

Products Liability *Perspectives*



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Notes From the Editors

"Summertime and the living is easy," so the song goes, but not so this summer. From the debt crisis, to the wild roller coaster ride of the stock market, to the unrelenting heat in the Midwest and terrible draught in Texas, the summer of 2011 has, like many product liability cases, presented many unexpected challenges -- some new, some not so new. Keeping in step with challenges new and old, our contributing authors to this Summer edition of the Newsletter address issues from "Greenwashing" and the U.S. Supreme Court's recent decision in *Nicastro*, to defending a fire claim and applying the Learned Intermediary Doctrine to Off-Label Use claims. The insight they provide just might change the way you respond to the next claim confronting one of your products.

Navigating the legal landscape in the product liability arena continues to be daunting. It seems like every new development in technology or business (like environmentally friendly or "green" products) generates new claims to attack these advancements. At the same time,

manufacturers continue to be confronted with age old claims that their products -- not the users -- are the cause of accidents. The goal of the members of ALFA's Product Liability Practice Group is to keep our clients ahead of the curve in predicting and responding to the numerous challenges -- old and new -- that manufacturers and other businesses face. Let us know what particular issues are knocking at your door so we can help you turn them away without much effort or disruption. In the meantime, we hope to see many of you at the upcoming ALFA International product liability seminar next month in Nashville, Tennessee.

-Colleen Murnane, Stanton Shuler and
Jackson Ables

How Not to Get Burned While Investigating a Fire Claim: A Primer on Exculpating Your Product as the Cause of a Fire

By Dennis B. Keene, Esq.

“With few exceptions, the proper methodology for a fire or explosion investigation is to first determine and establish the origin(s), then investigate the cause.”¹ The methodology is fully explained in the widely accepted guide to fire investigations published by the National Fire Protection Association: NFPA 921. Anyone handling any aspect of a fire claim must be familiar with the content of this publication. This article provides an overview of origin and cause determinations as discussed in NFPA 921 and explores how to support or attack an expert’s opinions in a fire claim case.

Before we begin the overview of basic fire investigation, a few important pointers need to be mentioned. First, time is of the essence in preserving and examining a fire scene. Inclement weather, a desire to repair the burned structure (particularly if it is a residence), and other factors may destroy evidence. The sooner the investigation begins, the greater the likelihood that evidence will be preserved.

Second, all of the important players should be present during the fire scene investigation. Often, a plaintiff’s lawyer or insurer will conduct an initial, non-destructive inspection that may reveal the general area of origin of the fire and potential ignition sources. Manufacturers of products found in the area of origin may be notified and offered the opportunity to participate in the investigation before any fire debris or other evidence is moved. As a manufacturer whose product may be the suspect cause of the fire, have your team assembled and be prepared to try to exculpate your product at the fire scene. Send a qualified origin expert as well as a technical representative who is very familiar with the product at issue, and, depending on the size of the claim, consider sending in-house or outside counsel to help evaluate potential evidentiary concerns and to advocate your position during the investigation. If you can persuade the opposing investigator of your position at the scene, you may avoid lengthy litigation. Since this is the time to begin developing your defense, it is important to have the main players on your fire investigation team in place from the start.

Finally, if after inspecting the fire scene it looks like your product may be a target, be prepared to continue the investigation and analysis after leaving the scene. Obtain

copies of all official reports and photographs; send a spoliation letter, if appropriate; determine the size of the loss; and continue to attempt to exculpate your product by determining the origin of the fire and testing your own hypothesis as to why your product could not have been the cause.

With these points in mind, let’s turn to the two main components of the investigation: determining the origin and cause of the fire.

DETERMINING THE ORIGIN OF THE FIRE

“The origin of a fire is one of the most important hypotheses that an investigator develops and tests during the investigation.”² The origin is the physical location where a heat source and fuel come in contact with each other and a fire begins. Investigators should never look for heat sources first and then look for the fire origin. The area of origin is merely the broader space where the fire originated; it may contain several potential sources of the fire. For example, the photograph below shows that the general area of origin is most likely on the left half of the home based on the relative lack of apparent fire damage to the right half of the home.



Testing this hypothesis should result in finding that the fire origin is contained within that area. As a caveat, one cannot make any assumptions about an opponent’s origin determination as some investigators are more concerned with finding a deep pocket to pay for the damage, rather than finding the area of origin.

The fire origin is often determined by considering eyewitness accounts, fire patterns, arc mapping, and fire dynamics. An eyewitness can be a person who witnessed the ignition or spread of the fire, police, first responders, neighbors or even fire reconstruction personnel. Many times eyewitnesses are overlooked and they typically do not come for-

ward to volunteer information so an aggressive, early effort must be made to secure witness perceptions and observations. Although eyewitness accounts can be relevant in determining origin, their reliability must always be consistent with other findings. When witness statements are not supported by the investigator's interpretation of the physical evidence, the investigator should evaluate each separately.

Flames, radiation, hot gases, and smoke create patterns that may lead investigators to the area of fire origin.³ These patterns often show the history and direction of a fire. Each time another fuel source is ignited or the ventilation to the fire changes, the rate of energy production and heat distribution will change.⁴ When observed by a trained investigator, these pattern changes can expose the point of origin. There are two basic types of fire patterns: movement and intensity patterns.⁵ Flame and heat movement patterns are produced by the growth and spread of fire away from an initial heat source, whereas flame and heat intensity patterns are produced by the response of materials to the effects of various intensities of heat exposure.⁶ As shown in the photograph below, fire patterns can produce lines of demarcation that can indicate, but are not definitive of the direction of fire spread:



However, as the size and duration of the fire increase, following fire patterns to locate the area of origin becomes increasingly difficult, particularly in rooms completely engulfed in the fire.

In addition to fire patterns, electrical arcs can point to the area of origin. An arc is a high-temperature luminous electric discharge across a gap or through a medium such as charred insulation or wires. It is but one source of potential heat generation that must be examined.⁷ The disparity in temperatures within an arc is thousands of degrees, depending on circumstances including current, voltage drop, and metal involved, but the heat can dissipate very rapidly and can only start a fire with sufficient fuel nearby. Investigators look for evidence of arcing, usually in the form of "beads" left at the ends of wires:



However, the formation of these beads can be the *result of* the fire, and not necessarily its cause.

"Arc mapping" is the technique by which an investigator uses the identification of arc locations to aid in tracing the area of fire origin. For example, if arcing is found on one side of a room, it is clear that electrical current was still flowing through the affected wires when the fire hit it. It may also indicate the source of the fire when looked at in conjunction with other evidence.

The final key to help identify the fire origin is having an understanding of fire dynamics, that is, the physics and chemistry of fire initiation and growth, and the interaction between the fire and the building's systems. Without a solid grasp of fire dynamics, an investigator may miss or overstate the relevance of fire patterns, arcing and witness accounts.

In some cases no single item of evidence will be sufficient to establish the area of origin.⁸ In those cases the investigator should use all available resources to develop potential fire scenarios and determine which scenarios plausibly fit all of the available evidence. In other cases it will be impossible to unquestionably fix the origin of a fire,⁹ and an investigator should not make a determination of a single point of origin unless the evidence is conclusive.

DETERMINING THE CAUSE OF THE FIRE

Generally speaking, if the origin cannot be determined, the cause cannot be determined. Once an origin is determined, the investigation turns to the cause of the fire and should identify all heat-producing devices, appliances, or equipment within the area of origin that could have caused the ignition.¹⁰ These heat-producing components are potential competent ignition sources and should be eliminated from consideration only if there is definitive evidence that it none of the components could be the ignition source for the fire.¹¹

In order to identify and eliminate competent ignition

sources, and to understand the cause of the fire, one must have a good understanding of the principles of fire and fire spread. Fire can result only from the combination of a fuel and an ignition source. Neither one alone can start a fire. Determining the cause of a fire requires the identification of a competent ignition source, the identification of the material first ignited (the fuel that first sustains combustion beyond the igniting source), and the circumstances that allowed these factors to come together to allow the fire to occur. With respect to the material first ignited, investigators must consider its (1) ignition temperature, (2) combustion properties, and (3) the size, shape, and orientation of the material.¹² Identifying the initial fuel is critical to understanding and investigators must do so by employing the scientific method discussed in NFPA 921 when gathering this data, and developing and testing various hypotheses.¹³ For example, if an investigator hypothesizes that an electrical wire shorted and ignited a wooden beam, testing must confirm that the electrical wire is a competent ignition source that could generate sufficient temperature and energy and will be in contact with the beam (the first material ignited) long enough to raise it to its ignition temperature. If the heated electrical wire reaches 300 degrees, but the ignition temperature of the wooden beam is 600 degrees, there is no likelihood the beam is sufficient fuel for ignition.



Any determination of fire cause should be based on evidence rather than on the absence of evidence; however, when the origin of a fire is clearly defined, it is occasionally possible to make a credible determination regarding the cause of the fire, even when no physical evidence of the ignition source is available.¹⁴ This finding may be accomplished through credible elimination of all other potential ignition sources, provided that the remaining ignition source is consistent with all known facts. Elimination, which involves the developing, testing, and rejection of alternate hypotheses, becomes more difficult as the degree of destruction in the area of origin increases. If the level of certainty of the investigator's opinion is only "possible" or "suspected," the cause should be listed as undetermined.¹⁵

THE ADMISSIBILITY OF EXPERTS' ORIGIN AND CAUSE DETERMINATIONS

The U.S. Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), ruled that the Federal Rules of Evidence serve as the proper source for

evaluating the admissibility of expert testimony and specifically addressed the regulation of scientific evidence admissible under F.R.E. 702. Under F.R.E. 702 an expert opinion is admissible "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." 553 F.3d at 643. When determining the reliability of an expert's opinion, courts may examine whether the theory has been tested, whether the theory has been subjected to peer review and publication, the known potential rate of error, and the method's general acceptance. 509 U.S. at 593-94.

