1 of 21 DOCUMENTS



***Fitzsimmons on the Duty to Provide Product Warnings in Other Languages***

*2010 Emerging Issues 5411*

Tracy D. Fitzsimmons on Assessing the Duty to Provide Product Warnings in Languages Other Than English

By Tracy Fitzsimmons

November 22, 2010

**SUMMARY:** The non-English-speaking consumer or worker is likely unable to comprehend a product warning printed only in English. The duty to protect non-English speakers from dangerous products may already include the duty to warn in their native language. Lawmakers, judges and practitioners are scrambling to redefine the duty to warn. Attorney Tracy Fitzsimmons discusses relevant case law and statutes, and provides practical advice for product warnings.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE: Scope**

Burgeoning immigration has resulted in unprecedented numbers of non-English-speaking consumers and workers residing in the United States. Keeping these residents safe from toxins and other dangerous products at home and at work presents new challenges. The non-English-speaking consumer or worker is likely unable to comprehend a product warning printed only in English. The duty to protect non-English speakers from dangerous products may already include the duty to warn in their native language. Lawmakers, judges and practitioners are scrambling to redefine the duty to warn. Courts in a handful of jurisdictions have decided that the issue of adequacy of English-only warnings should at least reach the jury as a question of fact. n1 Other courts are reluctant to recognize the duty to provide bilingual warnings absent a clear statutory mandate. n2 A few statutes require, recommend, or at least allow bilingual warnings under certain circumstances. n3 If a manufacturer client markets a product to a particular group of non-English-speaking persons and advertises in that group's native language, the practitioner should consider advising the client to include a product warning in that language.

**Expanding Non-English-Speaking Population Raises Issues Regarding Product Warnings**

Recent immigration trends have resulted in a dramatic increase in the number of non-English-speaking consumers and workers in the United States. According to the year 2000 Census, approximately 47 million people aged five and older spoke a language other than English at home. n4 Furthermore, the foreign-born population grew by 57 percent since 1990. n5 The percentage of foreign-born workers rose from a low of five percent in 1970 to 16 percent in 2009. n6 Estimates of the foreign-born agricultural workers are as high as 78 percent, 75 percent of whom are Mexican. n7 Non-English language media is at an all-time high. Companies are spending big money advertising in foreign

languages, especially Spanish. Manufacturers and sellers naturally want to increase revenues from the spending power of this growing segment of consumers. They must remember, however, that profitability comes hand-in-hand with responsibility. A large percentage of the non-English-speaking persons in the United States are employed in unskilled or semi-skilled positions. The locations of such jobs are often factories, farms, or other settings where dangerous machinery or toxic chemicals are used. Adding to the hazards of the industrial or agricultural workplace is the fact that many foreign-born workers are unable to understand the English-only warnings posted or appearing in safety manuals or product labels. Practitioners must guide clients through issues of whether and how to warn consumers and workers of product dangers in their native languages. Manufacturers may be required to translate instruction manuals and warnings into the native language of an employee, or face liability for injuries caused by exposure to a toxic substance.

**Plaintiff's Argument: Warning must be "Comprehensible" to *Every* Consumer**

The duty to warn is set forth in Section 2(c) of the *Restatement of the Law Third, Torts: Products Liability,* which states that a product "is defective because of inadequate instruction or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller and the omission of the instructions or warnings renders the product not reasonably safe." n8 A toxic tort plaintiff may argue that a warning written in English only is "inadequate" when a non-English-speaking person uses the product. The plaintiff may also contend that the manufacturer or seller did not provide "reasonable" instructions or warnings if the person using the product cannot read them.

The comments to Section 2 provide additional language upon which personal injury plaintiffs will likely depend in bringing failure-to-warn claims. Section 2 sets forth factors to use in evaluating whether a warning is sufficient. The factors include: "the gravity and risk posed by the product; the content and comprehensibility of the warning; the intensity of expression; and characteristics of and knowledge of foreseeable users." A non-English-speaking plaintiff will argue that an English-only warning is incomprehensible, and that if a manufacturer or seller markets a product to a particular group of non-English-speaking persons, those persons are foreseeable users of that product. It is possible that the defendant may be held liable on the basis that the consumer did not have 'knowledge' enough to comprehend the English-only warning. Courts Are Split on Whether Duty to Provide Warnings in Language Other Than English Exists

What is the likelihood that a toxic tort plaintiff will actually prevail on a claim based on an English-only warning? Courts that have addressed the issue have headed in two different directions. Several courts hold steadfast to the belief that if a duty to warn in another language existed, it would be codified in statutory form by the legislature. These courts reason that if there is no 'law' requiring a warning in a language other than English, then there is no duty to include a warning in any other language. n9

A few other courts, in contrast, have determined that factors such as the amount of advertising and marketing by a defendant manufacturer in a language other than English may result in a duty to warn in that language. These courts have held that the adequacy of a warning to a certain foreseeable non-English-speaking user is a question of fact that should reach the jury. n10

Even courts within the same jurisdiction do not agree on the existence of a duty to include warnings in languages other than English. In *Medina v. Louisville Ladder, Inc.,* n11 plaintiffs brought a personal injury action against a ladder manufacturer for failure to warn in Spanish. The federal court for the Middle District of Florida granted the manufacturer's motions to exclude expert testimony and for summary judgment, holding that Florida law did not require bilingual warnings. The court was unwilling to "extend the bounds of strict product liability law and negligence" to the extent that a product may be found unreasonably dangerous merely because it lacks bilingual warnings and instructions. n12 The court explicitly disagreed with *Stanley Indus., Inc. v. W.M. Barr & Co., n13* decided 15 years earlier by the Southern District of Florida. *Stanley* arose when linseed-soaked rags spontaneously caught on fire in the plaintiff's plant. The plaintiff's employees-who had recently come from Nicaragua and read little or no English-had used the oil. The label on the linseed oil can warned of spontaneous combustion but contained no graphics or pictographs. The *Stanley* court concluded that the jury should determine whether the warning needed to contain language other than English or

pictorial warning symbols to be adequate, given the "advertising of defendants' product in the Hispanic media and the pervasive presence of foreign-tongued individuals in the Miami workforce." n14 In rejecting *Stanley's* reasoning, the *Medina* court noted that the decision stood in "isolated precedent," having not been followed by a single published opinion. n15 Nevertheless, counsel should carefully consider the extent of the manufacturer's or seller's participation in the foreign language market when advising the client as to whether a duty to warn in other languages exists.

**Lack of Pictorial Danger Symbol May Render Label Warning Inadequate**

Counsel advising a client should consider alternatives to language warnings in situations in which a universally-recognized drawing or symbol can easily be used. Interestingly, as early as 1965, at least one court was willing to impose liability upon a manufacturer for labeling its toxic product in English only. The case, *Hubbard-Hall Chemical Co. v. Silverman, n16* was one of the first cases to address the need for multilingual warnings. It arose when two farm workers from Puerto Rico died after using the chemical Parathion. The warning label on the Parathion was in English only. Only one of the farm workers could read a limited amount of English. The jury found that the manufacturer failed to exercise reasonable care in giving the workers adequate warning and proper instruction for use of chemical. The federal Court of Appeals for the First Circuit affirmed, holding that the manufacturer could have reasonably foreseen that its product would be used by farm laborers "of limited education and reading ability." The court explicitly recognized that a warning label could be inadequate due its lack of skull and cross bones or other universally recognized danger symbol, even if approved by the Department of Agriculture. n17

Federal and State Legislation Requiring Non-English Warnings

It may soon be "game-over" for manufacturers and sellers who rely on the lack of legislation requiring multilingual warnings as the basis for denying the existence of a duty to include such warnings on their products. Although limited, such legislation does exist. The U.S. Environmental Protection Agency (EPA) now requires some warnings to be written in Spanish. n18 For Level I toxins, the word "peligro" (danger) must be included, and for Level II toxins, the word "aviso" (advisement) must be included. n19 Furthermore, labels must now guide readers in Spanish to find someone to explain the label to them if they do not fully understand it. n20 Counsel may guide other manufacturer clients to voluntarily include this type of phrase in the consumer's native language to advise that consumer to seek out a proper translation of an English-only warning. The Food and Drug Administration (FDA) stops short of requiring any language other than English, but makes clear that manufacturers are welcome to include warnings in another language in areas where English is not prevalent. The regulation provides that warnings must appear in English, but adds that "in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English." n21

There are also state statutes mandating non-English warnings. For example, California Food & Agricultural Code § 5777 requires pesticide notices to be written in English and other languages in cities or counties in which over five percent of persons receiving the notice speak only the other language. n22

**Practice Tips for Counsel Representing Manufacturers of Products Utilized by Non-English-Speaking Persons**

- If a manufacturer or seller markets a product specifically to a non-English-speaking group, the safest course of action is to voluntarily add warnings to the product in the language of that group. Doing so will prevent non-English speaking plaintiffs from pointing out to the court or jury that the same defendant that spent substantial sums of money to translate advertisements into other languages could not be troubled with the cost of translating warnings. n23 Although many jurisdictions currently do not impose a duty to warn in a language other than English in the absence of a law requiring such a warning, some courts leave the adequacy of an English-only warning for the jury's determination.
- Certain small products do not lend themselves easily to lengthy warnings in several languages. One suggestion is to add a short message in the foreign language advising that the consumer or worker should not use the product until the attached instructions or warnings in English have been read to him or her and are understood. If the product is toxic or flammable, the universally-recognized symbols to warn of these dangers are relatively easy to add to even a small

product.

- Factors to consider when analyzing the duty to warn in a language other than English include: (1) The existence (or lack) of legislation requiring or recommending a warning in another language; (2) the logistical feasibility of adding additional warnings to a particular product; (3) the cost of adding additional warnings; (4) the cost of defending litigation for allegedly defective products; (5) the consumer's responsibility in seeking out translations of an English-only warning; (6) the amount of advertising and marketing by the manufacturer in languages other than English; (7) whether a product is designed for or targeted especially to a particular group of non-English-speaking persons; and (8) prior judicial decisions on the issue. n24

Return to Text

n1 **Courts holding that adequacy of English-only warnings presents question of fact.** *See e.g.:*

**Florida:**

*Stanley Industries, Inc. v. W.M. Barr & Co., 784 F. Supp. 1570, 1576 (S.D. Fla. 1992).*

**New York:**

*Arbaiza v. Delta Int'l Mach. Corp., 1998 U.S. Dist. LEXIS 17886,* at *19 (E.D.N.Y. 1998).

n2 **Other courts are reluctant to impose bilingual warnings.** *See e.g.:*

**California:**

*Ramirez v. Plough, Inc., 863 P.2d 167 (Cal. 1993).*

**Florida:**

*Medina v. Louisville Ladder, Inc., 496 F.Supp.2d 1324, 1329*-1330 (M.D. Fla. 2007) (*specifically disagreeing with Stanley Industries, Inc. v. W.M. Barr & Co., 784 F. Supp. 1570, 1576 (S.D. Fla. 1992)).*

**Puerto Rico:**

*Vargas v. R.J. Reynolds Tobacco Co., 218 F.Supp.2d 109, 117 (D.P.R. 2002)* (federal Labeling Act preempted claims that manufacturer had duty to provide cigarette warnings in Spanish).

n3 **Statutes requiring, recommending, or allowing bilingual warnings.** *See, e.g.:*

**Federal**

R. Geoffrey Dillard *Notes: Multilingual Warning Labels; Product Liability, "Official English," and Consumer Safety, 29 Ga. L. Rev. 197, 202 (1994)* (citing *15 U.S.C. sections 4401*-08 (1998), 16 C.F.R. section 307.5 (1994) and 40 C.F.R. section 156 (1993); 21 CFR section 201.15(1993).

**California:**

Keith Sealing: *Peligro!: Failure to Warn of a Product's Inherent Risk in Spanish Should Constitute a Product Defect, 11 Temp. Pol. & Civ. Rts. L. Rev. 153, 170 (2001)* (citing Cal. Food & Agric. Code § 5777).

n4 *See* Census 2000 Brief, *Language Use and English-Speaking Ability* (Oct. 2003), *available at* http://www.census.gov/prod/2003pubs/c2kbr-29.pdf.

n5 *See* Census 2000 Brief, *The Foreign-Born Population 2000* (Dec. 2003), *available at* http://www.census.gov/prod/2003pubs/c2kbr-34.pdf.

n6 *See* Roberts, Sam, *Census Finds Rise in Foreign Workers,* New York Times (Dec. 7, 2009), *available at* http://www.nytimes.com/2009/12/08/us/08census.html?_r=1.

n7 U.S. Dept of Labor, *The National Agricultural Workers Survey* (2001-2002) Ch. 1, Birthplace, Employment Eligibility, & Migrant Types, *available at* http://www.doleta.gov/agworker/report9/chapter1.cfm#summary.

n8 Restatement of the Law Third, Torts: Products Liability § 2(c).

n9 **Courts focusing on whether there is "law" requiring non-English warnings.** *See, e.g:*

**California:**

*Ramirez v. Plough, Inc., 863 P.2d 167 (Cal. 1993)*(FDA and California's Health & Safety Code do not expressly require warning labels in any language other than English).

