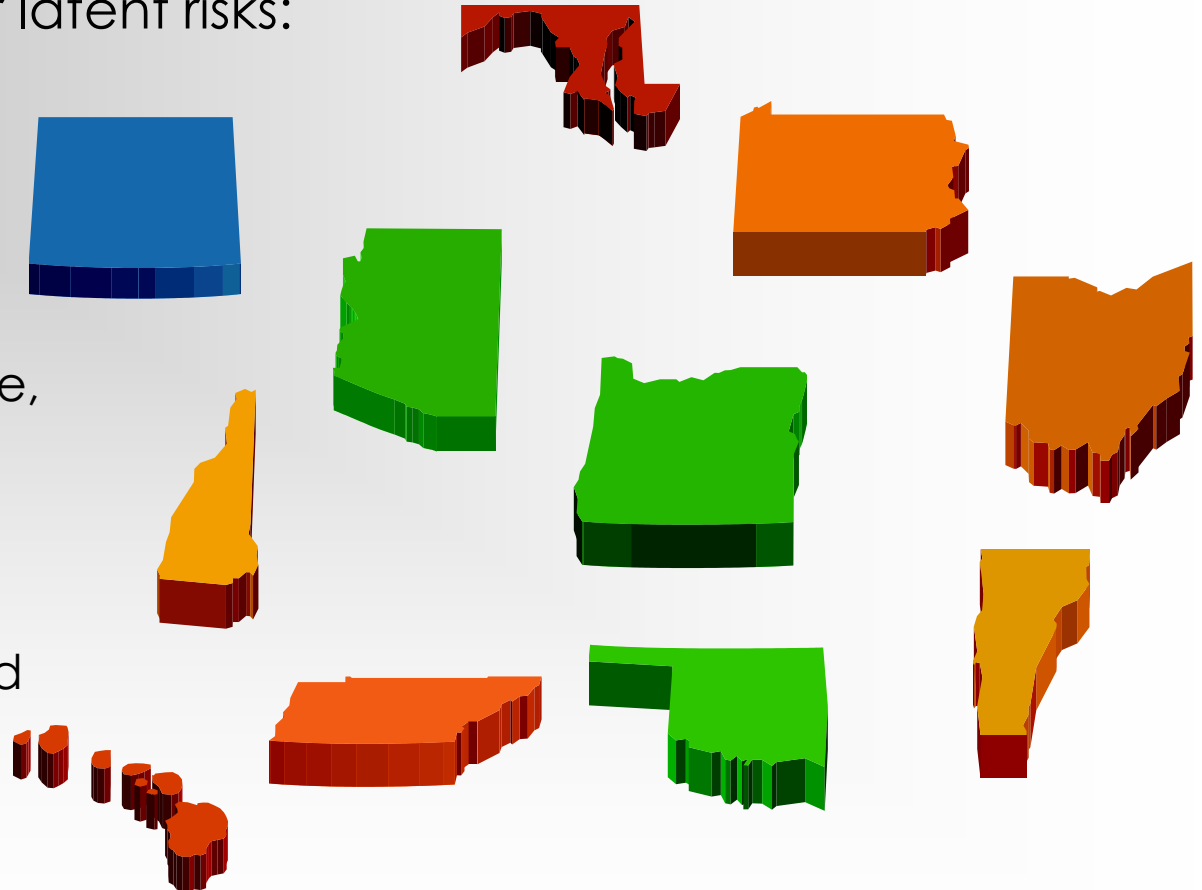
Just Say No! Some states expressly reject Restatement's adoption of post-sale duty to warn.

- This duty is not imposed in Texas.
- “Under Texas products liability law, a manufacturer has no duty to warn about a product after it has been manufactured and sold.”
- Language similar to that used by other states who do not recognize post-sale duty to warn.
- Analysis is clear: If manufacturer later gains knowledge of risk, there is no duty to warn.
- Duty to warn ends at point of sale.
- Some question might remain whether post-sale duty could be imposed for medical device manufacturers, however, as even the Restatement (Third) recognizes heightened duty in this area, as do many states - So, no guarantees, and a paucity of case law.

What They Wont See Can't Hurt You

The following states take a more moderate approach. That is, the risk must exist at time the product is sold and impose a post-sale duty to warn only for latent risks:

- Arizona,
- Colorado,
- Hawaii,
- Maryland,
- Michigan,
- New Hampshire,
- Ohio,
- Oklahoma,
- Oregon,
- Pennsylvania,
- Tennessee, and
- Vermont.



What They Wont See Can't Hurt You

- As *Wilson v. United Sates Elevator Corp.*, 193 Ariz. 255 (Ariz. App. 1998), explained:

In these circumstances, saying that there is a 'continuing duty to warn' is, of course, a tacit recognition that the duty existed in the first instance. Such an obligation is not at all synonymous, however, with the claim -- made here by plaintiff -- that where a product is free from all defects when sold, the seller, nevertheless, has a duty to monitor changes in technology and notions of safety and, either periodically or otherwise, notify its purchasers thereof. For where, as here, no initial duty to warn exists, none can be said to 'continue.'