As courts have recognized, NFPA 921 is the industry guideline for fire investigations. See *Presley v. Lakewood Engineering and Mfg. Co.*, 553 F.3d 638 (8th Cir. 2009); *Fireman's Fund Ins. Co. v. Canon U.S.A., Inc.*, 394 F.3d 1054 (8th Cir. 2005). Accordingly, the admissibility of an expert's opinion regarding a fire investigation may hinge on that expert's adherence to the methodology described in NFPA 921. Assuming you are in a jurisdiction that has adopted *Daubert* and its progeny, a fire investigator's methods, as applied following NFPA 921, will be analyzed under *Daubert*. Courts, and federal courts in particular, are apt to strike fire investigators' origin and cause opinions if they are not sufficiently reliable. See, e.g., *Presley, supra.* (affirming exclusion of expert's opinion due to expert's failure to conduct appropriate data analysis and testing); *Fireman's Fund, supra.* (affirming exclusion of expert testimony because the expert did not apply reliably the standards of NFPA 921); *Bryte v. American Household, Inc.*, 429 F.3d 469 (4th Cir. 2005) (affirming exclusion of expert's opinion because expert did not examine lamp or wiring at issue, and failed to exclude another competent ignition source); *Truck Insurance Exchange v. Magnetek, Inc.*, 360 F.3d 1206 (10th Cir. 2004) (affirming exclusion of expert's opinions about cause of fire as they were not based on a sufficiently reliable scientific theory).

Application of an expert's investigative technique to the particular facts of the case is crucial to the admissibility of an expert's testimony. NFPA 921 requires the investigator to "compare. . . his or her hypothesis to all known facts" and to examine the fire theory against empirical data obtained from the fire scene and appropriate testing.¹⁶ Even if an expert claims to address the particular facts of the case, a speculative opinion is insufficient for admissibility of a fire

expert's testimony. For example, the court in *Weisgram v. Marley Co.*, 169 F.3d 514 (8th Cir. 1999), excluded an otherwise qualified fire investigator's opinion that was based on general observations regarding fire origin rather than specific evidence substantiating the chain of events in the fire causation theory. The court explained that an expert's "qualification as a fire investigator [does] not give him free rein to speculate before the jury as to the cause of the fire by relying on inferences that have absolutely no record support." 169 F.3d at 519; *see also State Farm Fire & Gas Co. v. Holmes Prods, Inc.*, No. 04-4532 (3d Cir., Jan. 31, 2006) (unpublished)(excluding expert's opinion where expert had no methodological or factual basis to support opinion that lamp came into contact with drapes).

So when should the principles of *Daubert* and F.R.E. 702 be considered in a fire claim case? From the moment you receive notice that your product is suspected of having caused a fire you and your team should be developing and challenging all expert opinions in light of the principles in NFPA 921. In order to do so, consider the following questions that all origin and cause experts should be able to address:

Origin Experts:

- Have fire patterns been reliably interpreted?
- How was the fire suppressed/fought (direction and methods)?
- What ventilation was available to spread the fire?
- Have all the witnesses been interviewed and reports/photos obtained?
- Is the growth and spread of the fire consistent with the origin hypothesis?
- Are the first fuel ignited and secondary fuel sources consistent with fire growth?
- Has arc mapping been completed?
- Have all sources of heat within the area of origin been identified?

Cause Experts:

- Can the temperature of the ignition source be validated?
- Can the first material ignited be properly identified?
- What is the temperature of the ignition source compared to the temperature needed to ignite the first material?
- Can the ignition source transfer enough energy to the first material ignited to start the fire?
- Was the ignition source generating heat prior to the ignition (i.e., was it turned on or capable of heating at the moment the fire occurred)?

- Have all other causes of the fire been eliminated?

Although not exhaustive, these questions should serve not only as the foundation to determine the reliability and admissibility of any fire expert's opinions, but also to help to determine whether your case should be settled or tried.

¹ NFPA 921: *Guide for Fire and Explosion Investigations*, ¶ 4.1 (National Fire Protection Association; 2011 Ed.) (hereinafter "NFPA § ____").

² NFPA 921 § 17.1.

³ NFPA § 6.3 *et seq.*

⁴ *See generally, Id.*

⁵ NFPA § 6.4.

⁶ NFPA §§ 6.4.1.1, 6.4.1.2.

⁷ NFPA § 8.9.4.1.

⁸ NFPA § 17.2.1.2.

⁹ NFPA § 17.2.1.3.

¹⁰ NFPA § 18.3.2.

¹¹ NFPA § 18.5.

¹² In evaluating the material's combustion properties, the investigator must consider, in part, whether the material is of "char formation," as opposed to "melting formation," and whether the material is "self-propagating," as opposed to "self-extinguishing". A discussion of these concepts is beyond the scope of this article, but they are defined and discussed in NFPA 921.

¹³ NFPA § 18.5.

¹⁴ NFPA § 18.2.1.

¹⁵ NFPA § 18.7.4.

¹⁶ NFPA § 18.6.2.



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Nicastro Doesn't Resolve Uncertainty for Foreign Manufacturers

By Jules S. Zeman and William "Skip" Martin

Those who were anticipating any bright-line rules for the application of specific jurisdiction over foreign manufacturers from the Supreme Court's opinion in *Nicastro* may have been disappointed last week. *J. McIntyre v. Nicastro*, 564 U.S. ____ (2011)

On June 27, the last day of the U.S. Supreme Court 2010 term, the Court overturned the New Jersey Supreme Court's overbroad application of specific jurisdiction over a U.K. manufacturer that had virtually no contacts with New Jersey. However, because of the overwhelming absence of any facts which could have validly given rise to personal jurisdiction and because the decision was a mere plurality, the precedential value of the decision is not strong. As Justice Stephen G. Breyer noted in his concurring opinion, joined by Justice Samuel A. Alito, Jr., there are many situations in international commerce that are not reached by *Nicastro*.

The case arose from an accident involving Robert Nicastro, a scrap metal plant worker in New Jersey, who severed four of his fingers while using a shear machine manufactured by United Kingdom company, J. McIntyre (McIntyre). McIntyre sold its machines through a U.S. distributor, McIntyre Machinery America (MMA), a distinct and separate entity with no common ownership or control. McIntyre did not undertake any activity in New Jersey and had no contacts there. It had never advertised, sold or solicited the business of anyone in New Jersey to buy its products. The sale to Nicastro's New Jersey employer was obtained at a booth jointly maintained by McIntyre and MMA at a trade show in Las Vegas, one of a number of trade shows in which McIntyre and MMA participated in the U.S.—none of which were in New Jersey.

The Supreme Court reversed the New Jersey's Supreme Court's holding that New Jersey could exercise jurisdiction over McIntyre. The reversal was widely expected based on the complete absence of any connection of McIntyre with New Jersey, other than the fact that one of its machines ended up there. There were no facts on which a valid finding that McIntyre purposefully availed itself of the privilege of doing business in New Jersey. Justice Kennedy's opinion, writing for the plurality, and joined by Chief Justice John G. Roberts, Justice Anton M. Scalia and Justice Clarence Thomas, which made jurisdiction dependent on purposeful availment, is consistent with Justice Sandra Day O'Connor's opinion in *Asahi Metal Industry Co. v. Superior Court*,

480 U.S. 102 (1987). However, what constitutes "purposeful availment" of the privilege of doing business in a particular jurisdiction is no clearer after *Nicastro* in many common situations.

The primary contribution of *Nicastro* to the law will likely be to clarify that most current members of the Supreme Court reject the premise that the mere placement of a product into the stream of commerce by a manufacturer absent something more is sufficient for imposition of personal jurisdiction. Justice Kennedy criticized any impression arising from Justice William J. Brennan Jr.'s opinion in *Asahi* that traditional concepts of sovereign authority had been replaced by considerations of fairness and foreseeability.



Justice Kennedy acknowledged, however, that placing goods into the stream of commerce with the expectation that they will be purchased by consumers within the forum *may indicate purposeful availment* of the privilege of conducting activities within that state, thus invoking the benefits and protections of its laws, and has always allowed for the imposition of jurisdiction over foreign corporation. (*World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 288, 290 (1980)). He pointed out that this statement merely observed that a defendant may in an appropriate case be subject to jurisdiction without entering the forum, as where manufacturers or distributors "seek to serve" a given state's market. While noting that a defendant may sometimes take actions amounting to legal submission to the jurisdiction of a particular state's court by sending its goods rather than its agent, he explained that, as a general rule, it is not enough that the defendant might have predicted that its goods will reach the forum state.

One must resist any temptation to conclude that *Nicastro* has ended the "stream of commerce" theory of specific jurisdiction. The critical question of what actions constitute "purposeful availment" of the privilege of doing business within a particular state has always been a complicated one. In other words, what is the "something more" than mere placement into the stream of commerce that would satisfy the standard. In today's world of rapid advances in technology, communication and marketing, the question is becoming far more unpredictable and complex. This is where the limitations on the utility of *Nicastro* are seen. As *Nicastro* involved only a relatively simple set of business transactions and relationships, its holding has no useful application to business and marketing transactions having

modern day complexities. The “Stream of Commerce” theory, as advanced by Justice Brennan in *Asahi*, may play an important role in jurisdiction determinations in a variety of situations more complex than that in *Nicastro*.

Justice Breyer recognized the limitations arising from Justice Kennedy’s opinion as applied to today’s world and disagreed with the plurality’s language assailing simple “stream of commerce” theory for all situations. Justice Breyer argued that the New Jersey Supreme Court’s exercise of jurisdiction over McIntyre could have been reversed simply upon the prior precedents of the Court because the record clearly showed that McIntyre had no actual or constructive knowledge that its products would end up there.