**Florida:**

*Medina v. Louisville Ladder, Inc., 496 F.Supp.2d 1324, 1329*-1330 (M.D. Fla. 2007) (defendants entitled to judgment as a matter of law because Florida does not impose duty to provide bilingual warnings on consumer products).

**Puerto Rico:**

*Vargas v. R.J. Reynolds Tobacco Co., 218 F.Supp.2d 109, 117 (D.P.R. 2002)* (failure-to-warn claim was preempted by Federal Labeling Act, which does not require tobacco warnings in Spanish).

n10 **Courts holding that adequacy of warning to foreseeable non-English speaking user is question of fact.** *See, e.g.:*

**Florida:**

*Stanley Indus., Inc. v. W.M. Barr & Co., 784 F. Supp. 1570, 1576 (S.D. Fla. 1992)* (jury to decide whether warning must contain language other than English or pictorial warning symbols).

**New York:**

*Arbaiza v. Delta Int'l Mach. Corp., 1998 U.S. Dist. LEXIS 17886* at *19 (E.D.N.Y. 1998) (warning was placed very low, in small print and only in English).

n11 *Medina v. Louisville Ladder, Inc., 496 F. Supp. 2d 1324 (M.D. Fla. 2007).*

n12 *Medina v. Louisville Ladder, Inc., 496 F. Supp. 2d 1324, 1329 (M.D. Fla. 2007).*

n13 *Stanley Indus., Inc. v. W.M. Barr & Co., Inc., 784 F. Supp. 1570 (S.D. Fla. 1992).*

n14 **Question of fact as to whether English-only warning with no pictorial was adequate.** *Stanley Indus., Inc. v. W.M. Barr & Co., Inc., 784 F. Supp. 1570 (S.D. Fla. 1992).*

n15 *Medina v. Louisville Ladder, Inc., 496 F. Supp. 2d 1324, 1229 (M.D. Fla. 2007).*

n16 *Hubbard-Hall Chem. Co. v. Silverman, 340 F.2d 402, 405 (1st Cir. 1965).*

n17 **Warning label was inadequate due to lack of pictorial.** *Hubbard-Hall Chem. Co. v. Silverman, 340 F.2d 402, 405 (1st Cir. 1965).*

n18 **U.S.E.P.A. requires non-English warnings in certain circumstances.** *See* U.S. Environmental Protection Agency, Label Review Manual, Ch. 10, section IV.

n19 *See* U.S. Environmental Protection Agency, Label Review Manual, Ch. 10, section IV.

n20 *See* U.S. Environmental Protection Agency, Label Review Manual, Ch. 10, section IV.

n21 **Labels for drugs distributed in territories where predominant language is not English.** 21 CFR § 201.15(c)(1).

For other examples of laws requiring warnings in languages other than English, *see* Thomas H. Lee: A Purposeful Approach to Products Liability Warnings and Non-English-Speaking Consumers, *47 Vand. L. Rev. 1107 at 1121-1122* (May, 1994).

n22 **Statute requiring pesticide notices in other languages.** *See* Cal. Food & Agr. Code § 5777.

n23 *See* Keith Sealing, *Peligro!: Failure to Warn of a Product's Inherent Risk in Spanish Should Constitute a Product Defect,11 Temp. Pol. & Civ. Rts. L. Rev. 153, 170 (2001).*

n24 For additional discussion of this issue, *see:*

S. Mark Mitchell, *RECENT DEVELOPMENT: A Manufacturer's Duty to Warn in a Modern Day Tower of Babel*, 29 Ga. J. Int'l & comp. L. 573 (Summer 2001).

Douglas R. Richmond, *When Plain English Isn't: Manufacturers' Duty to Warn in a Second Language, 29 Tort & Ins. L.J. 588 (Spring 1994).*

Roger Enriquez, *I'm Warning You: Over-the-Counter Drug Manufacturers That Advertise in Spanish Should Warn in Spanish, 4 J. Gender Race & Just. 353* (Spring, 2001).

Tseming Yang: *Environmental Regulation, Tort Law and Environmental Justice: What Could Have Been, 41 Washburn L.J. 607 (Spring 2002).*

Kelly Cox: *The Duty to Warn: Should California Extend the City to Include Foreign Language Warnings? 1 San Diego Justice J. 517 (Summer 1993).*

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Tracy Fitzsimmons has practiced law for almost ten years in the area of civil litigation, with an emphasis in product liability. She completed her undergraduate studies in Law and Society and in Spanish at Purdue University and earned her J.D. from Villanova University School of Law. While at Villanova, she won the 40th annual Anthony Reimel Moot Court competition.



***Alford on Salmonella Litigation***

*2010 Emerging Issues 5317*

Margie Searcy Alford on Salmonella Litigation

By Margie Alford

September 8, 2010

**SUMMARY:** Margie Searcy Alford looks at the most important Salmonella opinions handed down over the past several years and gives practice tips for handling these cases. Issues discussed include (1) whether removal to federal court was proper; (2) whether plaintiff established the elements of his or her claim; (3) whether expert scientific testimony was admissible; and (4) whether Salmonella poisoning was excluded from coverage under an insurance policy.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE: Overview of *Salmonella***

It seems that scarcely a month goes by without *Salmonella* making headline news. In the summer of 2010, approximately 1,470 cases of *Salmonella* were linked to eggs produced by two Iowa farms, resulted in the recall of 550 million eggs from the U.S. market. n1 Previous years were marked by *Salmonella* outbreaks in peanut butter products. The Centers for Disease Control and Prevention (CDC) estimates that *Salmonella* causes more than 500 deaths and 1.4 million cases of foodborne illnesses each year in the United States alone. n2

What exactly is *Salmonella*? *Salmonella* is a genus of bacteria that usually live in animals' and humans' intestines and are transferred by feces. Contaminated food or water is the most common means of *Salmonella* infections. *Salmonella* bacteria may also be passed by infected persons, especially if they do not properly wash their hands. *Salmonella* bacteria may be present in animal feces. Many reptiles and birds carry *Salmonella*.

Although over 2,300 serotypes of *Salmonella* bacteria exist, only a few are responsible for most infections. n3 *S. typhi* causes typhoid fever, the symptoms of which include high fever, prostration, confusion, respiratory symptoms, diarrhea, and rash. *S paratyphi* causes paratyphoid fever, which is similar to typhoid fever but less severe. n4 *S. choleraesuis* sometimes results in metastatic abscesses or infection of the bones, joints, and lungs. Some people with *Salmonella* also contract Reiter's syndrome, which may last for years and cause chronic arthritis. *S. Enteritidis* and *S. typhimurium* are the most common of the *Salmonella* infections, resulting for about half of all human infections. Symptoms include fever, chills, nausea, vomiting, cramping, and diarrhea, which is sometimes bloody. Outbreaks are common in hospitals and other similar facilities. n5

Just because someone has some or all of these symptoms does not mean that he or she has *Salmonella* poisoning. Other types of foodborne illnesses may cause the same symptoms. Salmonella is just one of a number of types of food poisoning. Others include *Staphylococcus aureus* , n6 *Escherichia coli* (i.e. *E. coli*), n7 Enteritis, *Shigella*, n8 *Campylobacter*, n9 Cholera, n10 Botulism, n11 mushroom poisoning, n12 *Listeria*, n13 *Bacillus cereus*, n14 fish tape worms, n15 and *Yersinis*. n16 Stool samples should be cultured for the *Salmonella* bacteria. If the finding is positive, further testing should be performed to determine which type of *Salmonella* is present.

**Contaminated Peanut Butter Gives Rise to Variety of Claims Nationwide**

In 2007, the U.S. FDA began an investigation into reports of a possible connection between Conagra's 2111 coded peanut butter and *Salmonella* Tennessee (a serotype of *Salmonella*) contamination. The peanut butter sickened over 600 persons in 47 states. FDA's multistate case-control study revealed a strong link between Peter Pan and Great Value brands peanut butter produced by a ConAgra plant in Sylvester, Georgia and the disease. The food manufacturing giant ceased production of peanut butter in the Georgia facility and recalled the products. Numerous lawsuits against Conagra soon began to pile up. A nationwide class action was filed in Georgia state court in March 2007. The Judicial Panel on Multidistrict Litigation transferred hundreds of federal actions to the Northern District of Georgia for consolidated and coordinated pretrial proceedings. n17 The plaintiffs sought recovery under a wide variety of theories, including unjust enrichment, negligence, and strict products liability. n18

Conagra is not the only company to have produced tainted peanut butter. In 2009, at least nine people died and more than 700 others were injured after eating peanut products produced by Peanut Corporation of America (PCA). The products were contaminated with *Salmonella typhimurium*. Over 100 lawsuits were filed. PCA filed for bankruptcy in February 2009. In October of that year, a bankruptcy judge approved the creation of a $12 million settlement fund to resolve claims pending against the debtor. n19 Plaintiffs also filed actions against other manufacturers, including Kellogg Company, n20 which used peanut butter paste provided by PCA in their products.

**Variety of Other Food Products Give Rise to *Salmonella* Cases**

In addition to eggs and peanut butter, many other foods have been contaminated with *Salmonella* across the nation. Other cases involving *Salmonella* poisoning include:

- A case against a restaurant in Wisconsin following an outbreak of *Salmonella enteritidis*. n21
- A case by a college student who was infected with *Salmonella* after eating in a Mexican restaurant in Athens, Ohio. At least 45 other persons were made ill by the outbreak. n22
- A products liability case against ConAgra. Its Marie Callender's brand frozen "Cheesy Chicken and Rice" dinner sickened 30 people in 15 states, including the plaintiff. n23
- A products liability action against Barber Foods Inc. The plaintiffs alleged that they suffered *Salmonella* poisoning after eating the defendant's chicken cordon bleu product. n24
- A case against the Subway sandwich chain, following an outbreak of *Salmonella* in 28 counties in Illinois. 90 persons, including plaintiff, were sickened in the outbreak. n25
- A wrongful death action on behalf of a 69-year-old woman who consumed contaminated pepper at a hospital following lung surgery. The *Salmonella* outbreak at the food manufacturer sickened 87 persons in the western United States. n26
- Actions following a *Salmonella* outbreak linked to pepper used in salami products. Over 203 persons in 42 states became ill after eating Daniele International brand salami. n27

**Removal to Federal Court: Motions to Remand May Hinge on Amount-in-Controversy**

A defendant may remove a *Salmonella* case-like any other toxic tort case-to federal court under the removal statute. n28 A plaintiff who prefers to litigate the case in state court will need to file a motion for remand. n29 If the

defendant removed the case on diversity grounds, it will have to show not only that complete diversity exists, but also that the amount in controversy exceeds $75,000, exclusive of interest and costs. When the plaintiff had suffered relatively minor injuries from *Salmonella*, the defendant may be unable to meet its burden on this issue.

*Colvin v. Conagra Foods, Inc.* n30 is an example of an order granting plaintiff's motion to remand in a peanut butter/*Salmonella* case. Plaintiff filed the case in a Washington state court, alleging that he ate defendant's peanut butter, suffered headaches and severe diarrhea, was unable to work, and was restricted to a special diet. No specific amount was alleged for damages. Defendant removed the case to federal court. The Judicial Panel on Multidistrict Litigation then transferred the case to the Northern District of Georgia. Plaintiff filed a motion to remand, arguing that the case did not meet *28 U.S.C. § 1332*(a)'s "amount in controversy" requirement. The court agreed, pointing out that the plaintiff had not been hospitalized, suffered no permanent or life threatening injuries, and missed only two weeks of work.