Some states impose a post-sale duty to warn only for latent risks.

- In a state that recognizes a post-sale duty to warn for latent defects, first question that must be asked is whether defect existed at time of sale:
- If answer is yes, then analysis is similar to that imposed by the Restatement (Third).
- If no, then no post sale duty.

Factors in Deciding Whether to Advise to Warn Post Sale

- (1) If “open and obvious”/common sense – no, applies equally to post sale obviousness
- (2) If users—specific end users—easily identified – yes.
- (3) Degree of seriousness of bodily harm is a factor—paper cuts – no! Many states *do not* impose unless risk is life threatening.
- (4) Existence of learned intermediary, who has been warned, and/or instructed, may lessen duty; A critical factor with medical devices
- (5) State of the Art Principles/Defense may be argued to negate post sale duty (*i.e.*, state of scientific knowledge at time device was manufactured)

Factors in Deciding Whether to Advise to Warn Post Sale

- (6) Efficient, comprehensive supply chain product tracking and distribution systems, may be good for business, but could enhance the duty.
- (7) Remember—Awareness of post sale issues is good for ameliorating claims early and preventing future claims—so, balancing required.
- (8) If change significantly improves product's safety, and easy to identify end users—should probably warn.

Litigation and Discovery: Problems and Ramifications

- May open discovery floodgates—Plaintiffs argue more discovery of post sale incidents—traditionally excluded as irrelevant to notice of defect.
- May enhance punitive damage likelihood (75% of punitive damage awards in product cases based upon failure of manufacturer to take post sale actions)
- Plaintiffs may now argue that Defendant's post sale warning program for particular product was insufficient (“could always do more”)

Problems/Ramifications

- Plaintiff's also seek to impose broader duty to obtain information from the field (more jury optics for punitives, especially if system easy to establish); So, establishing a post sale warning system, even if not required, may reduce punitive likelihood.
- May be HIPPA/Privacy issues in identifying end users.
- Statutes of Repose may also negate duty.
- Always argue, preemption, because still murky.

CONCLUSION

- The Restatement (Third) approved heightened standard for courts to apply in cases involving prescription drugs and medical devices.
- Probably not preempted for medical device manufacturers by the FDA's regulation of these devices.
- Still not any uniformity across the United States with regard to recognizing and imposing post-sale duty to warn.
- Majority of the states do recognize and impose some type of post-sale duty to warn, in certain situations, whether by statute or common law.
- Since can't predict Lawsuit *situs*, worst case scenario may govern internal procedures

Superior Insurance Solutions

for the Medical Technology and Life Sciences Industry.

Medmarc is the **one-stop-shop** for insurance solutions for manufacturers and distributors of medical technology and life sciences products.

Request a quote today and find out how Medmarc can satisfy all your insurance needs.

[Request a Quote](#) >>



Medtech & Life Sciences News Articles

[More >>](#)

[Responding to Form 483s and Warning Letters](#)

[Do Distributors Require Professional Liability](#)

Combined Expertise Superior Protection

[Learn more >>](#)

Medmarc teams with **The Hartford** and **Biomedic-Insure** to offer comprehensive "all-lines" insurance to the companies we serve.

- [My Account](#) >>
- [Generate a Loss Run](#) >>
- [Report a Claim](#) >>

News and Resources



Publications

Medical Device and Life Sciences News

Medmarc offers a variety of publications specifically designed to help you enhance your quality management system, reduce your potential products liability risk exposure, and improve your litigation defense position.



Articles

Our articles provide in depth discussions regarding risk management and products liability issues in the industry.

[Read All »](#)



Ask an Expert

Medmarc's panel of industry experts is available to assist you with your questions regarding products liability risk management, litigation management and regulatory compliance.

[Read All »](#)



Risk Management 101

Our Risk Management 101 series contains brief, one page summaries of important FDA, products liability and risk management topics.

[Read All »](#)



The Hartford Loss Control

Our partner, The Hartford, provides practical insights on a variety of risk management and safety concerns through their publications, Technical Information Paper Series (TIPS) and Technology Best Practices.

[Read All »](#)

Webinars & Podcasts

Addressing industry issues and trends



Responding to Form 483s and Warning Letters

[Register Now »](#)

FDA has already issued more than 875 Warning Letters this year, compared with 873 last year. This enforcement trend is expected to continue, making it essential that medical technology and life sciences companies know...

[Learn More »](#)



[View All Webinars & Podcasts »](#)

Announcements & Events

The latest news and events about Medmarc



Medmarc Joins Florida Medical Manufacturers' Consortium

Medmarc is pleased to announce that we have joined Florida Medical Manufacturers' Consortium...

[Sara Dyson to Present at Advamed MTLI Workshop](#)

[In3 Summit 2011](#)

[AdvaMed 2011 - The MedTech Conference](#)

[View All Announcements & Events »](#)