Justice Breyer questioned what possible application the plurality’s standards would have when a company targets the entire world by selling products from its website or through an intermediary like Amazon.com that then receives and fulfills the orders. He also questioned what would happen if a company markets its products through popup advertisements that it may know will be viewed in the forum state.

Additional difficult questions arise from even slight modifications of *Nicastro*’s facts. For example, how would the plurality’s standards apply if McIntyre’s unrelated distributor were successful in selling 10,000 units of McIntyre’s machines in New Jersey, instead of merely one or four, and dozens of New Jersey residents were injured instead of merely one? Or what if there were 100,000 units sold and a few hundred injuries to residents?

Difficult questions also arise in the context of foreign component part manufacturers, which now produce greater volumes of parts for domestically sold finished products than ever before. For example, how would the plurality’s standards apply to a foreign component part manufacturer with no direct contacts with a forum state and no distributor in the U.S., where the manufacturer actually knows or should know that all of its components are incorporated into finished products that are and will be successfully marketed to a few (or all) states by a finished product manufacturer, with hundreds of thousands of units sold annually in a forum state and hundreds of injuries allegedly caused by defects in its component part?

There likely will be attempts to cite *Nicastro* for a rule that marketing to the entire United States, but not to any specific states, will not give rise to specific jurisdiction in any state. But can such an argument withstand scrutiny where great volumes of products are sold throughout the United States through mechanisms such as web sites, distributors or finished product manufacturers that actually reach thousands or hundreds of thousands of a forum’s residents annually?

While there is a reluctance to base jurisdictional determinations on the intentions of manufacturers, cannot an objective approach be achieved by a focus on the actual knowledge of manufacturers of the volume of its products sold into a particular forum?

These situations may generate a need for analysis closer to Justice Brennan’s concurring opinion in *Asahi* than the plurality in *Nicastro*. Based on Justice Breyer’s concurrence and Justice Ruth Bader Ginsburg’s dissent, collectively representing five justices, it’s possible that *Nicastro* will be factually distinguished into obscurity in many instances. In the alternative, the *Nicastro* methodology may continue, but with an ever-broadening definition of “purposeful availment.” That would include a significant aspect of foreseeability or actual knowledge of the state or states in which a manufacturer’s products will end up. Meantime, the law will likely evolve to acknowledge modern, global trade conditions.



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User's Gross Mishandling of Product Does Not Entitle Defendant Manufacturer to Summary Judgment in New York

By Cathleen B. Clark, Esq. and William D. Yoquinto, Esq.

Under the federal rule, a defendant is entitled to summary judgment if he successfully establishes that the plaintiff has failed to make a showing sufficient to establish the existence of an element essential to the plaintiff's case, and on which the plaintiff bears the burden of proof at trial. See Celotex Corp. v. Catrett, 477 U.S. 317 (U.S. 1986) citing Fed. R. Civ. P. 56(c). In a recent products liability case, the New York Court of Appeals, the state's highest court, reminded and cautioned product liability litigants moving for summary judgment in the Empire State of a unique burden they face in New York, which does not follow the federal rule. Yun Tung Chow v. Reckitt & Colman, Inc., 2011 NY Slip Op 3888, 6 (N.Y. May 10, 2011). It now seems clear that in New York, even if the sole proximate cause of the plaintiff's injury was a failure to follow product warnings and instructions, a defendant manufacturer must affirmatively establish that its product was reasonably safe for its intended use to gain summary judgment. Chow, 2011 NY Slip Op 3888.

The plaintiff in Chow was injured when using Lewis Red Devil Lye ("RDL") to unclog a floor drain in the kitchen of the restaurant where he worked. RDL is 100% Sodium hydroxide, commonly known as lye. The RDL bottle was marked with a skull and cross bones and contained explicit instructions and warnings, including warnings of the possibility of splash back and the possibility of serious injury if the product is not used as directed. Under the label's directions, users were instructed to wear protective eye wear and rubber gloves and were warned never to pour the lye directly from the container into the drain. Rather, users were instructed to use a plastic spoon to scoop out one tablespoon of lye and pour the RDL into the drain. Users were also cautioned to keep RDL away from aluminum utensils. After waiting thirty (30) minutes, according to the instructions on the RDL label, users could pour several cups of cold water down the drain to clear it.

Mr. Chow, who could not read English, testified that he did not read the label or ask anyone to interpret the directions for him. He learned how to handle the RDL by watching his co-workers use the product. In violation of the product use instructions, Mr. Chow put three spoonfuls of the lye into a dry aluminum container and then mixed it with approximately three cups of cold water. The plaintiff then poured the combined mixture down the drain. Immediately

thereafter, a back splash occurred and the mixture sprayed Mr. Chow's face causing serious injury to him, eventually resulting in the loss of his vision in one eye. At the time of the incident, the plaintiff was not wearing any protective gear.

As a result of this incident, Mr. Chow and his wife sued the defendant entities responsible for the manufacture, distribution and package design of RDL, bringing negligence and strict liability claims based on theories of inadequate warning and design defect. See Chow, 2011 NY Slip Op 3888, 1. In New York, a defectively designed product is defined as one which, "at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use; that is one whose utility does not outweigh the danger inherent in its introduction into the stream of commerce." Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 107 (N.Y. 1983) quoting Robinson v. Reed-Prentice Div. of Package Mach. Co., 49 N.Y.2d 471, 479 (N.Y. 1980).



In order for a plaintiff in New York to establish a prima facie case for defective product design, the plaintiff must demonstrate that: (1) the manufacturer breached its duty to market safe products when it marketed a product designed so that it was not reasonably safe; and (2) that the defective design was a substantial factor in causing the plaintiff's injury. Id. at 107. In order to show that a product was not "reasonably safe," a plaintiff bringing a design defect claim in New York must produce evidence that there was a "substantial likelihood of harm" associated with the use of the product and it was "feasible to design the product in a safer manner." Id. at 108. In opposition, the defendant may present evidence that the product was safe, meaning its utility outweighed its risks when the product was designed, such that the risks were reduced to the "greatest extent possible while retaining the product's inherent usefulness at an acceptable cost." Id.

The Chows' complaint was originally dismissed by the Supreme Court, Bronx County, which granted the defendants' motion for summary judgment. Yun Tung Chow v. Reckitt & Colman, Inc., 2010 NY Slip Op 13, 1 (N.Y. App. Div. 1st Dep't 2010). On appeal, the Appellate Division, First Department, unanimously upheld the dismissal of the plaintiffs' inadequate warning claims, noting that Mr. Chow

had made no attempt to read, or obtain assistance in reading, the RDL label. *Id.* The court, in a divided decision, ultimately also upheld the dismissal of the plaintiffs' design defect claim, finding that the defendants had met their summary judgment burden by making a prima facie showing that Mr. Chow's failure to follow the label's warning and instructions was the sole proximate cause of the accident. *Id.* at 2. The court cited two other New York Appellate Division cases with nearly identical facts wherein the plaintiffs' product liability claims were dismissed because the evidence established that the plaintiffs' failure to follow packaging instructions on drain cleaners was the cause of the plaintiffs' injuries. *Chow*, 2010 NY Slip Op 13, 2 citing *Sabbatino v. Rosin & Sons Hardware & Paint*, 253 A.D.2d 417 (N.Y. App. Div. 2nd Dep't 1998) (finding plaintiff's failure to follow label's instruction to cover drain after using drain cleaner was cause of plaintiff's injury when product back splashed); *Guadalupe v. Drackett Prods.*, 253 A.D.2d 378 (N.Y. App. Div. 1st Dep't 1998) (concluding any labeling or design defects were not proximate cause of plaintiff's accident where plaintiff made no attempt to read label on drain cleaner or obtain assistance with product before use). In addition to finding that Mr. Chow's misuse of the RDL was the "sole proximate cause of the accident", the Appellate Division also found that the plaintiffs had not successfully met their burden in establishing that RDL was unreasonably dangerous for its intended use, or that a safer alternative was feasible. *Chow*, 2010 NY Slip Op 13 at 2 - 3.

The Chows appealed the Appellate Division's decision and the Court of Appeals heard oral arguments on the case on March 24, 2011.² At oral argument, plaintiffs' counsel urged that the plaintiffs had established, through their expert's affidavit, that there was a reasonably safer way to design RDL (mainly through dilution) and that the defendants had never established that 100% Sodium hydroxide (NaOH) was the only way to clear a clogged drain. Plaintiffs' counsel further argued that the defendants' summary judgment argument was centered upon the claim that Mr. Chow's actions were the sole proximate cause of his injuries but, in order to meet their summary judgment burden, the defendants should have produced evidence from an expert establishing that it was not feasible to design RDL in a safer manner.

Defense counsel countered that the defendants had successfully established that Mr. Chow's mishandling of the RDL was the sole proximate cause of his injuries and, under the holdings of *Guadalupe* and *Sabbatino*, a plaintiff's defective design claim is defeated where the plaintiff's misuse of a product is found to be the sole proximate cause of the plaintiff's injuries. Defendants also claimed that "lye is

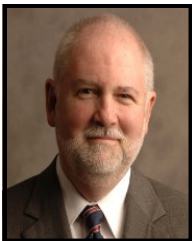
what it is" and diluting it (as plaintiffs suggested) would not be a "safer alternative," but rather an entirely different product. Defendants also pointed out that NaOH, a chemical compound, was not "designed" for purposes of a product liability analysis, and in any event NaOH is known to be inherently dangerous. At oral argument, the Court of Appeals made note of the fact that the defendants had not supported their claim that there was no safer alternative to their product with an expert affidavit.