**Amount-in-Controversy in Class Actions**

When the plaintiff is seeking class certification, the defendant must show that the amount in controversy is at least $5,000,000 to remove the action. n31 The defendant met its burden in *Hart v. Conagra Foods, Inc.*, n32 a *Salmonella*/peanut butter class action. The plaintiff, who suffered gastrointestinal problems, filed a class action in Indiana state court. The defendant removed the action based on diversity and the Class Action Fairness Act. Pointing to other *Salmonella* poisoning cases in which substantial damages were awarded, the defendant argued that it had a good-faith belief that more than $25,000 was at stake for each of the approximately 200 class members. The court agreed. Even if only 16 of the Indiana plaintiffs were documented to have suffered serious symptoms, a handful of plaintiffs could push the total amount in controversy past the $5,000,000 threshold. The court denied plaintiff's motion to remand.

**Failure to Link Defendant's Food Product to Plaintiff's *Salmonella* Resulted in Dismissal of Action**

When *Salmonella* poisoning is suspected, it is critical that the plaintiff immediately identify the probable source and, when possible, have the suspect food tested and find other persons who ate the same food and developed food poisoning. The importance of linking the defendant's food product to the plaintiff's illness cannot be underestimated. *Payano v. Hempstead Union Free School District* n33 is an example of a case dismissed on grounds of failure to prove causation. The plaintiff, a student, became ill after eating chicken nuggets in the school lunchroom. She was diagnosed with *Salmonella* about two weeks later. She sued the school district but did not offer sufficient proof that the chicken nuggets were contaminated with *Salmonella*. The court dismissed the case, pointing out that "[m]ere conclusions that the plaintiff felt ill sometime after consuming the chicken nuggets" was insufficient to defeat the defendant's motion for summary judgment. n34

**Strength of *Salmonella* Case May Depend on Strength of Expert Testimony**

Food poisoning cases, like other toxic tort cases, often depend upon expert testimony. The strength of a *Salmonella* case may well depend upon the strength of the testimony of the plaintiff's physician or other specialist, which in turn may depend on the results of bacteriological studies of the patient and the suspect food. n35 For the testimony to be admitted, the expert must be sufficiently qualified to the court's satisfaction. The testimony must also meet the applicable standard for admissibility of scientific evidence. n36 *Dragovich v. Magical Cruise Co*. n37 is an example of a *Salmonella* case in which the testimony of plaintiff's medical expert was excluded. The case was brought by a pregnant woman who alleged that shrimp contaminated with *Salmonella* and *E. coli* caused her to contract gastroenteritis, ultimately resulting in the premature delivery of her baby. The trial court excluded her expert's testimony under the standard applicable to Florida law -the *Frye* standard n38- and granted the food supplier's motion for summary judgment. The appellate court affirmed.

**Insurer's Attempt to Avoid Coverage of *Salmonella* Claims**

Be aware that insurers may claim that that have no duty to defend or indemnify claims for *Salmonella* claims. In

*Iowa Mutual Insurance Co. v. Hennings*, n39 for example, a worker allegedly contracted *Salmonella* from his employer's hogs. He sued his employer and the veterinarian who destroyed samples that would have helped determine what kind of *Salmonella* had infected the hogs. The employer had two business insurance policies and its owner had one personal farming policy, all of which were issued by Iowa Mutual Insurance Company. The insurer filed a declaratory judgment action to determine if it had to defend the suit under the three policies. The court granted its motion for summary judgment in part because the relevant policy excluded actions by employees and the injuries did not arise during the relevant policy period.

**Prisoners Representing Themselves Make Mistakes in Handling Their *Salmonella* Cases**

A review of *pro se* cases unsuccessfully brought by inmates alleging *Salmonella* poisoning reveals the dangers of representing oneself in a foodborne illness case. In *Towner v. Dow*, n40 a prisoner brought action pursuant to *42 U.S.C. § 1983* claiming that he developed *Salmonella* after eating tainted peanut butter products. He alleged that he had been originally misdiagnosed but later had an adverse reaction to the CT/MRI contrast dye used in a diagnostic test and required surgery as a result of the adverse reaction. He alleged that prison officials were wrongfully withholding the surgery. The court dismissed the case because the prisoner failed to prove the elements of a § 1983 case and failed to properly identify the defendants as his medical providers. Notably, the prisoner did not sue the processors of the peanut butter products.

*Baldwin v Johnson* n41 is another § 1983 case brought by a prisoner who allegedly consumed *Salmonella*-contaminated food while incarcerated. An investigation conducted by the Center for Disease Control revealed a rare strain of *Salmonella* in the tuna fish the prisoner had eaten. The prison health care unit had prescribed Tylenol, which, by itself, is generally not considered proper treatment for *Salmonella* poisoning. The prisoner thus had a plausible claim for inadequate medical care. The court granted the defendants' motions to dismiss, but the case might have gone much further if the prisoner had had access to a competent attorney.

Yet another unsuccessful case that might have been won if the prisoner had an attorney well-versed in food poisoning cases is *Polmounter v. Keystone Food Products, Inc.* n42 The prisoner in this Texas state court case alleged that he became sick within hours after sharing with other inmates a bag of defendant's party mix. The prisoner was no longer ill by the time a nurse responded to his request for emergency medical care, and he was never seen by a physician. The court of appeals affirmed the summary judgment granted in favor of the defendant on several grounds, including the lack of proof that the prison food was contaminated with *Salmonella*.

**Practice Tips for Proper Handling of *Salmonella* Cases**

1. Many *Salmonella* cases are not worth the money and time they would cost to bring, so best practice dictates that counsel carefully screen potential cases. For example, *Colvin v. Conagra Foods, Inc.*, n43 discussed above, required the plaintiff's attorney to expend an enormous amount of time and effort on a case involving injuries that were relatively minor and would not produce much income. On the other end of the spectrum, when screening cases, counsel should not overlook cases similar to *Anonymous 32 Year Old Plaintiff v. Anonymous Restaurant*, n44 which settled for $4,000,000 after plaintiff suffered permanent injuries from *Salmonella* poisoning.

Before taking a case, counsel should make sure that it will be worth his or her time. Consider delegating to someone else in the office the job of counseling the client on representing himself or herself in small claims court. Counsel can spend the saved time on more lucrative matters.

2. In addition, counsel should make sure the potential defendant has sufficient assets to make a case worthwhile. Peanut Corporation of America-which, as discussed above, is the target of many suits due to its *Salmonella*-contaminated peanut butter-filed for bankruptcy but supposedly has $24,000,000 in personal liability insurance.

3. When defendant is insured, counsel should, if possible, examine the policy before filing suit to determine

whether the insurance is sufficient to cover the case. You do not want a situation such as the one in *Iowa Mutual Insurance Co. v. Hennings,* n45 where the court determined that the insurance in part did not cover the alleged matter as it related to one or more parties.

4. If a party files for bankruptcy and the bankruptcy court has jurisdiction over the case and fees, counsel should become acquainted with the bankruptcy laws regarding attorneys' fees. Even when plaintiff's attorneys have a contingency fee contract, counsel will often need to have contemporaneous time records to receive the bankruptcy court's approval of the fees. The same is often true in multidistrict litigation and class actions suits. Use Lexis.com to research what your judge and laws require for the payment of fees in these cases.

Because many plaintiffs' attorneys are not accustomed to keeping time records, best practice dictates that counsel learn what the judge requires in this regard. For example, some judges will not award fees for a time notation such as "Phone call with defense attorney" unless the notation also tells what was discussed on the call. Of course, the date and amount of time spent on the matter is required.

1. Remember that simply showing that a person contracted *Salmonella* poisoning after eating defendant's food is usually not sufficient to win the case. You need to be able to prove that that the defendant's food was contaminated with *Salmonella*.

2. Best practice dictates that when possible, the attorney looking at a potential *Salmonella* case preserve for testing samples of all possible sources of the *Salmonella* as soon as possible. In the case of peanut butter, for example, have tested as soon as possible any remaining peanut butter left in the jar from which the sick person ate. Physicians and hospitals may culture samples from a sick person, but these cultures frequently do not reveal which food that the person ate caused the illness.

3. Counsel should be prepared to show that plaintiff either was or was not exposed to sufficient *Salmonella* to cause the sickness. Which side counsel chooses to prove depends on which party in the case counsel is representing.

4. Look for other people who ate the same food and became sick, or look for other people who ate the same food and did not become sick, depending on which option helps your case. Various publications, such as those provided by the American Association for Justice and state trial lawyer associations, may be good sources of information about other persons with *Salmonella* poisoning.

5. *Salmonella* symptoms generally begin about 8 to 48 hours after a person eats contaminated food, so taking a good history of what the person ate 8 to 48 hours before the onset of symptoms is important. Make sure to obtain statements from everyone who ate with the plaintiff at the time he or she consumed the suspect food. Rather than counsel taking these statements, counsel should have someone else take the statements so counsel will not put himself or herself in a position where he or she might potentially be needed as a witness.

6. Best practice dictates that counsel review the exact elements of each cause of action being claimed. Draft the complaint using the exact words of those elements as established by law, and produce evidence using those words so they will match the judge's jury charges.

7. In drafting a complaint for multidistrict litigation, make sure you allege all the relevant statutes for the states from which the suits arose.

8. When possible counsel should try to get his or her case in front of the judge and jury most likely to give the outcome best for his or her client.

9. Counsel should make sure that he or she can prove that the allegedly contaminated food was in fact contaminated with *Salmonella*. There are numerous strains of *Salmonella*, and sometimes knowing exactly which one was present in the food and which one sickened the plaintiff may be important.

10. *Salmonella* is caused by a gram negative bacteria. Some forms of it respond better than others to antibiotics. Sometimes knowing how and to which antibiotics the infection responded may be important in helping prove which kind of *Salmonella* caused the illness. The *Salmonella* caused by the Peanut Corporation of America peanut butter seems to respond fairly well to antibiotics.

11. When having allegedly contaminated food tested, counsel should make sure to preserve the chain of custody and not put himself or herself in the chain. The attorney should not get in a position where he or she might need to be a witness in the case.

12. Counsel should always know the laws regarding the admissibility of scientific evidence in his or her jurisdiction, and make sure that the experts can adequately testify on the required elements of such laws.

Return to Text

n1 Dep't of Health & Human Servs., Centers for Disease Control & Prevention, *Investigation Update: Multistate Outbreak of Human Salmonella Enteritidis Infections Associated With Shell Eggs* (Aug. 27, 2010), *available at* http://www.cdc.gov/Salmonella/enteritidis/.

CNN Health, *No Further Egg Recalls Expected, Feds Say* (Aug. 24, 2010), *available at* http://www.cnn.com/2010/HEALTH/08/23/eggs.Salmonella/index.html.

n2 U.S. Dep't of Agriculture, Food Safety & Inspection Serv., Fact Sheets, *Foodborne Illness & Disease* (last modified Sept. 20, 2006), *available at* http://www.fsis.usda.gov/factsheets/Salmonella_Questions_&_Answers/index.asp.

n3 *See* 8-49B Attorneys' Textbook of Medicine P 49B.41[1].

n4 *See* 7-33 Attorneys' Textbook of Medicine P 33.65[4d].

n5 *See* 7-33 Attorneys' Textbook of Medicine P 33.65[4e].

n6 *See* 8-49B Attorneys' Textbook of Medicine P 49B.41[2].

n7 *See* 8-49B Attorneys' Textbook of Medicine P 49B.41[4].

n8 *See* 8-49B Attorneys' Textbook of Medicine P 49B.41[5].

n9 *See* 8-49B Attorneys' Textbook of Medicine P 49B.41[11].

n10 *See* 8-49B Attorneys' Textbook of Medicine P 49B.41[8].

n11 *See* 8-49B Attorneys' Textbook of Medicine P 49B.41[10b].

n12 *See* 8-49B Attorneys' Textbook of Medicine P 49B.46[4].

n13 *See* 8-49B Attorneys' Textbook of Medicine P 49B.41[13].

n14 *See* 8-49B Attorneys' Textbook of Medicine P 49B.41[9].

n15 *See* 8-49B Attorneys' Textbook of Medicine P 49B.43[4].

n16 *See* 8-49B Attorneys' Textbook of Medicine P 49B.41[12].

n17 In re: Conagra Peanut Butter Prods. Liab. Litig. (N.D. Ga. 2009).

n18 In re: *Conagra Peanut Butter Prods. Liab. Litig., 2008 U.S. Dist. LEXIS 40753* (N.D. Ga. May 21,

2008).

n19 *Judge Approves $12M Fund for Victims of Salmonella Outbreak,* 3-7 Mealey's Food Liability 5 (2009),

n20 Arcure v. Kellogg Co. (M.D. Fla. March 29, 2010), *available at* 4-2 Mealey's Food Liability 9 (2010).