In its decision, however, the Court of Appeals ultimately rejected the defendants' arguments. *Chow*, 2011 NY Slip Op 3888. As an initial matter, the Court of Appeals concluded that the defendants failed to show that Mr. Chow's handling of RDL constituted the sole proximate cause of his injuries "because a factfinder could conclude...that the product was so inherently dangerous that it should never have found its way into the stream of commerce as packaged and marketed." *Id.* at 4, citing *Voss*, 59 NY2d at 107. In concluding that a jury could find that RDL was "so inherently dangerous" it never should have entered the stream of commerce as packaged and marketed, the Court did not explain how RDL, as a drain cleaner, differed from the drain cleaning products at issue in *Guadalupe* or *Sabbatino*. In those cases the courts found that each user's failure to read the drain cleaning product label was the proximate cause of his injuries, as opposed to the design of the drain cleaning product itself. See *supra* *Sabbatino*, 253 A.D.2d 417; *Guadalupe*, 253 A.D.2d 378.

In *Chow*, the Court of Appeals noted that the defendants' claim that lye is inherently dangerous only "begs the question at the heart of the merits of [plaintiffs'] defective design claim: knowing how dangerous lye is, was it reasonable for defendants to place it into the stream of commerce as a drain cleaning product for use by a layperson?" *Chow*, 2011 NY Slip Op 3888 at 3. To this question, the Court of Appeals stated the defendants offered no answer and the assertions made in their attorney affirmation that RDL is inherently dangerous, its danger is well known, and RDL's label explicitly warned of its danger were insufficient to establish the defendants' entitlement to summary judgment. *Id.* at 2 - 3. Rather, to prevail on summary judgment, the defendants were required to show that RDL was "reasonably safe for its intended use," meaning that the utility of RDL as a drain cleaner outweighed its inherent danger. *Id.* at 2. Fatal to the defendants' summary judgment argument was the absence of an expert affidavit establishing that RDL was reasonably safe for its intended use. *Id.* See also *Voss*, 59 N.Y.2d at 108. In a concurring opinion, Judge Smith further explained that the Court's conclusion was the "result not of the merit of the plaintiff's case," but of the fact that parties in New York moving for sum-

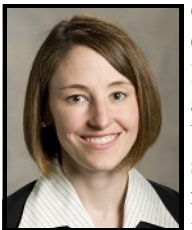
mary judgment in a products liability case in New York State, might have been falsely reassured by the case law in New York that, as a matter of law, they would be entitled to summary judgment upon a showing that the plaintiff's misuse of their product was the sole proximate cause of the plaintiff's injuries. See e.g. *supra* Sabbatino, 253 A.D.2d 417; Guadalupe, 253 A.D.2d 378. However, the Court of Appeals decision in Chow has clarified the burden defendants must meet in defeating a products liability claim in New York at the summary judgment phase. As explained in Chow, even evidence of a plaintiff's gross misuse of a product will not defeat the plaintiff's defective design claim - defendants moving for summary judgment against a defective design claim must also establish, through an expert affidavit, that their product was reasonably safe for its intended use. Chow, 2011 NY Slip Op 3888. This procedural distinction, which seems unique to New York practice, can be added to the list of reasons for defendants to consider removal to Federal Court when faced with a product liability action brought in New York.

¹A video of the oral argument before the Court of Appeals is available on the New York Court of Appeals website at http://www.courts.state.ny.us/CTAPPS/arguments/2011/Mar11/Mar11_OA.htm.



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“Greenwashing” Claims, A Pitfall to Those Marketing Products as Environmentally Friendly

By Geron J. Bird

You are likely familiar with the old phrase “whitewashing the truth.” However, you may not yet be familiar with the term “greenwashing.” This is a term that is growing in recognition and can create liability for your clients who manufacture or sell consumer products. There can be little doubt that branding one's product as environmentally friendly can make it more appealing in our ever greening society. Thus, a substantial trend in marketing is to classify a product – whether a cleaning product or a shirt – as being “green.” Being green can mean many different things in our modern lexicon. Green may refer to the sort of materials used in manufacturing, explain how the product operates, or communicates the product's use. The common denominator is that there is some claim about the product, extolling some particular aspect of it as beneficial to the environment.

Many consumers make purchasing decisions based upon the perceived, environmental friendliness of the product they are purchasing. As a result, there is growing scrutiny of the veracity of environmental claims about products. The term “greenwashing” refers to false or exaggerated claims about the eco-friendly characteristics of products. Regulators, consumer protection groups, environmental groups and individuals are all players in this rising area of exposure for manufacturers, distributors and sellers of products.

State Consumer Protection Statutes

Cases for greenwashing have been popping up around the country in the sphere of consumer protection litigation. This can be readily seen in California, where actions have been brought under that state's various consumer protection statutes. Recently, for example, a lawsuit was brought against S.C. Johnson & Sons, Inc., alleging that certain products falsely represent that they are environmentally friendly or certified when they are not.¹ The plaintiff alleged the product's labeling strategy was calculated to justify a premium price and take market share from competitors that do not make environmental claims. This case is a prime example of how state consumer statutes can be a vehicle for claims against manufacturers for exaggerated or false claims of environmentally friendly product characteristics.

In another case arising out of California, *Hill v. Roll Int'l Corp.*, plaintiff sued under some of the same consumer statutes, in addition to common law theories, claiming Fiji water made false environmental claims on its water bottles.² The plaintiff alleged Fiji misrepresented its product as environmentally superior to competitor's products when it is not. Specifically, the plaintiff alleged that a "Green Drop" on the label indicated a false environmental "seal of approval." Eventually, the California Court of Appeals affirmed dismissal of plaintiff's claim. However, this case is again illustrative of the type of exposure manufacturers can face in relation to green marketing claims.

While these two examples are from California, most states have enacted laws that prohibit unfair or deceptive marketing claims. Furthermore, many of these laws allow for the recovery of attorneys fees and in some cases punitive damages.³

Watchdog Actions

In the state of New York, a conglomerate of environmental and other public interest groups filed suit in 2009 against the manufacturer of common household cleaners.⁴ The groups included Sierra Club and The American Lung Association. The action was brought under a little known, seldom used New York law requiring manufacturers to file reports on certain product ingredients. The primary goal in the action was to force the disclosure of the products' ingredients.⁵ The plaintiffs want information about the ingredients to determine if they are harmful or if false claims are being made about the environmental friendliness of the ingredients. Statements from spokespersons for the groups involved indicate an intent to scrutinize manufacturers on the contents of their products. Accordingly, greenwashing claims could become more prevalent as a means for watchdog and advocacy groups to force disclosure of the environmental qualities of products.

Federal Trade Commission Act (FTC)

The Federal Trade Commission Act is often mentioned in discussions of greenwashing claims. The FTC has issued what have become known as Green Guides.⁶ The Green Guides provide general principles intended to instruct readers on what types of green marketing claims will likely be permissible or impermissible under the Federal Trade Commission Act.⁷ The Green Guides set forth what manufacturers should do in terms of substantiating claims they make about the environmental qualities of their products.⁸ The Green Guides are not legislative rules, are not independ-

ently enforceable, and do not have the force of law.⁹ However, failure to comply with the Green Guides could certainly prove persuasive in litigation about green labeling or claims. Further, compliance can be a safe harbor for a company facing claims of false advertising.¹⁰

Enforcement of the Federal Trade Commission Act is accomplished by the Federal Trade Commission. While the Green Guides are not independently actionable, the FTC can pursue claims for unfair or deceptive business practices.¹¹ Notably, in determining whether a marketing claim is misleading, the FTC will consider the question purely from the consumer's perspective. Furthermore, even where the advertisement may not be specifically misleading, if the manufacturer cannot substantiate the marketing claim, a violation may still be found. The FTC has pursued actions against companies for false or misleading green claims about products.¹² In fact, 2009 and 2010 have seen increased activity by the FTC in pursuing these types of claims.¹³

As green advertising continues to rise, the FTC has stated "the agency will continue its efforts to ensure that environmental marketing is truthful, substantiated, and not confusing to consumers."¹⁴

What to Do?

When advising clients about risks associated with green marketing, consider the following principals that, while partially applicable to all advertising claims and marketing campaigns, bears special consideration in an environment of heightened consumer awareness for greenwashing:

- (1) Be aware and make your client aware of the FTC's Green Guides;
- (2) Make sure claims that the product is eco-friendly are able to be substantiated—be able to provide documentation and hard facts; and
- (3) Precision is preferable to broad strokes when making claims about the environmentally beneficial properties of a product—don't make yourself a target.

¹*Koh v. S.C. Johnson & Son, Inc.*, 2010 WL 94265 (N.D. Cal., Jan. 6, 2010).

²*Hill v. Roll Int'l Corp.*, No. A128698, 2011 WL 2041574, *1 (Cal. Ct. App. May 26, 2011).



²*Hill v. Roll Int'l Corp.*, No. A128698, 2011 WL 2041574, *1 (Cal. Ct. App. May 26, 2011)

³Michelle Diffenderfer and Keri-Ann C. Baker, *Greenwashing: What Your Client Should Know To Avoid Costly Litigation And Consumer Backlash*, 25-WTR NAT. RESOURCES & ENV'T 21 (2011)

⁴Susan Carpenter, *Groups set to sue cleaning product makers for ingredients*, (L.A. TIMES) February 18, 2009, <http://articles.latimes.com/2009/feb/18/business/fi-toxics18>

⁵Tresa Baldas, *Claims of Greenwashing on the Rise*, [NAT'L L. J.], June 10, 2009

⁶16 C.F.R., § 260 (2011).

⁷Brooks Beard and Robert Falk, *The New "Green" Marketing Strategy-How Does This Affect Portfolio Companies?*, June, 2011, <http://nvcatoday3.nvca.org/index.php/green-marketing.html>

⁸Diffenderfer & Baker, *supra* note 3, *Greenwashing: What Your Client Should Know To Avoid Costly Litigation And Consumer Backlash*, 25-WTR NAT. RESOURCES & ENV'T 21

⁹*Hill*, 2011 WL 2041574, at *1 (citing 16 C.F.R. § 260.1 (2011)).

¹⁰*Id.* (referencing 16 C.F.R. § 260.3 (2011)).

¹¹Beard & Falk, *supra* note 7.

¹²*See, e.g., Kmart*, FTC File No. 082 3186, Docket No. C-4623 (July 15, 2009)

¹³Michelle Diffenderfer and Keri-Ann C. Baker, *Greenwashing: What Your Client Should Know To Avoid Costly Litigation And Consumer Backlash*, 25-WTR Nat. Resources & Env't 21

¹⁴Ucilia Wang, *Greenwashing: A Case Study*, Sept. 28, 2009, <https://www.greentechmedia.com/articles/read/greenwashing-a-case-study>



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Defending Products Liability Suits Involving Off-Label Use: Does the Learned Intermediary Doctrine Apply?

By Marisa A. Trasatti and Lindsey N. Lanzendorfer

I. Introduction

The False Claims Act (FCA), which prohibits any person from knowingly causing the submission of false claims to the federal government for payment or approval, includes a *qui tam* provision that allows people who are not affiliated with the government to file actions on behalf of the government. *See* 31 U.S.C. §§ 3729–33. Several states have also created FCA statutes with *qui tam* provisions. Recently, these acts have been used to bring claims against pharmaceutical companies for marketing drugs and medical devices for off-label uses—uses other than those specified on the product labels approved by the Food and Drug Administration (FDA). As a result, many pharmaceutical companies have paid staggering claims to settle these cases. For example, Pfizer paid \$430 million in 2004 to settle a claim that it encouraged physicians to prescribe the drug Neurontin, to treat bipolar disorder rather than epilepsy (its FDA approved use). Gardiner Harris, *Shamed Drug Firm Pays up \$636m*, *The Age* (May 15, 2004), <http://www.theage.com.au/articles/2004/05/14/1084289882827.html>. In 2010, Elan Pharmaceuticals settled a claim of unauthorized promotion for \$214.5 Million. Steven Meyerowitz, *Elan Missing As Pharmaceutical Companies Pay \$214.5 Million to Settle FCA and Other Claims*, *Financial Fraud Law* (Dec. 16, 2010, 12:53 PM), <http://www.financialfraudlaw.com/lawblog/elan-missing-pharmaceutical-companies-pay-2145-million-settle-fca-and-other-claims/1813>. There, the company was alleged to have promoted Zonegran—another drug FDA approved to treat epilepsy—for bipolar disorder, migraine headaches, chronic daily headaches, eating disorders, and obesity. *Id.* As a final example, AstraZeneca agreed to pay \$68.5 million in a 2011 settlement. Matthew Perrone, *AstraZeneca Paying \$68.5M in Seroquel Settlement*, *Wash. Post* (Mar. 10, 2011), <http://www.washingtonpost.com/wp-dyn/content/article/2011/03/10/AR2011031003328.html>. In this multi-state claim, AstraZeneca was alleged to have pushed doctors to prescribe the drug Seroquel for insomnia and Alzheimer's, although the FDA approved the drug as an anti-psychotic. Litigators may be wondering if these large settlements from FCA claims will translate into larger financial outcomes in personal injury tort claims arising from off-label use. This depends, in part, on whether the learned intermediary doctrine is an affirmative defense for manufacturers in these lawsuits. The learned intermediary doctrine serves as a shield for manufacturers against consumer claims arising

from allegations of failure to warn of a product's risks. Essentially, the doctrine protects manufacturers from liability if they warn physicians of the risks associated with a drug or device. However, physicians commonly engage in off-label use, and it is impossible for manufacturers to warn physicians of every risk associated with all uses of a medical product. Thus, the question becomes whether the learned intermediary doctrine would still insulate manufacturers when physicians prescribe drugs or devices for off-label uses. Unfortunately, court decisions that address this issue vary widely across circuits. Still, analysis of these decisions offers some guidance for defense attorneys who may defend pharmaceutical companies in personal injury lawsuits.

II. Off-Label Use of Prescription Drugs and Medical Devices

By way of background, the FDA regulates manufacturers' marketing and distribution of medical devices and prescription drugs. To market drugs and devices, the manufacturer must first obtain FDA approval for the drug or device. The FDA will only approve a prescription drug or device for the uses that the manufacturer shows are safe and effective. 21 U.S.C. § 355 (2006). Once approved for a particular use, the FDA historically has prohibited manufacturers from promoting their products for other uses, with limited exceptions.

Physicians, however, often prescribe drugs or use medical devices off-label. Richard C. Ausness, *"There's Danger Here, Cherie!": Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses*, 73 Brook. L. Rev. 1253, 1253 (2008). Physicians are free to take these actions in the exercise of good medical judgment because the FDA does not regulate individual physicians. In fact, the Supreme Court of the United States called off-label prescription "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001). The federal government has made clear that its regulations do not restrict a physician's ability to prescribe products for off-label uses. Ausness, *supra*, at 1259.

Physicians prescribe off-label for many reasons. One reason is that sometimes no drug exists to treat a particular condition. For instance, one neurologist has noted that Rituximab, which is FDA-approved for treatment of non-Hodgkin's lymphoma, is the only known treatment for

"progressive encephalomyelitis with rigidity and myoclonus" (PERM). Tom Valeo, *A Catch 22: Neurologists Can Prescribe Off-Label, But Risk Health Insurers' Denials for Reimbursement*, *Neurology Today*, Apr. 7, 2011, at 28–30. If physicians did not prescribe Rituximab to treat this condition, it essentially would go untreated, and the patient could die. Physicians may also prescribe off-label because patients respond to prescription drugs differently. Cynthia Harden, M.D., chief of the Division of Epilepsy and Electroencephalography at Long Island Jewish Hospital, commented that drugs are not targeted for specific types of epilepsy. *Id.* While some seizures start in the frontal lobe, others originate in the temporal lobe. *Id.* As such, treating epilepsy can require doctors to prescribe the drug differently than described on the drug's label depending on the locus of the seizure activity.

Physicians also often prescribe off-label when treating children. This occurs because children do not take part in clinical tests or trials. As such, only twenty to thirty percent of FDA approved drugs are labeled for use in children. *Should Your Child be in a Clinical Trial?*, U.S. Food and Drug Administration, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048699.htm> (last visited May 28, 2011). If physicians were not permitted to prescribe off-label, many childhood diseases would go untreated.



Although physicians typically prescribe off-label, manufacturers do not rush to have the FDA approve drugs or devices for these additional uses. If a manufacturer wishes to have an already marketed medical product approved for a new use, the manufacturer must go through a lengthy and expensive process to obtain FDA approval for a new use. But, because physicians can prescribe off-label without FDA approval, manufacturers have little incentive to obtain new approval once a product goes to market. It is easier and less costly to allow physicians to deviate from the label instructions and prescribe the approved drug or medical device for new uses.

Though physicians can engage in off-label prescribing, pharmaceutical companies are only permitted to disseminate peer-reviewed scientific information to physicians regarding off-label uses. The FDA allows this dissemination for several reasons. For one, if an off-label use is common enough that it becomes the standard of care, a physician may commit medical malpractice if he fails to prescribe the drug or device for that off-label use. Additionally, if physicians are aware of these off-label uses they will advance public health by properly treating patients. *FDA Good Re-*

Print Practices of Medical Journal Articles and Medical Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (2009).

The FDA provides strict guidance on the type of information that manufacturers can distribute to physicians and how they issue the information. The guidelines have changed slightly over the years, but are currently found under the “Good Reprint Practices of Medical Journal Articles and Medical Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices.” *Id.* The guidelines suggest that any reprints or articles that drug companies provide to physicians be scientific or medical journals. These journals should be peer-reviewed and not funded by the manufacturer. *Id.* The journals should also state the risks associated with the off-label use. *Id.* The FDA guidelines also suggest that the journals be unabridged reprints with no markings or highlights by the manufacturer, and they should be distributed separate from promotional material. *Id.* Finally, the

guidelines encourage manufacturers to include a statement disclosing that the uses described have not been FDA approved and identifying the manufacturer’s financial interest in the drug or device. *Id.*

If manufacturers provide more information than the FDA guidelines permit, they are considered to have engaged in unauthorized promotion. This is against the law and is referred to as misbranding. See 21 U.S.C § 331(b), 352(f), 333 (2006). In 2010 *qui tam* actions, brought on behalf of the government under the False Claims Act or similar state laws, at least six (6) manufacturers settled charges pertaining to off-label marketing. Molly Cohen, *Study: Whistleblower Cases Involving Off-Label Promotion Pervade Industry*, Drug Indus. Daily, Apr. 11, 2011. The following is a chart outlining these six (6) settlements. It includes the name of the manufacturer, the related drug, the approved use of the drug, a non-exhaustive list of the off-label use the company was alleged to have promoted illegally, and the settlement amount.