n21 Dzinovic v. L & K Tricoli LLC (Kenosha County., Cir. Ct. Wis. July 21, 2010), *available at* 4-5 Mealey's Food Liability 8 (2010).

n22 Nay v. Casa Lopez Inc., Athens County, Ohio, Ct. Common Pleas June 16, 2010), *available at* 4-4 Mealey's Food Liability 4 (2010).

n23 Taylor v. ConAgra Foods Packaged Foods LLC (D. Ore. June 24, 2010), *available at* 4-5 Mealey's Food Liability 9 (2010).

n24 Weiss v. Barber Foods Inc. (D. Minn. Feb. 22, 2010), *available at* 4-1 Mealey's Food Liability 4 (2010).

n25 Bush-Bailey v. Subway (Will County, Ill., Circ. Ct. June 21, 2010), *available at* 4-4 Mealey's Food Liability 3 (2010).

n26 Lucier v. U.F. Union Int'l Food Inc. Alameda County, Cal., Super. Ct. Feb. 25, 2010), *available at* 4-1 Mealey's Food Liability 1 (2010).

n27 Hanks v. Daniele Int'l Inc., Camden County, Mo., Circ. Ct. Feb. 3, 2010), *available at* 3-12 Mealey's Food Liability 16 (2010).

n28 *28 U.S.C. § 1441*.

n29 *28 U.S.C. § 1447*(c).

n30 *Colvin v. Conagra Foods, Inc., 2007 U.S. Dist LEXIS 84381,* at *6 (W.D. Wash. Nov. 5, 2007).

n31 *28 U.S.C. § 1332*(d)(2).

n32 *2007 U.S. Dist. LEXIS 57840,* at *7 (S.D. Ind. Aug. 7, 2007) (not suitable for commercial publication).

n33 *Payano v. Hempstead Union Free Sch. Dist., 2007 N.Y. Misc. LEXIS 873* (Feb. 16, 2007).

n34 *Payano v. Hempstead Union Free Sch. Dist., 2007 N.Y. Misc. LEXIS 873,* at *7 (Feb. 16, 2007). *See also* Frumer & Friedman, Products Liability, Ch. 48, *Food & Beverages*, § 48.20[1].

n35 *See* Frumer & Friedman, Products Liability Ch. 48, *Food & Beverages*, § 48.06[3].

n36 *See* § 6.09[3].

n37 *Dragovich v. Magical Cruise Co., 925 So. 2d 1141 (Fla. Dist. Ct. App. 2006).*

n38 Frye v. United States, 293 F.1013 (D.C. Cir. 1923).

n39 *Iowa Mut. Ins. Co. v. Hennings, 2006 U.S. Dist. LEXIS 74640* (C.D. Ill. Oct. 12, 2006).

n40 *Towner v. Doe, 2008 U.S. Dist. LEXIS 8431* (N.D.N.Y. Feb. 5, 2008).

n41 *Baldwin v. Johnson, 2007 U.S. Dist. LEXIS 51301* (E.D. Va. Jan. 10, 2007).

n42 *Polmounter v. Keystone Food Prods., 2006 Tex. App. LEXIS 7954*, at *7-*13 (Tex. Ct. App. 2006).

n43 *Colvin v. Conagra Foods, Inc., 2007 U.S. Dist LEXIS 84381*, at *6 (W.D. Wash. Nov. 5, 2007).

n44 Anonymous 32 year Old Single Male v. Anonymous Restaurant (Arlington County, Va., Circ. Ct. 2002), *as reported in* 2002 JAS Publications, Metro Verdicts Monthly, Vol. 14, No. 10.

n45 *Iowa Mut. Ins. Co. v. Hennings, 2006 U.S. Dist. LEXIS 74640* (C.D. Ill. Oct. 12, 2006).

**RELATED LINKS:** Contaminated Peanut Butter Cases:

- In re: Conagra Peanut Butter Prods. Liab. Litig., 2008 U.S. Dist. LEXIS 40753 (N.D. Ga. May 21, 2008);
- Judge Approves $12M Fund for Victims of Salmonella Outbreak, 3-7 Mealey's Food Liability 5 (2009);
- Arcure v. Kellogg Co. (M.D. Fla. March 29, 2010).

Salmonella Cases Involving Other Foods:

- Dzinovic v. L & K Tricoli LLC (Kenosha County., Cir. Ct. Wis. July 21, 2010);
- Nay v. Casa Lopez Inc., Athens County, Ohio, Ct. Common Pleas June 16, 2010);
- Taylor v. ConAgra Foods Packaged Foods LLC (D. Ore. June 24, 2010);
- Weiss v. Barber Foods Inc. (D. Minn. Feb. 22, 2010);
- Bush-Bailey v. Subway (Will County, Ill., Circ. Ct. June 21, 2010);
- Lucier v. U.F. Union Int'l Food Inc. Alameda County, Cal., Super. Ct. Feb. 25, 2010);
- Hanks v. Daniele Int'l Inc., Camden County, Mo., Circ. Ct. Feb. 3, 2010).

Motion to Remand Salmonella Case:

- Colvin v. Conagra Foods, Inc., 2007 U.S. Dist LEXIS 84381, at *6 (W.D. Wash. Nov. 5, 2007).

Failure to Link Defendant's Food Product to Plaintiff's Salmonella:

- Payano v. Hempstead Union Free Sch. Dist., 2007 N.Y. Misc. LEXIS 873 (Feb. 16, 2007).

Plaintiff's Expert's Testimony Excluded in Salmonella Case:

- Dragovich v. Magical Cruise Co., 925 So. 2d 1141 (Fla. Dist. Ct. App. 2006).

Insurer Claiming No Duty to Defend or Indemnify Salmonella Claims:

- Iowa Mut. Ins. Co. v. Hennings, 2006 U.S. Dist. LEXIS 74640 (C.D. Ill. Oct. 12, 2006).

Pro Se Salmonella Cases Unsuccessfully Brought by Inmates:

- Towner v. Doe, 2008 U.S. Dist. LEXIS 8431 (N.D.N.Y. Feb. 5, 2008);
- Baldwin v. Johnson, 2007 U.S. Dist. LEXIS 51301 (E.D. Va. Jan. 10, 2007);
- Polmounter v. Keystone Food Prods., 2006 Tex. App. LEXIS 7954, at *7-*13 (Tex. Ct. App. 2006).

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Margie Searcy Alford is the Principal Author and Editor-in-chief of the five volume set *A Guide to Toxic Torts* (LexisNexis), a contributing author to the four volume set *Drug Product Liability* (LexisNexis), and a contributing author to the two volume set *Alabama Civil Practice Forms* (LexisNexis), plus many other publications.

She served two years as National Chairperson of the American Association for Justice Section on Toxic, Environmental, and Pharmaceutical Tort Law and two years as National Chairperson of the Women Trial Lawyer's Caucus of the American Association for Justice. She was National head of the Dioxin Litigation Group for three years.

Margie Searcy Alford practices in the area of serious personal injury with a special focus on toxic torts. Attorney Alford has handled toxic tort cases in sixteen states. She graduated from The University of Alabama School of Law in 1974. She is a Fellow with the National College of Advocacy and a Trial Warrior for Justice.

Attorney Alford was chosen the most outstanding young career women in Alabama by the Alabama Federation of Business and Professional Women and is in more than a hundred Who's Who type publications. She has served on many boards, committees, and commissions.

3 of 21 DOCUMENTS



***Alford on How U.S. Courts Have Ruled In Thimerosal/Autism Cases***

*2010 Emerging Issues 5023*

Margie Searcy Alford on How U.S. Courts Have Ruled In Thimerosal/Autism Cases

By Margie Searcy Alford

June 14, 2010

**SUMMARY:** Toxic tort litigator and author Margie Searcy Alford reviews recent court decisions in cases alleging a link between thimerosal and autism.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE: Overview**

According to the Centers for Diseases Control, about one out of every one hundred and ten children in the U.S. is autistic. n1 Some parents believe that their children were meeting normal developmental milestones until they received thimerosal n2-containing vaccines, and that the children developed autism immediately afterwards. These parents believe that their children at once developed brain damage with symptoms such as cessation of talking, repetitive movements, poor eye contact and frequently but not always decreased intelligence.

Many of these parents filed suit in the U.S. Court of Claims, but all of the recent cases have been lost on causation issues. The courts generally have held that there is not sufficient credible evidence to prove that thimerosal causes autism. Many parents continue to believe that it does-but that the scientific evidence has not yet been developed to the point that can be proven to the satisfaction of courts hearing these cases.

**The Law**

The United States Claims Court has jurisdiction over most vaccine cases under the "National Childhood Vaccine Injury Act of 1986," which created the National Vaccine Injury Compensation Program (VICP). *42 U.S.C. §§ 300aa-1* to *300aa-34*. "The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines." n3

- *42 U.S.C. §300aa-11* provides that civil actions relating to vaccine-related injury or death for damages greater than $1,000 cannot be filed *until* a petition is filed under the VICP and the Claims Court has issued judgement on that petition.
- *42 U.S.C. §300aa-15(e)* allows awards of reasonable attorney fees and costs regardless of whether the court awards compensation to the petitioner.
- Under *42 U.S.C. § 300aa-16*, petitions must be brought within 36 months of the first symptom of injury.

- *42 U.S.C. §300aa-22* establishes limitations on the liability of vaccine manufacturers and provides a basis for federal preemption of state law claims.

**Statute of Limitations**

There are several reasons why the three-year statute of limitations might be missed in thimerosal/autism cases. Parents and doctors may not recognize within the same length of time that children are not meeting normal developmental milestones. For example, not all children start talking at the exact same age. Also, doctors may not always suspect a connection between developmental delays and vaccines. So, varying amounts of time may pass between when children first develop symptoms of autism and when they are actually diagnosed with autism. Lastly, parents and doctors may simply not be aware of the statute of limitations for vaccine claims until it is too late.

Numerous attempts have been made to overcome problems with the thirty-six month statute of limitations. The courts have strictly construed the thirty-six month period. *See Schroeders v. Secretary of Health and Human Services, 2009 U.S. Claims LEXIS 442* (June 25, 2009).

The issue of *when* the thirty-six month period begins was addressed in *Bono v. Secretary of Health and Human Services, 87 Fed. Cl. 98 (2009).* The *Bono* court held that the statute of limitations begins to run when the general medical community would recognize "a symptom or manifestation of an injury." The injury need not be specifically linked to vaccines.

Even if a child was diagnosed as having speech and other developmental delays but was not diagnosed as being autistic until later, the statute of limitations still began when the first symptoms were diagnosed. *See Carson v. Secretary of the Department of Health and Human Services, 2009 U.S. Claims LEXIS 449* (August 26, 2009).

Parents have unsuccessfully argued that the statute of limitations had not begun to run because the medical community did not yet recognize autism as a vaccine-caused injury. *See Scott v. Secretary of the Department of Health and Human Services, 2009 U.S. Claims LEXIS 141* (January 16, 2009).

However, when a child developed the first symptoms more than three years prior to filing suit but the parents alleged that additional vaccines given within the three-year period had *aggravated* the earlier symptoms, the court held that the statute of limitations had not run on the aggravation claims. *See Armstrong v. Secretary of Health and Human Services, 2008 U.S. Claims LEXIS 708* (September 9, 2008); *Jones v. Secretary of the Department of Health and Human Services, 2008 U.S. Claims LEXIS 165* (April 30, 2008); *Emkey v. Secretary of Health and Human Services, 2009 U.S. Claims LEXIS 455* (October 20, 2009).

Parents have unsuccessfully argued that the statute of limitations is unconstitutional. *See Hoogacker v. Secretary of the Department of Health and Human Services, 2009 U.S. Claims LEXIS 190* (January 23, 2009).

**Federal Preemption of State Court Claims**

Courts have interpreted *42 U.S.C.S. § 300aa-22(b)(1)* to preempt state court design defect claims. *See Bruesewitz v. Wyeth, Inc., 508 F. Supp. 2d 430 (E.D. Penn. 2007).* On a similar note, *42 U.S.C.S. § 300aa-22(b)(2)* establishes a presumption that vaccine warnings are adequate if the manufacturer complied with FDA requirements.

**"Table" v. "Non Table" Cases**

The thimerosal/autism cases have mostly been brought as what are called "non-table" cases. In non-table cases the injuries that petitioners claim are not listed on the Vaccine Injury Table maintained at *42 CFR 100.3*. n4 If a claim is brought as a table case-i.e. the child has a condition listed on the table and the child developed the condition within the time interval on the table-there is a presumption that the vaccine caused the condition.