Company Name	Drug	Approved Use(s)	Off-label Use(s) Allegedly Promoted	Settlement Amount
AstraZeneca	Quetiapine (Seroquel)	Schizophrenia and manic episodes in bipolar disorder	Alzheimer's disease, anger management, anxiety, attention deficit hyperactivity disorder, dementia, depression, and post-traumatic stress disorder	\$520 million
Ortho-McNeil-Janssen	Topiramate (Topamax)	Epilepsy and prevention of migraines	Alcohol dependence and weight loss	\$81 million
Novartis	Tobramycin (TOBI)	Cystic Fibrosis in adults	Cystic Fibrosis in patients under the age of six	\$72.5 million
Forest	Citalopram (Celexal) and Escitalopram (Lexapro)	Antidepressant for adults	Antidepressant for children and adolescents	\$313 million
Allergan	OnabotulinumtoxinA (Botox)	Blepharospasm (spasm of the eyelids), Cervical Dystonia (severe neck muscle spasms), and severe Primary Axillary Hyperhidrosis (excess sweating)	Headache, pain, and juvenile cerebral palsy.	\$600 million
Novartis	Oxcarbazepine (Trileptal)	Epilepsy	Bipolar disorder and neuropathic pain	\$422.5 million

III. The Learned Intermediary Doctrine

Although the above chart refers to actions involving misbranding in violation of the FCA or similar state laws, off-label use may also create civil liability for manufacturers based on consumer injuries allegedly sustained because of off-label use. When a patient claims an injury from a prescription drug or medical device, he or she usually sues both the physician and the drug or device manufacturer. In such products liability lawsuits, plaintiffs' claims include those for negligence and/or strict liability against the product manufacturers or failure to warn of the potential risks of a particular drug or device. Restatement (Third) of Torts §, cmt. d (1998). In most cases, however, the learned intermediary doctrine protects manufacturers from liability; it has been found to apply in negligence and strict liability claims, including design defect, misbranding, and breach of implied warranty claims. *See, e.g., Fellows v. USV Pharm. Corp.*, 502 F. Supp. 297 (D. Md. 1980). Before discussing whether the learned intermediary doctrine applies in cases involving off-label use, it will be helpful to give a general overview of the learned intermediary doctrine.

The doctrine holds that when a manufacturer who provides a treating physician with adequate notice of a product's possible risks, the manufacturer has no additional duty to warn the end consumer. Richard B. Goetz & Karen R. Growden, *A Defense of the Learned Intermediary Doctrine*, 63 Food & Drug L.J. 421, 421 (2008). This doctrine exists because physicians, as learned intermediaries, are in the best position to weigh the risks and benefits of a particular drug or device based on patient selection, needs, and conditions. *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 94-95 (D. Md. 1989), *aff'd*, 898 F.2d 146 (4th Cir. 1990). Essentially, a manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising patients of the risks associated with the drug or device.

For the doctrine to apply, however, the physician must be aware of the product's risks. *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 377 (D. Md. 1975). But, even if a manufacturer's warning is inadequate, the doctrine will still apply if the physician has been sufficiently warned from other sources. *See, e.g., Dean v. Eli Lilly & Co.*, 387 F.App'x 28, 30 (2d Cir. 2010) (finding learned intermediary doctrine applied where plaintiff alleged manufacturer failed to warn because doctor had actual knowledge of the alleged warning); *Sita v. Danek Medical, Inc.*, 43 F. Supp. 2d 245 (E.D.N.Y. 1999) (finding learned intermediary doctrine applied where plaintiff claimed manufacturer failed to warn physician of risks because physician was aware of risks

notwithstanding). In essence, the learned intermediary doctrine encompasses the physician's entire field of knowledge. *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 572 (D. Md. 2006).

Every State in the country has some precedent concerning the learned intermediary defense. *See The Closing of the Learned Intermediary Frontier*, Drug and Device Law (June 2, 2011), <http://druganddevicelaw.blogspot.com/2011/06/closing-of-learned-intermediary.html>, for an extensive list of the relevant case law. In thirty-five states and the District of Columbia, the jurisdiction's highest court or the legislature by statute has adopted the learned intermediary doctrine. These include Alabama, Alaska, Arkansas, California, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, and Wyoming.

Intermediate appellate authorities in five states have applied the rule: Arizona, Colorado, Indiana, Louisiana, and New Mexico. In seven states, federal courts applying state law have assumed the state would adopt the doctrine. These include Iowa, Maine, New Hampshire, North Dakota, Rhode Island, South Dakota, and Wisconsin. In Vermont, only a trial court has applied the rule. Finally, West Virginia's highest court, the Supreme Court of Appeals, is the only court to have rejected the learned intermediary doctrine.

IV. Applying the Learned Intermediary Doctrine to Claims Involving Off-Label Use

Personal injury claims increasingly allege injury from off-label use of medical products. This situation creates a paradox for pharmaceutical companies: the learned intermediary doctrine applies when physicians are aware of the risks associated with drug or device, but manufacturers are to warn physicians of risks associated with on-label uses and cannot know of all other possible uses of a medical product and the risks associated with those other uses. In turn, this paradox has resulted in substantial differences among state court decisions regarding a manufacturer's liability for failure to warn claims involving off-label use.

Following is a survey of case law addressing when the learned intermediary doctrine will and will not insulate manufacturers from liability for off-label use based on fail-

ure to warn tort claims. This survey is not exhaustive but merely provides examples of how some jurisdictions have approached the issue. Additionally, this survey does not address the causation defense: that any failure to warn did not cause the plaintiff's injuries. For instance, the failure to warn cannot cause a plaintiff's injuries when the physician was aware of the off-label risks from a different source or the physician would have prescribed the drug or device regardless of whether he knew of the risks—both of which turn on the facts of an individual case. *See, e.g., Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1310 (N.D. Okla. 2000) (“Dr. Hayes testified that he was fully informed on the FDA status of the Rogozinski System, know of its risks, did not rely on Defendant’s informational materials, and exercised his independent judgment based on the standards of care and Ms. Dentis’s situation in recommending the surgery. Plaintiff has presented no evidence to the contrary, nor has Plaintiff shown that the device caused her current physical ailments. Given these facts, Plaintiff can show no injury resulting from any failure to warn Dr. Hayes”).

A. The Learned Intermediary Doctrine Always Insulates Manufacturers from Liability for Off-Label Use

1. Maryland

The United States District Court for the District of Maryland, applying Maryland law, addressed the learned intermediary doctrine and off-label use in *Robak v. Abbott Laboratories*. 797 F. Supp. 475 (D. Md. 1992). There, the plaintiff, Robak, argued that the manufacturer had a duty to warn physicians of the risks associated with Omniflox when used for sinusitis (an off-label use). *Id.* at 476. The court rejected this argument, reasoning that the physician, as a learned intermediary, made the decision to prescribe the drug for that off-label use, not Abbott Laboratories, the manufacturer. *Id.* In fact, the court found that the learned intermediary doctrine applies in every case where the patient suffered injuries resulting from an off-label use of a drug. *Id.*

2. Louisiana

In *Bell v. Danek Med., Inc.*, No. CIV. A. 96-1393, 1999 WL 335612 (E.D. La. May 24, 1999), an unreported opinion, the United States District Court for the Eastern District of Louisiana held that the learned intermediary doctrine always protects drug manufacturers from liability for off-label use injuries. In that case, the plaintiff, Bell, alleged that a Texas-Scottish Rite Hospital Spinal System, which was implanted in her spine, caused her extreme lower back pain, numbness, charley horses, and cramps. *Id.* at *1. Her physician’s placement of pedicle screws into her spine was



an off-label use of the screws given that the FDA approved the screws for some bones but not for the spine. *Id.* at *4. Bell filed a lawsuit, naming the manufacturer, Danek Medical Incorporated (Danek), as one of the defendants, contending that Danek failed to warn her physician adequately of the risks associated with this off-label use. *Id.* at *3. Specifically, she alleged that Danek actually promoted the off-label use and therefore had a duty to warn the physician of its risks. *Id.* at *4. The court found that Danek’s over promotion did not affect the learned intermediary doctrine because Bell failed to provide any case law from Louisiana for her contention that over promotion defeats the doctrine. *Id.*

B. The Learned Intermediary Doctrine Only Insulates Manufacturers Who Warn of The Risks Associated with Off-Label Use

1. Florida

In *Upjohn Co. v. MacMurdo*, 562 So. 2d 680, 683 (Fla. 1990), the Florida Supreme Court held that Upjohn Company (Upjohn), the manufacturer, had a duty to warn physicians of the risks associated with the off-label use of Depo-Provera. *Id.* at 683. There, a physician prescribed Depo-Provera to MacMurdo for contraceptive purposes even though the drug was labeled for endometrial carcinoma. *Id.* at 682. MacMurdo ultimately required a hysterectomy to stop excessive and continuous menstrual bleeding. *Id.* The court failed to truly address off-label use and merely assumed Upjohn had a duty to warn, stating, “the more crucial question is whether the warnings were adequate to warn a physician of the possibility that Depo-Provera might be causing the condition experienced by MacMurdo.” *Id.* at 683.

C. The Learned Intermediary Doctrine Does Not Insulate Manufacturers Who Have Knowledge of the Off-Label Use

1. New Jersey

The United States District Court for the Eastern District of Pennsylvania applied New Jersey law in *Knipe v. Smith-Kline Beecham*. 583 F. Supp. 2d 602 (E.D. Pa 2008). The court found that a drug manufacturer has a duty to warn of the risks associated with known drug uses as soon as reasonably feasible. *Id.* at 628. There, Knipe alleged that despite having evidence of an increased suicide risk in younger patients taking Paxil, the manufacturer, GlaxoSmithKline, failed to warn physicians of this finding. *Id.* at 609. The court rejected GlaxoSmithKline’s argument that it did not have a duty to warn of risks associated with off-label uses of a drug, finding that its knowledge of the suicide risks rebutted any use of the learned intermediary de-

fense. *Id.* At 628. But see *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419 (E.D. Pa 2004) (finding a manufacturer's knowledge of off-label use does not automatically subject the manufacturer to liability for failure to warn).