**Omnibus Autism Proceedings**

Approximately 5000 cases that were filed in the Claims Court are currently being managed in a consolidated proceeding called the Omnibus Autism Proceedings (OAP). n5 Plaintiffs selected a steering committee and that committee at the outset identified three general theories of causation:

- that thimerosal alone could cause autism;
- that thimerosal and the measles, mumps, and rubella (MMR) vaccine could cause autism;
- that the MMR vaccine alone could cause autism (this theory was eventually incorporated into the second theory)

The plaintiffs' steering committee proposed that the first case to be heard be a test case on the second theory of causation: that thimerosal and the MMR vaccine could cause autism. The Chief Special Master then decided that three test cases on the second theory would be heard and that each would be heard by a different special master (although each of the three of the special masters could sit in and observe the two cases that were not assigned to them).

**OAP Limited to Autism Cases**

The OAP is only for autism-related cases, not just any case in which developmental delays are allegedly linked to thimerosal. A mother's motion to transfer a case to the OAP was denied because the child had not been diagnosed with an autism spectrum disorder. *See Doe v. Secretary of the Department of Health and Human Services*, 2009 U.S. claims LEXIS 165 (April 2, 2009).

**Test Cases on the Theory that Thimerosal and MMR Vaccine Could Cause Autism**

The three test cases on the theory that thimerosal and the MMR vaccine could cause autism were:

- *Cedillo v. Secretary of Health and Human Services, 2009 U.S. Claims LEXIS 146* (February 12, 2009), *affirmed, 89 Fed. Cl. 158 (2009).*
- *Hazlehurst v. Secretary, Department of Health & Human Services, 2009 U.S. Claims LEXIS 183* (February 12, 2009), *affirmed, 88 Fed. Cl. 473 (2009).*
- *Snyder v. Secretary, Department of Health & Human Services, 2009 U.S. Claims LEXIS 193* (February 12, 2009), *reconsid. denied, 88 Fed. Cl. 706 (2009).*

In these cases, the plaintiffs claimed that thimerosal affected their childrens' immune systems such that the measles virus stayed in the childrens' bodies where it affected stomach linings and brains. With the permission of the parties, the evidence from all three cases was considered in each case. The *Cedillo* case was heard in June 2007; the *Hazlehurst* case was heard in October 2007; and the *Snyder* case was heard in November 2007.

The special masters' decisions in all three cases were rendered February 12, 2009. In all three cases, the special masters found that there was not a preponderance of credible scientific evidence to show that thimerosal and the MMR vaccine had caused autism.

In the *Cedillo* case, one of the most contested issues was the accuracy of the lab in Ireland where tissue from a child's stomach was tested for the measles virus. The court found that the lab was not accredited and did not have any sort of "independent quality control program." The court further found that the procedure used to test the tissue was itself questionable. This issue also affected the other test cases.

The special master in *Hazlehurst* decided that the government's experts were more credible than the plaintiff's experts. She found that they did a better job of discrediting literature that was adverse to the government's case. She found that the plaintiffs' experts relied on a number of scientifically flawed articles on important issues. She thus ruled for the government.

In the *Snyde*r case, the special master found that the plaintiffs failed to prove their case for reasons similar to those raised in the other test cases.

**Test Cases on the Theory that Thimerosal Alone Could Cause Autism**

The three test cases on the theory that thimerosal could cause autism were:

- *Dwyer v. Secretary of Health and Human Services, 2010 U.S. Claims LEXIS 86* (March 12, 2010);
- *King v. Secretary of Health and Human Services, 2010 U.S. Claims LEXIS 87* (March 12, 2010);
- *Mead v. Secretary of Health and Human Services, 2010 U.S. Claims LEXIS 88* (March 12, 2010).

Once again, evidence from all three cases was considered in each case. The same group of three special masters from the first set of cases also heard these cases.

In *Mead*, the special master considered over 1200 exhibits, twenty expert reports, and a lot of other offered evidence. Despite all of this evidence, the special master concluded that the plaintiffs' had not presented sufficient proof of a credible theory of how thimerosal had caused plaintiff William Mead's autism.

Similar conclusions were reached in the *Dwyer* and *King* cases.

**Scientific Article Not the Same as an Expert Report**

Parents acting pro se were required to produce an expert report showing that their child had an autism spectrum disorder. In one case they instead attached an article. The court held that the article was not a sufficient substitute for an expert report. *See McLaughlin v. Secretary of Human Services, 2008 U.S. Claims LEXIS 646* (September 9, 2008).

**Interim Costs and Attorney Fees**

Under *42 U.S.C § 300aa-15(e)*, interim costs and attorney fees have been awarded in thimerosal-autism cases. *See, e.g. Hazlehurst v. Sec'y of the HHS, 2009 U.S. Claims LEXIS 164* (March 5, 2009) ($221,977.57 in interim attorneys' fees and costs awarded); *Cedillo v. Sec'y of HHS, 2009 U.S. Claims LEXIS 144* (March 11, 2009) ($1,452,806.11 in interim attorneys' fees and costs awarded); *Gorton v. Sec'y of the HHS, 2009 U.S. Claims LEXIS 476* (August 18, 2009) ($3,530.50 in interim attorneys' fees and costs awarded); *Macneir v. Sec'y of the HHS, 2010 U.S. Claims LEXIS 51* (February 12, 2010) ($12,062 in interim attorneys' fees and costs awarded).

**Conclusion**

At the present time courts are not finding sufficient valid evidence that autism is caused by vaccines with thimerosal in them even though many parents continue to believe that it is. In spite of losing these cases, plaintiffs' attorneys may be paid fees and their costs.

**Practice Tips**

1. Plaintiff's counsel should think carefully about taking any new autism cases since there does not seem to be sufficient scientific evidence at the present time to convince the courts that there is a thimerosal-autism link. In general, best practice dictates that plaintiff's counsel should research the scientific literature about an alleged toxin to make sure there are sufficient valid studies to prove that the toxin caused the alleged injuries.

2. When embarking on defending a toxic tort case, defense counsel should become well familiar with all of the scientific literature about the alleged toxin and evaluate how each adverse study may be impeached.

3. In toxic tort cases, counsel should find the best experts possible and if possible get ones who have been involved in research involving human subjects and the alleged toxin.

4. In autism cases, best practice dictates that counsel should carefully review medical records for evidence of any sign of autism symptoms. The statute of limitation begins to run at the time of the first symptom, not when a doctor first diagnoses autism. The exception to this general rule is when later vaccines have allegedly caused aggravation to the

autism.

Return to Text

n1 Centers for Diseases Control and Prevention, "How Many Children Have Autism?" http://www.cdc.gov/ncbddd/features/counting-autism.html (last visited June 14, 2010).

n2 "Thimerosal is a mercury-containing organic compound (an organomercurial). Since the 1930s, it has been widely used as a preservative in a number of biological and drug products, including many vaccines, to help prevent potentially life threatening contamination with harmful microbes." U.S. Food and Drug Administration, "Thimerosal in Vaccines." http://www.fda.gov/biologicsbloodvaccines/safetyavailability/vaccinesafety/ucm096228.htm (last visited June 14, 2010).

n3 U.S. Department of Health and Human Services, Health Resources and Services Administration, "National Vaccine Injury Compensation Program (VICP)" http://www.hrsa.gov/vaccinecompensation/ (last visited June 14, 2010).

n4 The table is also available at http://www.hrsa.gov/vaccinecompensation/table.htm (last visited June 14, 2010).

n5 *See* http://www.uscfc.uscourts.gov/omnibus-autism-proceeding (last visited June 14, 2010).

**RELATED LINKS:** National Childhood Vaccine Injury Act of 1986:
- 42 USCS Section 300aa-1 et al.

Thimerosal/Autism Causation Test Cases:
- Cedillo v. Secretary of Health and Human Services, 2009 U.S. Claims LEXIS 146 (February 12, 2009);
- Hazlehurst v. Secretary, Department of Health & Human Services, 2009 U.S. Claims LEXIS 183 (February 12, 2009);
- Snyder v. Secretary, Department of Health & Human Services, 2009 U.S. Claims LEXIS 193 (February 12, 2009);
- Dwyer v. Secretary of Health and Human Services, 2010 U.S. Claims LEXIS 86 (March 12, 2010);
- King v. Secretary of Health and Human Services, 2010 U.S. Claims LEXIS 87 (March 12, 2010);
- Mead v. Secretary of Health and Human Services, 2010 U.S. Claims LEXIS 88 (March 12, 2010)

For a more detailed discussion of vaccine litigation, see
- A Guide to Toxic Torts, Chapter 29

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Margie Searcy Alford is the Principal Author and Editor-in-chief of the five volume set *A Guide to Toxic Torts* (LexisNexis), a contributing author to the four volume set *Drug Product Liability* (LexisNexis), and a contributing author to the two volume set *Alabama Civil Practice Forms* (LexisNexis), plus many other publications.

She served two years as National Chairperson of the American Association for Justice Section on Toxic, Environmental, and Pharmaceutical Tort Law and two years as National Chairperson of the Women Trial Lawyer's Caucus of the American Association for Justice. She was National head of the Dioxin Litigation Group for three years.

Margie Searcy Alford practices in the area of serious personal injury with a special focus on toxic torts. Attorney Alford has handled toxic tort cases in sixteen states.

She graduated from The University of Alabama School of Law in 1974. She is a Fellow with the National College of Advocacy and a Trial Warrior for Justice.

Attorney Alford was chosen the most outstanding young career women in Alabama by the Alabama Federation of Business and Professional Women and is in more than a hundred Who's Who type publications. She has served on many boards, committees, and commissions.





***Alford on Wyeth v. Levine***

*2009 Emerging Issues 4040*

Margie Searcy Alford on Wyeth v. Levine, 129 S. Ct. 1187 (2009)

By Margie Alford

May 15, 2009

**SUMMARY:** Toxic tort litigator and author Margie Searcy Alford comments on the landmark case Wyeth v. Levine, in which the U.S. Supreme Court held that federal law did not preempt state failure-to-warn claims against drug manufacturers.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE: Overview**

On March 4, 2009, the U.S. Supreme Court issued an opinion in *Wyeth v. Levine, 129 S. Ct. 1187 (2009)* -- one of the most important decisions of the year. In this hotly contested failure-to-warn drug liability case, the Court ruled that plaintiff Diane Levine could recover for her hand and forearm amputations caused by a caustic IV push of Phenergan, a drug manufactured by defendant Wyeth. The Court determined that Levine's state law claim was not pre-empted by federal laws regulating drug labels.

The Court in this surprisingly six-to-three decision held that federal regulation of what goes on a drug label does not bar state causes of action for injuries caused by inadequate warnings on the label. In addition, the case gives insight into what the justices might do in other types of pre-emption cases such as other kinds of product liability cases.

If counsel has been reluctant to take failure-to-warn drug liability cases because of the pre-emption issue and rulings in some recent defense cases prior to Wyeth v. Levine, counsel should give those cases a second look. They may be better cases than counsel first thought.

**Facts of the Case**

For a migraine headache, Diane Levine, a professional musician who used her hands a lot to do her work, went to a clinic where she received a shot of Phenergan and Demerol. Later that day she returned to the clinic and received an IV push of Phenergan and Demerol. The IV push went into her artery instead of her vein.

When Phenergan is pushed in rapidly through an IV drip, it can be dangerous because Phenergan is caustic. The IV

push damaged Ms. Levine's artery and caused tissue to die. The damaged artery caused a lack of adequate blood flow that resulted in gangrene. As a result, Ms. Levine's right hand was amputated; later, to save her life, her right forearm was also amputated.

Ms. Levine filed common-law negligence and strict-liability claims in Vermont state court. Among other allegations, she claimed that Wyeth, the manufacturer of the Phenergan, did not give adequate warnings against the dangers of IV pushes of the drug. She settled with the health center where she received the IV push of Phenergan and the clinician who gave her the IV push.

During the five-day trial, Levine's attorneys presented evidence that an IV drip in contrast to an IV push of Phenergan almost eliminates the risks of gangrene and amputation. Levine won her case. The total verdict was for $7,400,000 but this amount was reduced by the sum Ms. Levine had previously settled for with the health center and clinician. Wyeth appealed the decision to the Vermont Supreme Court where Levine again prevailed.