2. Ohio

In *Krumpelbeck v. Breg, Inc.*, 759 F. Supp. 2d 958 (S.D. Ohio 2010), the Federal District Court for the Southern District of Ohio applied Ohio law in finding that a manufacturer does not have a duty to warn until it knows or should know of the risks associated with a particular off-label use. *Id.* at 960; see also *Monroe v. Zimmer US Inc.*, 566 F. Supp. 2d 1012, 1033 (E.D. Cal. 2011) ("Accordingly, plaintiff must provide evidence that demonstrates defendants failed to give adequate warning of a risks associated with their product that defendants know or should have known about at the time the product was distributed."). There, Krumpelbeck alleged that she developed chondrolysis from a prescribed and implanted catheter of a Breg Pain infusion pump. *Id.* On Krumpelbeck's negligence claims, the court granted summary judgment in favor of Breg Incorporated (Breg), the manufacturer, because Krumpelbeck did not show that Breg knew or should have known of the off-label risks associated with the product. *Id.* at 975.

3. Georgia

In *Medics Pharm. Corp. v. Newman*, 378 S.E.2d 487 (Ga. Ct. App. 1989), the Georgia intermediate appellate court found that a manufacturer has a duty to warn of risks associated with foreseeable off-label uses. *Id.* at 488–89; see also *Woodbury v. Janssen Pharm., Inc.*, No. 93 C 7118, 1997 WL 201571 (N.D. Ill. Apr. 10, 1997) (finding manufacturer who should reasonably know of dangers associated with an off-label use has a duty to warn physicians of those dangers under Illinois law). There, a physician prescribed Diastyl to prevent a miscarriage. *Id.* at 488. The daughter of the woman prescribed Diastyl developed genital cancer later in life. *Id.* The daughter alleged her cancer was a risk inherent in the off-label use of Diastyl to prevent miscarriages and brought a lawsuit against the manufacturer for negligence. *Id.* The court concluded that whether the manufacturer, Medics Pharmaceutical Corporation (Medics), could have foreseen the use of Diastyl for the prevention of miscarriages was a question for the jury. *Id.* at 488–89. Importantly, if the use was foreseeable, Medics would have had a duty to use reasonable care to determine if the drug was safe for that use. *Id.*

4. Indiana

In *Meharg v. I-Flow Corp.*, No. 1:08-cv-184-WTL-TAB, 2010 WL 711317 (S.D. Ind. Mar. 1, 2010), the United States District Court for the Southern District of Indiana found, in an unreported opinion, that under Indiana law, if a

manufacturer does not promote an off-label use, the manufacturer does not have a duty to warn of the risks unless it (1) knows that the off-label use occurs and (2) knows that the off-label use carries a risk of the harm at issue. *Id.* at *2. In that case, Meharg developed chondrolysis after receiving bupivacaine through a pain pump. *Id.* at *1. Bupivacaine was a pain reliever, but it was not approved to be used with pain pumps. *Id.* Thus, Meharg's physician prescribed the pain pump as an off-label use. *Id.* Meharg alleged that the manufacturer had a duty to warn the physician of the risk of chondrolysis, but the court dismissed the claim. *Id.* The court pointed out that the line between having or not having a duty to warn of a particular risk often is hard to draw. *Id.* at *3. On the facts at hand, however, the court found that it would not assume the manufacturer had knowledge of the risks merely because experts in the relevant field had such knowledge. *Id.*

5. Minnesota

In *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009), United States District Court for the District of Minnesota held that a manufacturer does not have a duty to warn of known risks associated with an off-label use. There, a physician implanted a "Cypher stent" in a patient's coronary artery. This was an off-label use of that stent, and the patient, Riley, suffered a heart attack. *Id.* at 775. Riley alleged that the manufacturer of the Cypher stent, Cordis Corporation (Cordis), was liable for his injuries because Cordis failed to warn the physician of the risks associated with the off-label use of this product. *Id.* at 780–81. The court found that at the time of this incident, the FDA had permitted manufacturers to disseminate information about off-label uses of drugs or medical devices without warning the physicians of the risks associated with those uses. *Id.* at 781–82. (The current guidelines require manufacturers that disseminate information about off-label uses to include the relevant risks. *FDA Good Reprint Practices of Medical Journal Articles and Medical Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (2009)). Thus, merely being aware of off-label uses could not require a manufacturer to warn physicians of the risks of such uses under the FDA standards. *Riley*, 625 F. Supp. 2d at 782. As such, the court found that the learned intermediary doctrine shields a manufacturer from liability even if the manufacturer is aware of off-label uses, as long as the manufacturer did not promote the product to physicians beyond what the FDA permitted. *Id.* at 783.

D. The Learned Intermediary Doctrine Does Not Shield Manufacturers Who Receive a Large Volume of Sales from Off-Label Use

1. California

In *Miles Laboratories, Inc. v. Superior Court*, a California intermediate appellate court found that a manufacturer could be liable for failure to warn when it profited from an off-label use of a medical product because, in that instance, the manufacturer knew or should have known the product was being used for an off-label use. 133 Cal. App. 3d 587, 595 (Cal. App. 4th Dist. 1982). There, plaintiff, Miles, alleged that as a result exposure to diethylstilbestrol (DES), a drug prescribed for miscarriages, she was required to undergo surgical removal of her female reproductive organs. The plaintiff alleged that although Miles Laboratories did not sell DES as a miscarriage preventative, it was common knowledge that other manufacturers sold DES for that purpose and that pharmacists prescribed whatever brand of the drug they had on hand, including Miles Laboratories' brand. *Id.* at 102. The court found that Miles Laboratories knew or should have known that its brand of DES was being used for an off-label use because it benefited from that use. Thus, it had a duty to warn physicians of the possible risks associated with the use. *Id.* at 103. Not providing a description of those risks prevented the physician from being a "learned intermediary," so the doctrine did not apply.

2. Texas

In *McNeil v. Wyeth*, 462 F.3d 364 (5th Cir. 2006), the Fifth Circuit Court of Appeals, applying Texas law, found that manufacturers who substantially profit from off-label uses of their products must warn physicians of the risks associated with those off-label uses. *Id.* at 371. There, McNeil allegedly developed Tardive Dyskinesia, a severe neurological disease, from taking the prescription Reglan. *Id.* at 367. Reglan was approved to speed up the digestive system. *Id.* at 366. Prescribing Reglan for longer than twelve weeks, however, was considered an off-label use. *Id.* at 371. The court found that Wyeth had a duty to warn physicians of the risks associated with this prolonged use because Wyeth knew physicians were prescribing Reglan for longer than twelve (12) week cycles as a majority of its sales came from these extended prescriptions. *Id.*; see also *O'Neal v. Smithkline Beecham Corp.*, No. CIV S-06-1063 FCD/DAD, 2008 WL 1721891 (E.D. Cal. Apr. 10, 2008) ("In *McNeil*, the court determined the drug's extensive off-label use created the duty to warn; here, there was simply no evidence proffered by plaintiffs that prescriptions of Paxil to pediatric patients made up the majority of Paxil sales. Thus, there would be no basis to invoke the McNeil court's duty to warn.").

E. The Learned Intermediary Doctrine's Does Not Shield

Manufacturers Who Engage in Unauthorized Promotion of the Off-Label Use

1. Illinois

In *Proctor v. Davis*, 682 N.E.2d 1203 (Ill. Ct. App. 1997), the Illinois Appellate Court, an intermediate appellate court, found that the learned intermediary doctrine did not apply when a manufacturer openly promoted the off-label use. In that case, a physician injected a corticosteroid, Depo-Medro, into a patient's eye, disfiguring the eye. *Id.* at 1210–11. The drug was not approved for eye injections. *Id.* at 1206. The court found that Depo-Medro's manufacturer, Upjohn Company (Upjohn), was liable because it actively encouraged physicians to use the drug for eye injections. *Id.* at 1215. Indeed, Upjohn had paid a physician to experiment with the drug, and when the physician reported that all of his animal experiments were "very unsatisfactory," Upjohn did not include these findings in an article it sent to practicing physicians. *Id.* at 1207. This, in turn, falsely promoted the off-label use and diminished any warnings of risks associated with using the drug for eye injections. *Id.* at 1212–13. Therefore, physicians could not properly weigh the risks and benefits of the drug. As such, the court found the learned intermediary doctrine did not protect Upjohn. *Id.*

2. North Carolina

In *Dellinger v. Pfizer, Inc.*, No. 5:03CV95, 2006 WL 2057654 (W.D.N.C. July 19, 2006), the United States District Court for the Western District of North Carolina found, in an unreported opinion, that according to North Carolina law, a manufacturer cannot be liable for a plaintiff's resulting injuries unless the manufacturer acted unreasonably in failing to warn physicians of the risks associated with using the product that caused the injuries. *Id.* at *6. Dellinger's physician prescribed him Neurontin as a pain reliever. *Id.* at *1. Dellinger subsequently became very ill and was hospitalized. *Id.* After reading that Pfizer Incorporated (Pfizer) was found to have illegally promoted Neurontin for an off-label use, Dellinger brought a claim against Pfizer for his injuries. *Id.* at *3. The court found that if Pfizer unreasonably failed to warn physicians of Neurontin's off-label risks because Pfizer fraudulently promoted the off-label use of the drug. *Id.* at *6. Specifically, the learned intermediary doctrine did not protect Pfizer because Pfizer was aware of the off-label use dangers (because it promoted the use) but did not warn physicians of the dangers of the off-label use. *Id.*

3. Tennessee

In *Smith v. Pfizer, Inc.*, 714 F. Supp. 2d 845 (M.D. Tenn.