Wyeth claimed the failure to warn claim was pre-empted by federal law since the U.S. Food and Drug Administration regulates drug labels. The U.S. Supreme Court granted certiorari on the pre-emption issue.

The U.S. Supreme Court decided that state court cases for compensation for injuries caused when inadequate warnings are given, work together with federal law in protecting consumers. The Court held state lawsuits give compensation that federal law does not provide injured consumers and that federal law does not pre-empt state law in this case.

**Analysis**

How the Members of the Court Ruled

Justice Stevens wrote the majority opinion with Justices Breyer and Thomas writing concurring but separate opinions. Justices Thomas and Scalia so often decide the same way on cases but that was not the case on this one.

Justice Thomas' opinion was one of the strongest ones against pre-emption. His opinion reached the same conclusion as the majority but in different ways. Justices Roberts, Alito and Scalia dissented.

Constitutional and Federal Law Basis for Pre-emption Claim

The defense of pre-emption is based partially on Article VI, Clause 2 of the U.S. Constitution that in part says, "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."

The pre-emption argument is also based on federal laws Congress had passed to establish the U.S. Food and Drug Administration (FDA) and allow it to regulate certain drugs. See generally 21 U.S.C.S. Because the FDA regulates drug testing and labeling, Wyeth, the manufacturer of the Phenergan, claimed that Diane Levine could not sue them in state court under state causes of action. Wyeth argued federal laws pre-empted state laws.

For many years and through many cases, state lawsuits worked hand in hand with federal suits to make drugs safer for consumers. Then under the Bush administration, drug companies and Bush-appointed FDA officials started trying to claim drug companies were not liable for state failure-to-give-adequate-warnings- on-drug-label cases. Wyeth v. Levine was the first of these cases decided by the U. S. Supreme Court.

Types of Pre-emption

The majority of the Court in Wyeth v. Levine implied but did not go as far as saying that it usually will find pre-emption only when it finds that the specific intent of Congress was to pre-empt state law. Some other courts in other

cases have recognized two other kinds of pre-emption: (1) pre-emption where it is implied by federal law and (2) pre-emption where federal law so broadly covers an area of law that state law cannot coexist with it without a conflict. These two types of pre-emption are sometimes called implied pre-emption and conflict pre-emption, respectively. Pre-emption where it is expressly provided for in federal law is sometimes called express pre-emption.

Majority Analyzes and Rejects Wyeth's Ten Major Arguments

The majority states that Wyeth makes two pre-emption claims, but then, the majority opinion discusses the two major ones plus eight more, some of which were partially covered by the first two arguments. The majority rejected all of these arguments made by Wyeth.

First, Wyeth's attorneys argued that Wyeth could not have complied with both state law by giving better warnings, and federal law that gave the Food and Drug Administration (FDA) the authority to regulate labels. The majority of the Court held that while the FDA had the duty to regulate labels, that under the "changes being effected" (CBE), FDA regulation, Wyeth could have added additional warnings while it was applying to the FDA for approval of stronger warnings. See 21 C. F. R. § 314.105(b) (2008). There was no evidence whether the FDA would have approved such changes if they had been requested. See *Fidelity Fed. Sav. & Loan Assn. v. De La Cuesta, 458 U.S. 141, 153 (1982).*

Second, Wyeth argued that if a state required it to provide a stronger warning, such action would conflict with Congress' purpose of giving the FDA the duty to regulate drug labels. The majority of the Court found that Congress had not intended to pre-empt state law in failure-to-warn cases. See *Hines v. Davidowitz, 312 U.S. 52, 67 (1941).*

Third, Wyeth argued that the conduct of the clinician who injected the IV push of Phenergan was an intervening cause of the injuries but the trial Court found that the clinician's actions did not absolve Wyeth. Justice Alito's dissent seems to express the opinion that the clinician's actions were the sole cause of the injuries.

The majority ruled that since the trial court did not specify what warnings had to be given on the Phenergan label, but merely that the warnings were inadequate, that the Court did not have to decide if state required wording would be pre-empted. The Court held the narrower question it had to decide was "whether federal law pre-empts Levine's claim that Phenergan's label did not contain an adequate warning about using the IV-push method of administration." In answering that question, the Court looked first at two "cornerstones" the intent of Congress and the presumption against pre-emption. See *Medtronic, Inc. v. Lohr. 518 U.S. 470, 485 (1996)* and *Retail Clerks v. Schermerhorn, 375 U. S. 96, 103 (1963).*

In its fourth major argument, Wyeth tried to rely on the preamble of a 2006 FDA regulation that provided for pre-emption, but the Court found the preamble was not part of the law. See §§ 314.70(c)(6)(iii)(a)(c). Law requires that before regulations are enacted, that they be published and that the agency seeking to promulgate the regulation received comments on the proposed regulation. The preamble to this regulation in question had never been advertised and comments had never been taken.

In looking at the intent of Congress, the Court reviewed the history of the federal government's regulation of drugs and their labels. The Court especially noted the 1962 amendments to the FDCA that added a "saving clause, indicating that a provision of state law would only be invalidated upon a "direct and positive" conflict with *21 U.S. C. S. §202.*" The court pointed out that after the Levine injury and suit, Congress had amended the FDCA, *121 Stat 823,* "to make it clear that manufacturers remain responsible for updating their labels." See *121 Stat. 925-926.*"

In their fifth major argument, Wyeth's attorneys claimed that Wyeth could not change its warnings without FDA approval but the Court found that was not true. A FDA regulation provides that a manufacturer may make a change to "add or strengthen a contraindication, warning, precaution or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," if such changes are made at the same time an application for the changes is made to the FDA. See *21 U. S. C. A. §§ 314.*70(c)(6)(iii)(a)(c). Wyeth never made such a change in the warnings and it did not request a change in the warnings.

Wyeth's sixth major argument was that such change was only allowed when there was newly acquired information. See *73 Fed. Reg. 49609.* The Court did not buy this argument. Wyeth argued that if it had added a new warning, it would have broken federal laws but the Court also did not agree with this argument.

Seventh, Wyeth's attorneys tried to argue that the FDA had the primary responsibility for drug labeling but the Court disagreed. It said "Yet, through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged with both crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. See, e.g. 21 C. F. R. §201.80(e) . . . ."

The Court went on to point out that prior to changes in the law in 2007 at *121 Stat. 924-926*, the FDA did not have the authority to require label changes. The Court clearly stated that Wyeth had the ultimate responsibility for the label even though the FDA could reject a label. Wyeth did not offer sufficient proof that it had tried to make the label warnings stronger and that the FDA had rejected such proposed changes.

Eighth, Wyeth tried to argue impossibility pre-emption, the kind of preemption where federal law so broadly covers an area that complying with state law too is impossible. The Court found that Wyeth had not proved that it could not comply with both state and federal law.

Ninth, Wyeth argued that the FDCA establishes both a floor and ceiling for drug regulation. The Court did not agree with that argument.

In looking at the intent of Congress, the Court noted that Congress had not provided a federal law to compensate victims injured by unsafe drugs and that state laws did. The Court felt that Congress must have recognized that state laws provided such remedies.

The first version of the bill introduced in Congress provided remedies for injured victims, but testimony was presented in a subcommittee that such remedies were not needed because state laws provided such remedies. The pending federal legislation was then amended to exclude relief for victims of dangerous drugs.

The Court noted that *21 U.S.C. §§ 379r*(e), and 379s(d) say "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability section of any State."

Tenth, Wyeth argued that there is a conflict between federal and state law similar to the one in *Grier v. American Honda Motor Co., 529 U.S. 861 (2000).* Grier was a case in which the Department of Transportation (DOT) had adopted a rule giving car manufactures a number of choices of passenger restraint devices they could install in cars. Plaintiffs claimed that air bags should have been installed in all cars. The Court found that under the regulations, the manufacturers had options re which safety devices to install and that the Wyeth v. Levine case was different from Grier because in Grier the DOT had weighed the options and struck a balance re what to require in cars.

Justice Breyer's Concurring Opinion

Justice Breyer wrote, "I write separately to emphasize the Court's statement that 'we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law.' " See *129 S. Ct. 1205.* Breyer felt that some federal agency regulations could have the force of law and pre-empt state laws but such was not the case in Wyeth v. Levine since the preamble to the CBE regulation had not been advertised and comments had not been taken on the proposed preamble.

Justice Thomas' Separate Opinion Concurring In Judgment

In an opinion that surprised some, Justice Thomas wrote an opinion that agreed with the majority's final judgment but had some different ways of reaching that final conclusion. Justice Thomas agreed that state law was not pre-empted

by federal law in Wyeth but wrote, "I cannot join the majority's implicit endorsement of far-reaching implied doctrines." See *129 S. Ct. 1204-1217.*

Thomas felt that the powers of the federal government are limited by the Constitution to those "made in Pursuance of this Constitution" as stated in the supremacy clause and that the constitution gives the federal government "not all governmental powers, but only discrete, enumerated ones." See *Printz v United States, 521 U.S. 898 (1997)* at 919; *United States v. Morrison, 529 U.S. 598, 618, n. 8 (2000);* New York v. United States, supra, at 155-157; *McCulloch v. Maryland, 4 Wheat 316, 405 (1819).*

Thomas felt that Art. I, §7 of the Constitution set forth the requirements for making federal law. In Thomas' opinion, a federal agency did not have the authority to make regulations that pre-empt valid state laws if the agency's regulations were not made by Congress.

Thomas looked at two types of conflict pre-emption that Wyeth argued applied to the case. First Thomas looked at "pre-emption where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce." See *Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-143 (1963).* Second Thomas reviewed pre-emption "when under the circumstances of [a] particular case, [state] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." See *Hines v. Davidowitz, 312 U. S. 52, 67 (1941).* Thomas determined that neither type of conflict pre-emption would keep Diane Levine from winning her case.

Thomas found that Wyeth could have printed stronger warnings on its label without violating FDA regulations by printing the stronger warnings while Wyeth applied for approval of the stronger warnings. Justice Thomas found there was no conflict between state and federal laws.

Wyeth argued that allowing Levine's state law case would conflict with the "purposes and objectives of Congress." See *Hines v. Davidowitz, 312 U.S. 52, 67 (1941).* Wyeth contended that doing so would allow the jury's opinions to be substituted for the FDA's opinions. Thomas did not find such to be the case and he disagreed with the whole "purposes and objectives" of Congress standard that the Court had adopted in *Hines, supra, at 59-60.* He felt that the Court had gone too far from what was actually written in federal statutes when the Court looked at the "purposes and objectives." Thomas felt that the Court should look at the actual words of the relevant statute and the usual meanings of those words.

Dissent By Alito Joined by Roberts and Scalia

Alito, Roberts and Scalia felt the FDA should determine what goes on the Phenergan label and that a jury in Vermont should not have anything to do with such determination. In other words, federal law should pre-empt the Wyeth v. Levine state law cause of action. See *129 S. Ct. 1217-1231.* Alito with Roberts and Scalia espoused that the majority was wrong in saying that Grier did not apply.

The dissenters felt that the warnings on the Phenergan label were sufficient and that the practitioner was at fault for not following the warnings that were actually on the label. The label did contain warnings about the dangers of IV pushes of Phenergan but the majority of the Court found that they were not adequate.

IV pushes of Phenergan had caused at least twenty amputations prior to the Levine case. That fact seemed to have a bearing on the majority's opinion about the lack of sufficient warnings.

The dissenters believed the FDA had weighed the pros and cons of the wording of the label. They felt the FDA's opinions should not be substituted by the verdict of a jury not considering the benefits to the patients who had received relief after receiving IV pushes of Phenergan.

Practice Tips

1. Best practice dictates that counsel should analyze his or her pending cases to which Wyeth v. Levine might apply to see how Wyeth might affect those pending cases. Look at all negligence and product liability type cases, not just failure-to-warn drug liability cases.

2. If counsel represents a drug manufacturer, best practice dictates that counsel make the manufacturer aware of Wyeth v. Levine and that new warnings may be added even though they are not based on new information. Ask your drug manufacturer clients if their warnings are adequate.

3. Counsel should evaluate how other cases are different or analogous to Wyeth v. Levine. The Court narrowed the issues in Wyeth v Levine so there will still be many ways counsel may try to distinguish future cases from it and try to argue that pre-emption does or does not apply.

4. Best practice dictates that counsel in other kinds of products liability cases when pre-emption is not specifically provided for by federal law, look at minutes of Congressional hearings and debates to see the intent of Congress. Look at other versions of the law that were revised before it was enacted.

5. In addition, check to see if pre-emption appears to be implied by federal law and check to see if the area of law is so widely covered by federal law, that state law cannot co-exist without a conflict. Wyeth v. Levine with its majority opinion, two written concurring opinions and dissenting opinions, has so many conflicting ideas, that counsel in other product cases no matter which side counsel represents, may be able to find some things to quote and argue in counsel's other cases.

**RELATED LINKS:** See the Wyeth v. Levine decision at
- 129 S. Ct. 1187 (2009)

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Margie Searcy Alford is the principal author and editor-in-chief of the five-volume set A Guide to Toxic Torts (LexisNexis), a contributing author to the four volume set Drug Product Liability (LexisNexis), a contributing author to the two volume set Alabama Civil Practice Forms (LexisNexis), and a contributor to many other publications and commentaries.

She served two years as National Chairperson of the American Association for Justice Section on Toxic, Environmental, and Pharmaceutical Tort Law and two years as National Chairperson of the Women Trial Lawyer's Caucus of the American Association for Justice. Also, she was National Chair of the Dioxin Litigation Group for three years.

Margie Searcy Alford practices in the area of serious personal injury with a special focus on toxic torts. Attorney Alford has handled toxic tort cases in sixteen states.

She graduated from The University of Alabama School of Law in 1974. She is a Fellow with the National College of Advocacy and a Trial Warrior for Justice.

Attorney Alford was chosen the most outstanding young career women in Alabama by the Alabama Federation of Business and Professional Women and is in more than a hundred Who's Who type publications. She has served on many boards, committees, and commissions.

5 of 21 DOCUMENTS



***Alford on Kellogg v. Wyeth***

*2009 Emerging Issues 4038*

Margie Searcy Alford on Kellogg v. Wyeth, 612 F. Supp. 2d 421 (D. Vt. 2009)

By Margie Alford

January 18, 2009

**SUMMARY:** The U.S. District Court for the District of Vermont held that federal law does not preempt state law in a drug product liability case involving generic forms of metoclopramide. Toxic tort litigator and author Margie Searcy Alford reviews and comments on the court's decision.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE: Overview**

Plaintiff Kellogg took the drug metoclopramide for four years and allegedly developed numerous medical problems as a result. Kellogg sued Defendant Wyeth, the maker of the brand name drug, and several makers of generic forms of the same drug. Kellogg alleged among other things that the drug was only safe for short-term use but that the makers encouraged long-term use and knew that many doctors were prescribing the drug for long-term use.

Kellogg alleged in some of her counts that the makers of the drug failed to warn adequately of the dangers associated with long-term use. The makers of the generic drug argued that Federal Drug Administration (FDA) regulations and approval of the label preempted them from giving warnings other than those warnings approved by the FDA and given by the maker of the brand named drug. The court found that federal law did not preempt the manufacturers of the generic drug from giving warnings of the dangers of long-term use of the drug.

**Summary of Requirements to Put a Generic Drug on the Market**

Under federal law, the FDA is in charge of approving all new regulated drugs and their labels. See *21 U.S.C. §393*(b)(2)(B). All makers of new drugs must file a long application with data about the drug's safety, the proposed label with warnings, and other information. See *21 U.S.C. §355*(b)(1). The manufacturer of a generic form of a drug with an already approved brand named drug may file a shortened form for approval with the FDA. The Drug Price Competition and Patent Term Restoration Act of 1984 authorized abbreviated approval applications for generic drugs ("Hatch-Waxman Amendments"). See *21 U.S.C §355*(j).

FDA regulations issued in 1992 say that the labels for the generic drugs "must be essentially the same as labeling

approved for the non generic equivalent." See 21 C.F.R. §314.94(a)(8)(iv). The defendant makers of the generic form of metoclopramide claimed that federal law prohibited them from using any label except the one approved by the FDA when it approved the labeling for the brand name drug and then later approved the shortened approval process for the generic forms of the same drug. Based on these arguments defendants filed 12(b)(6) motions and 12(c)(3) motions for the court to dispose of the claims against them prior to trial.

**Initial Presumption**

The court started its analysis of the case by finding that there is a "presumption against preemption" when Congress has not specifically passed law that shows an intent to preempt state law and when federal law does not imply that the clear intent of Congress was to preempt state law. The court did point out in a footnote that several other district courts in failure-to-warn suits had not found a "presumption against preemption." See Mensing v.*Wyeth, Inc., 562 F. Supp. 2d 1056, 1061 (D. Minn. 2008)* and *Mason v. SmithKline Beecham Corp., 546 F. Supp. 618, 621-22 (D. Ill. 2008).* Since courts have ruled differently on this issue, the United States Supreme Court most likely will eventually rule on it and we will see this issue reappear numerous times in numerous courts.

**The Standard for Judging 12(b)(6) and 12(c)(3) Motions**

The *Kellogg* Court found that in deciding both 12(b)(6) motions and 12(c)(3) motions, it had to treat all the allegations in the complaint as if they were true and had to make " all reasonable inferences in favor of the nonmoving party." See *Desiano v. Warner-Lambert & Co., 467 F.3d 85.* 89 (2d Cir. 2006) and *Burnette v. Carothers, 192 F.3d 52, 56 (2d Cir.1999).*

**Allegations**

The court noted that there were eight counts in the Kellogg's complaint and that the claims against the generic drug makers were not limited to claims that the generic manufacturers did not give adequate warnings. However, this case focused on the motions to dispose the failure to warn claims involving the makers of the generic drugs.

The defendants based their preemption claims in part on U.S. Const. Art. VI, Cl. 2 that in part says the "constitution, and the Laws of the United States which shall be made in Pursuance thereof . . .shall be the supreme Law of the Land . . .anything in the constitution or Laws of any State to the contrary notwithstanding." See *Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 712-713 (1985).*

**Requirements to Find Preemption Might Apply**

The Court cited *Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 541 (2001)* in which the United States Supreme Court held that there were three situations in which state law is preempted by federal law. They are: when federal law expressly says it preempts state law, when federal law implies that it preempts state law, and when federal law so broadly covers an area that state law cannot be followed without a conflict. The court in the *Kellogg* case found that only one of these three was potentially relevant: conflict preemption.

The court recognized two kinds of conflict preemption: "impossibility conflict preemption" and "obstacle conflict preemption." The makers of the generic forms of metoclopramide claimed that both forms of conflict preemption were relevant and that they should prevail on their motions because of both types of conflict preemption.

**Impossibility Conflict Preemption**

The court first examined impossibility conflict preemption, which is where complying with both federal and state law is impossible." See *Barnett Bank of Marion County, N.A. v. Nelson, 517 U.S. 25, 31 (1996).* The court gave two fictitious examples of impossibility conflict preemption. In one example federal law stated that "you must sell insurance, while the state law said you may not." In the second example "federal orders forbade picking and marketing

avocados with more than seven percent oil, and California barred any avocado with less than eight percent oil content." See *Fla. Lime and Avocados Growers, 373 U. S. 25, 31 (1996).*

The makers of the generic drug argued that the FDA required them to always have the same label as the maker of the brand name drug and therefore they could not change the label to one with better warnings. The court held that there were two reasons why this was not a prevailing argument. First, the court said that a verdict for a plaintiff would not require the defendant to change the label but rather it might merely require that damages be paid. See *In re Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 276-77 (E.D.N.Y. 2007).* Second, the court said that if the FDA decided that a generic manufacturer had not properly labeled a drug, that the FDA would start an action against the manufacturer in federal district court.

The court stated "there is no evidence that FDA has ever brought, or threatened to bring, an enforcement action against (or otherwise sanctioned) a drug manufacturer who sought to strengthen or add a warning to its label." The court also said, "a hypothetical or potential conflict is insufficient to warrant preemption." See *Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982)* and *Witczar v. Pfizer, Inc., 377 F. Supp. 2d 726, 731 (D. Minn. 2005).* The court therefore found that the manufacturers of generic drugs were not put in a position where they could not comply with both state and federal laws -- that doing so was not "physically impossible."

**Obstacle Conflict Resolution**

The court then looked at obstacle conflict preemption, the second type of preemption the generic drug manufacturers argued should apply. Obstacle conflict preemption occurs when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress . . .whether the obstacle is described as conflicting; contrary to; . . .repugnance; difference; irreconcilability; inconsistency; violation; curtailment or interference." *Geier v. Am Honda Motor Co., 529 U.S. 861, 873 (2000).*

The court held that when Congress amended the Federal Drug and Cosmetic Act in1962 it included anti-preemption language that would allow both state and federal law to control in drug situations "unless there is a direct and positive conflict between" the federal and state laws. See Drug Amendments of 1962, Pub. L. No. 87-781, Sec. 202, *76 Stat. 780, 793 (1962).* The Court found no such conflict in the *Kellogg* case and further found that the FDA labeling standards are the minimum standards to which a manufacturer is held.

The generic drug manufacturer tried to argue that deference should be given to the FDA as the sole regulating agency for drug labels and warnings, and for interpreting the rules it is supposed to regulate. The court held that Congress had not given the FDA the sole authority to determine what warnings should be on labels.

The court distinguished the *Kellogg* case from another pending (at the time) drug preemption case, *Wyeth v. Levine* saying "The pre-discovery posture of this case distinguishes it from the situation in Wyeth."

**Conclusion**

The United States District Court for Vermont held that Federal law did not preempt plaintiff's failure to warn counts so the case could go forward to trial or settlement.

**Practice Tips**

If your case involves an important issue such as preemption, frequently other organizations, individuals, or firms may want to try to help you with amicus briefs. For example, in the Kellogg case, Public Justice, a national public interest law firm, filed a helpful brief in the case. Best practice dictates that counsel take advantage of briefs from others when they will help his or her case. When looking for amicus briefs for plaintiffs, start by contacting Public Justice, the American Association for Justice, and your state trial lawyers' association. For defendants you may want to start with the U.S. Chamber of Commerce.

If your potential case might make bad law "bad precedence" for cases to follow, consider not taking such a case or consider settling such a case before it can be made into bad law.

If there is a similar case pending in front of a higher court, counsel should do as Judge Session did in *Kellogg* and point how the two cases are different. Judges do not want to be reversed. Help them see how your case is different from the case in front of a higher court.

Remember every case is at least a little different from every other case, and the distinguishing facts may result in diverse opinions. For example, in *Downing v. Hyland Pharmacy*, a fen-phen case where the pharmacy did not warn the patient when the drug was recalled by the FDA, the Utah Supreme Court found that the pharmacy should have warned the patient even though a prior fen-phen case had held that since the drug was prescribed by a physician, the pharmacy did not have to warn the patient of the dangers of the drug. Even though there were similarities in the facts, a few changes made a big difference. See *Downing v. Hyland Pharmacy, 2008 UT 65.*

If you are a defense attorney, look for U.S. Constitutional issues and statutes that will help you remove state court cases to federal court if you think your case will do better with a federal judge, federal law, and/or federal juries.

Do not omit a defense just because one court has ruled a certain way on a specific case. One such ruling does not mean the issue will not come up again in other courts or even in the same court. Other courts in different jurisdictions with their judges and different facts may rule differently. In addition, just because one court rules one way on an issue does not mean that court will never change its opinion. For example, the Alabama Supreme Court in *Griffin v. Unocal Corp., 2008 Ala. LEXIS 19,* decided that it had been interpreting the law wrong for almost twenty-nine years and changed its opinion on when the two-year statute of limitations began to run in toxic tort cases.

In making an argument, give the negative things about your case and tell why they should not affect the court ruling for you. Hearing negative facts about your case from you first is less damaging than hearing them first from opposing counsel. You take some of the wind out of the sails of opposing counsel if the court first hears the negative things from you.

Carefully pick your local counsel. Judges are supposed to be impartial but they are not always so. Carefully consider retaining local counsel who is well liked and/or respected by the trial court and/or appellate court. Talk to other attorneys and with courthouse employees about which local attorneys have done well with your local trial judge. You do not want "home cooking" "preferential treatment for an opposing counsel who is well liked by the judge" but it is nice to have it if the judge's favored counsel is on your side.

**RELATED LINKS:** See the Kellogg v. Wyeth
- 612 F. Supp. 2d 421 (D. Vt. 2009)

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Margie Searcy Alford is the principal author and editor-in-chief of the five-volume set *A Guide to Toxic Torts* (LexisNexis), a contributing author to the four volume set *Drug Product Liability* (LexisNexis), a contributing author to the two volume set *Alabama Civil Practice Forms* (LexisNexis), and a contributor to many other publications and commentaries.