2010) the United States District Court for the Middle District of Tennessee found that a manufacturer who actively promotes an off-label use must warn physicians of risks associated with that use. In another case involving Neurontin, a widow alleged that Neurontin caused her husband to commit suicide. *Id.* at 848. She brought a claim against Pfizer alleging that it failed to warn physicians of risks related to using Neurontin as a pain reliever, an off-label use. *Id.* (The FDA approved Neurontin to treat Epilepsy. *Id.*). She alleged that Pfizer's unauthorized off-label promotion of Neurontin showed that Pfizer did not adequately test the drug as a pain reliever even though it knew physicians were prescribing the drug for that use. *Id.* at 854. As such, plaintiff argued, Pfizer could not adequately warn physicians of the risks. *Id.* Pfizer argued that because plaintiff did not show that Smith's doctor relied on any off-label promotion, it was irrelevant. *Id.* The district court applied Tennessee law and disagreed. *Id.* The court determined that Pfizer's unauthorized promotion of Neurontin for off-label uses made it more likely that the use was foreseeable. Thus, Pfizer was required to adequately test the drug and warn physicians of the risks associated with the use. *Id.*; see also *Ebel v. Eli Lilly and Co.*, 536 F. Supp. 2d 767 (S.D. Tex. 1999) (finding under Texas law, promotion of off-label use rebuts the presumption that warnings are adequate).

V. Conclusion

The law regarding the learned intermediary doctrine and off-label use is conflicting. This creates difficulty in determining the best way to defend drug manufacturers in cases involving off-label use. In some jurisdictions, whether the learned intermediary doctrine applies depends on the manufacturer's knowledge or the foreseeability of the off-label use. In other jurisdictions, the learned intermediary doctrine's application depends on the manufacturer's promotion of an off-label use. Still, in other jurisdictions, courts have assumed that manufacturers always have a duty to warn and have not applied the doctrine in the absence of warnings. Finally, some jurisdictions find that the learned intermediary doctrine applies in all cases because physicians use their entire knowledge base and training to determine what is best for the patient. Given these varied approaches, the foregoing survey of case law may help those who defend drug manufacturers determine the relevant evidence and the likelihood that the learned intermediary doctrine will protect manufacturers sued in the jurisdictions discussed.



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Supreme Court Expands Security Blanket Cloaking Generic Drug Manufacturers from Failure to Warn Claims

By Stanton E. Shuler, Jr.

Pliva, Inc. v. Mensing,
131 S. Ct. 2567; 180 L.Ed.2d 580; 2011 U.S. LEXIS 4793

On June 23, the Supreme Court ruled in a 5-4 decision that generic drug manufacturers cannot be held liable for failing to warn consumers of the dangers of their drugs on the package's label when the brand-name equivalent does not. The matter came before the court after two individual consumers developed tardive dyskinesia from taking the generic equivalent of the brand-named drug Reglan, a drug used to treat digestive tract problems. In separate actions in Minnesota and Louisiana, the consumers sued the manufacturers of the generic drug under state tort law for their alleged failure to provide adequate warning on the drug labels. The manufacturers argued that the plaintiffs' claims were preempted by federal law. They argued federal law required them to have the same safety and efficacy labeling on their generic drug labels as the labels on the equivalent brand-named drug. The defendants asserted that, because they had fulfilled this federal obligation, they could not be held responsible under conflicting state failure to warn obligations. The Fifth and Eighth federal circuits ruled in favor of the consumers, holding that the state-court claims were not preempted. The Court's recent ruling in *Pliva, Inc. v. Mensing* reversed those decisions.

The majority opinion was delivered by Justice Thomas. It hinged on the Food and Drug Administration's ("FDA") interpretation of its own regulations that there was no mechanism under federal law for the generic manufacturer

to deviate from the brand-named drug label. The Court recognized that the FDA's views are "controlling unless plainly erroneous or inconsistent with the regulations" or there is any other reason to doubt that they reflect the FDA's fair and considered judgment. See *Auer v. Robbins*, 519 U.S. 452, 461, 462 (1997). FDA took the position that its regulations require the warning labels of a brand-name drug and its generic equivalent to be the same. FDA denied that the regulations provide any avenue for a generic drug manufacturer to change its' label unilaterally, except as to match that of the brand-name equivalent. The Court accepted FDA's interpretation that the FDA regulations prevent generic manufacturers from independently changing their safety labels. Given that, where state tort law would require something more, the majority concluded that it would be impossible for generic manufacturers to fulfill the duty under state law and still be within the confines of federal regulation. Therefore, the Court held that the consumers' failure to warn claims were preempted under the Supremacy Clause of the U.S. Constitution.

The dissenting opinion, delivered by Justice Sotomayor, attacked the assertion that the generic manufacturer had met its burden to show the impossibility of complying with both laws. The burden of proof was previously set by the Court in *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963). There, the Court ruled that a defendant must demonstrate that compliance with federal and state law is a physical impossibility. Further, under *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) and *Gade v. National Solid Wastes Management Assn.*, 505 U.S. 88, 110 (1992), the existence of some hypothetical or potential conflict is insufficient to warrant preemption of state law. From the dissent's perspective, the generic manufacturer has the means to approach the FDA and ask for a label change for the brand-name drug label. According to Justice Sotomayor, the generic manufacturer could only show the impossibility of compliance with both state and federal law if it could show that the FDA would have specifically rejected the proposed label change. Justice Sotomayor and those joining her, proclaimed that this reasoning is most consistent with the Court's recent decision in *Wyeth v. Levine*, 555 U.S. 555 (2009). She also highlighted her view that the Majority opinion leads to absurd consequences, and concluded it unfathomable that Congress would have intended to preempt state law in these cases.

Although the amount of protection generic manufacturers have secured in failure to warn cases is immense, the Supreme Court has rightfully maintained its role under the separation of powers by deferring to the FDA's interpretation of the agency's regulations. Congress delegated power to the FDA to regulate the manufacturing, labeling, sale and distribution of drugs and medical devices when it passed

the Food, Drug and Cosmetic Act in 1938. By deferring to the FDA's interpretations that its regulations do not provide generic drug manufacturers a mechanism to change their labels unilaterally, the Court followed its well established jurisprudence, which holds the judiciary is obligated to give deference to the Agency's interpretation on a rule of law so long as it is based on a permissible statutory construction. *Chevron U.S.A., Inc., v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). The decision demonstrates the Court's caution to not usurp powers granted to the Legislative and Executive branches by the Constitution.

Those who are displeased with the *Pliva, Inc. v. Mensing* decision can rest assured that the generic drug manufacturer debate will likely continue. The Obama Administration has sided with the plaintiffs-consumers expressing apprehension that generic drug manufacturers will lose incentive to provide the most current safety information to the FDA if duty to warn claims are preempted by federal law. President Obama will likely take his concern to Congress, proposing legislation that would strip generic manufacturers of some of its nearly absolute immunity to failure to warn claims.

¹<http://www.cnn.com/2011/HEALTH/06/23/scotus.generic.drugs/index.html>

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“In the Trenches” Notable Accomplishments of ALFA Attorneys

California/Kentucky—Favorable Verdict for ALFA Client

Bombardier Recreational Products Inc., an ALFA international client, asked Skip Martin of Haight, Brown & Bonesteel, LLP (Los Angeles, California ALFA firm) to defend it in an ATV lawsuit filed in state court in Boone County, Kentucky.

On May 20, 2007, plaintiff, Melissa Shea, 47, was operating a 2007 Bombardier Can-Am Outlander XT 4-wheel drive 650 on a farm. As she went up the hill, the ATV flipped over and landed on top of her, rendering her quadriplegic. Shea sued Bombardier for products liability (failure to warn, design defect, false advertising). The Bombardier dealer, Pleasant Valley Outdoor Power, who sold the ATV to Shea, was sued for its alleged negligence for failing to install a brake safety recall kit. The dealer settled for an undisclosed amount on the last day of testimony.

Plaintiff's counsel asserted that the ATV's rear brake was defective in that motorists could inadvertently apply it without notice and that Shea's inadvertent release of the brake while climbing the hill caused the ATV to accelerate and tip over. Bombardier did have an earlier product recall

addressing the rear brake, but the dealer who sold the ATV to Shea had not installed the mandatory brake recall kit.

Bombardier argued that even if plaintiff had inadvertently applied the rear brake and then removed her foot, the subsequent acceleration would not have been enough to cause the ATV to tip over, relying upon testing done by Bombardier's experts. Thus, the absence of the brake recall kit was not a substantial factor in causing the accident.

After approximately 90 minutes of deliberation the jury returned a defense verdict finding there was no connection between the absence of the brake recall kit and the ATV's tip-over and that any failure to warn was not a substantial factor in causing plaintiff's injuries.

For further information contact Skip Martin of Haight, Brown & Bonesteel, LLP at 310-215-7572 or at wmartin@hbblaw.com.

Upcoming ALFA International Events

September 21-23, 2011

Product Liability Practice Group Seminar

Loews Vanderbilt Hotel

Nashville, Tennessee

PG Chair: Kevin G. Owens

Program Chair: Kara Troulson Stubbs

ALFA Contact:

Tara Miller at tmiller@alfainternational.com

October 12-14, 2011

Hospitality Practice Group Seminar

Westin Kierland Resort & Spa

Scottsdale, Arizona

PG Chair: Beth Kamp Veath

Program Chairs: Felice J. Cotignola & Richard W. Krieg

ALFA Contact:

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October 20, 2011

ALFA International and ACC Chicago Joint Seminar

The Westin Chicago River North

Chicago, Illinois

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November 9-11, 2011

International Law Practice Group Seminar

Hilton Sydney

Sydney 2000 New South Wales, Australia

PG Chairs: Alfred Meijboom & Edward T. Hayes

Program Chairs: Unavailable at this time

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