She served two years as National Chairperson of the American Association for Justice Section on Toxic, Environmental, and Pharmaceutical Tort Law and two years as National Chairperson of the Women Trial Lawyer's Caucus of the American Association for Justice. Also, she was National Chair of the Dioxin Litigation Group for three years.

Margie Searcy Alford practices in the area of serious personal injury with a special focus on toxic torts. Attorney Alford has handled toxic tort cases in sixteen states.

She graduated from The University of Alabama School of Law in 1974. She is a Fellow with the National College of Advocacy and a Trial Warrior for Justice.

Attorney Alford was chosen the most outstanding young career women in Alabama by the Alabama Federation of Business and Professional Women and is in more than a hundred Who's Who type publications. She has served on many boards, committees, and commissions.

*Information referenced herein is provided for educational purposes only. For legal advice applicable to the facts of your particular situation, you should obtain the services of a qualified attorney licensed to practice law in your state.*

6 of 21 DOCUMENTS



***Ohio Supreme Court Upholds Tort Reform***

*2009 Emerging Issues 3275*

Chapman on Ohio Supreme Court Rulings Upholding Tort Reform

By Michael Chapman

January 14, 2009

**SUMMARY:** In two recent landmark cases, Arbino v. Johnson & Johnson and Groch v. General Motors Corp., the Ohio supreme court upheld the state legislatures latest enactment of comprehensive tort-reform, known as Senate Bill 80. Michael Champman of Rendigs, Fry, Kiely & Dennis explores the history of the court's rulings on tort reform and explains why, after repeatedly striking down tort reform, the court found S.B. 80 to pass constitutional muster.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE: Ohio Supreme Court Upholds Tort Reform**

**I. Introduction**

In two recent landmark cases, *Arbino v. Johnson & Johnson* n1 and *Groch v. General Motors Corporation*, n2 the Ohio supreme court upheld the Ohio legislature's latest enactment of comprehensive tort-reform, known as Senate Bill 80 ("S.B. 80"). n3 Then-Governor Taft signed S.B. 80 on January 6, 2005, and it became effective on April 7, 2005. Significant reforms therein included: (1) the law placed limits on noncompensory and punitive damage awards; (2) the law changed civil practice and procedure relative to specific causes of action, such as by restricting conditions under which certain products would be considered defective; (3) the law implemented limitations periods on the time in which specific legal actions for personal injury based on product liability claims could be filed; and (4) the law created a ten-year statute of repose for: (a) product liability claims and (b) claims for services related to improvements to real property.

According to the legislature, S.B. 80 was necessary to improve the fairness and efficiency of Ohio's civil justice system. The goal was to improve Ohio's economy by assisting businesses that provide jobs and innovation. n4 To accomplish these goals, the legislature struck an essential balance between the rights of those who have been legitimately harmed and the rights of those who have been unfairly sued. n5 Now, only time will tell whether S.B. 80 will reduce the number of frivolous lawsuits and whether such reduction will, in turn, lead to a more predictable system of civil justice, decreased insurance and healthcare costs, and a generally favorable environment for Ohio business interests. n6

**II. History of Tort Reform in Ohio**

Tort reform has been a contentious and highly political subject in Ohio for many years. n7 Prior to S.B. 80, legislative efforts to adopt "so-called tort-reform acts" since 1975 have repeatedly been declared unconstitutional. n8 Ohio's first effort at tort-reform was enacted in 1975, but was held to be a violation of the due-process clause of the Ohio constitution as "irrational and arbitrary" because it implemented a $200,000 absolute cap on medical malpractice damages. n9 Later, a 1987 law requiring the trial court to reduce certain collateral benefits from a plaintiff's final award of compensatory damages was held unconstitutional in violation of the right to a trial by jury, due process, equal protection, and the right to a remedy under the Ohio constitution. n10

In 1994, the Ohio supreme court struck down multiple tort-reform statutes. Former section 2323.57 required awards of future damages in medical malpractice actions that exceeded $200,000 to be paid over time via a mandatory installment plan. n11 This remedy was likewise ruled to violate the right to a trial by jury and the due process clauses of the Ohio constitution. n12 The court also invalidated section 2315.21(C)(2)) requiring a trial judge to determine the amount of punitive damages to be awarded in a tort action -- even when the trier of fact was a jury. n13 This law was also deemed to violate the right to a trial by jury. n14

In yet another case, *Brennaman v. R.M.I. Company, n15* the court even went so far as to overrule one of its prior decisions, *Sedar v. Knowlton Construction Company, n16* in order to hold that a statute of repose for construction defects n17 was an unconstitutional violation of the right-to-a-remedy clause of the Ohio constitution. The statute of repose in these cases provided, in part: "No action to recover damages for any injury to property...or for bodily injury...arising out of the defective and unsafe condition of an improvement to real property...shall be brought against any person...more than ten years after the performance or furnishing of such services and construction...." n18 The *Sedar* court noted that no one has a vested right in rules of common law n19 and then based its decision, in part, on the distinction between a statute of limitations and a statute of repose: "Unlike a true statute of limitations, which limits the time in which a plaintiff may bring suit after the cause of action accrues, a statute of repose, such as R.C. 2305.131, potentially bars a plaintiff's suit before the cause of action arises." n20 The statute, according to *Sedar*, did not take away an existing cause of action, but prevented what might otherwise be a cause of action from ever arising. Thus, under the circumstances, an injured party literally has no cause of action. n21 The *Brennaman* court simply found that the statute deprived a plaintiff of a remedy before he or she could have known of their injury and overruled *Sedar*.

Most recently, in *State v. Sheward, n22* the court struck the legislature's attempt at tort reform as unconstitutional altogether. This 1997 tort-reform legislation amended, enacted, or repealed over 100 sections of the Revised Code contained in 18 titles and 38 chapters. n23 It modified the collateral-source rule in tort actions, capped noneconomic damages, and capped punitive damages. The law was held unconstitutional *in toto* as a violation of the separation-of-powers and single-subject clauses of the Ohio constitution. n24 In light of all these findings of unconstitutionality, it was quite a departure when the Ohio supreme court found that S.B. 80 passed constitutional muster.

**III. Arbino and Groch**

The Ohio supreme court was presented with an early opportunity to review the constitutionality of certain provisions of S.B. 80 on certified questions of law from cases pending in federal district courts.

On December 27, 2007, the court decided *Arbino*, the first challenge to S.B. 80. There, plaintiff Melisa Arbino filed a products-liability action against Johnson & Johnson alleging that she suffered blood clots and side effects from her use of an Ortho-Evra birth control patch. n25 She challenged S.B. 80's limits on noneconomic damages and punitive damages. The court held that such limits, in certain tort actions, do not violate the Ohio constitution's right to a jury trial; open-courts and right-to-a-remedy; due process; or equal protection clauses. n26

Next, on February 21, 2008, the court decided the second challenge to S.B. 80. In *Groch*, plaintiff Douglas Groch was injured while operating a trim press at a General Motors facility. n27 The trim press was delivered to the end-user, General Motors, more than ten years prior to Groch's injury. Groch sought damages from the manufacturers based on

alleged product defects. The manufacturers claimed immunity under S.B. 80, which had implemented a ten-year statue of repose for defective products. The court held the statute of repose for product liability actions was facially constitutional but improperly retroactive, as applied, as Groch's claim accrued within the established two-year limitations period prior to the enactment of S.B. 80. n28 The court also held statutes n29 enacted in prior legislation governing subrogation interests in a workers' compensation claimant's recovery from a third party were constitutional. n30

**A. The Challenge in *Arbino***

Two provisions of S.B. 80 were at issue in *Arbino*. The first provision concerned a method to limit noneconomic (pain and suffering) damages. Under section 2315.18, the jury first enters findings of fact that specify total compensatory damages and the portions of those damages representing economic and noneconomic losses. The court then caps noneconomic damages at the greater of: (1) $250,000 or (2) three times the economic damages up to a maximum of $350,000, or (3) $500,000 per single occurrence. These limits do not apply to noneconomic damages resulting from permanent disability.

The next provision concerns limits on the recovery of punitive damages to a maximum of two times the total amount of compensatory damages awarded per plaintiff, per defendant. n31 If the limits apply and the defendant is a defined small employer or an individual, the punitive damages are capped at the lesser of two times the amount of the compensatory damages awarded to the plaintiff from the defendant or ten percent of the employer's or individual's net worth when the tort was committed, up to a maximum of $350,000. n32 The limits are waived if the defendant committed a felony while causing the injury.

In its analysis, the *Arbino* court first needed to distinguish its prior decisions holding tort-reform unconstitutional and address *stare decisis*, the doctrine requiring that judges apply the same reasoning to lawsuits that have been previously decided on similar facts. Starting with a "strong presumption" that all statutes are constitutional, the court stated it would not apply *stare decisis* to strike down legislation merely because it is similar to prior unconstitutional enactments. The court indicated it would only follow the holdings of prior decisions when "the legislation [is] phrased in language that is substantially the same as that which we have previously invalidated." n33 Here, the court used a "highly deferential standard of review" to a facial challenge of S.B. 80 and concluded that the legislature appropriately responded to the court's previous decisions. n34 S.B. 80 was "more than a rehashing of unconstitutional statutes" and "sufficiently different from the previous enactments to avoid the blanket application of stare decisis." n35 The court then proceeded to discuss the merits.

**i. Trial by Jury.**

The right to a trial by jury n36 "protects a plaintiff's right to have a jury determine all issues of fact in the case. Because the extent of damages suffered by a plaintiff is a factual issue, it is within the jury's province to determine the amount of damages to be awarded." n37 The court, nevertheless, found sections 2315.18 and 2315.21 acceptable because the jury still *determines* the amount of damages -- even if those damages may not be recoverable by law. Thus, when a court simply applies limits to the facts as found by the jury it leaves the core jury function intact even if the award is abrogated. The court confirmed that the legislature's authority includes the power to make a policy choice that noneconomic damages exceeding set amounts are not in the best interest of the citizens of Ohio. n38

Judge Pfeifer's largely *ad hominem, name-calling* dissent questioned the point of having a constitutional right to a trial by jury. n39 Judge Pfeifer stated that a statute which automatically reduces a jury's factual determination of damages to an arbitrary level, no matter how high that level might be, must violate such constitutional right. n40

**ii. Open Courts / Right to a Remedy.**

Ohio's "open courts" and "right to a remedy" provisions n41 prohibit statutes that effectively prevent individuals from pursuing relief for their injuries. n42 Under section 2315.18 persons may still recover their full economic

damages and up to $350,000 in noneconomic damages, as well as punitive damages. Under section 2315.21, a person has no right to punitive damages because such damages are not compensation but fines to punish reprehensible conduct. Therefore, the noneconomic and punitive damage limits did not wholly deny a remedy and the remedies available are "meaningful" ones. n43

**iii. Due Course of Law/Due Process.**

The "due course of law" provision n44 is the equivalent of the U.S. Constitution's "due process of law" protections. Both sections of S.B. 80 that were at issue in the case were deemed to satisfy the two prongs of the rational-basis test because the legislature reviewed several forms of evidence and made numerous findings demonstrating that the limitations imposed were neither arbitrary nor unreasonable. n45 S.B. 80, therefore, bears a real and substantial relation to the public health, safety, morals or general welfare of the public and is not unreasonable or arbitrary. The court tiptoed around its prior ruling in *Sheward* by stating that *Sheward* was decided on other grounds and any related discussion was purely *dicta*.

**iv. Equal Protection.**

The Ohio constitution states: "All political power is inherent in the people. Government is instituted for their equal protection and benefit." n46 Because S.B. 80 was found not to infringe on fundamental rights or discriminate against a suspect class, it was then found to be rationally related to a legitimate government purpose, which purpose was to reform Ohio's civil justice system and improve the state's economy. n47

**iv. Separation of Powers.**

"The general assembly shall grant no divorce, nor exercise any judicial power, not herein expressly conferred." n48 The question in *Arbino* was whether S.B. 80 infringed on the judicial function to decide the amount of damages in civil cases. The court carved out an exception by holding that this fact-finding function was not so exclusively reserved to the judiciary as to prohibit the legislature from regulating the amount of damages available in certain circumstances. By corollary, the court reasoned that if numerous acceptable statutes permitted the trebling of damages, then the separation-of-powers rule should not limit the legislature's ability to impose damage caps. The court again avoided *Sheward* on an "admittedly similar" statute by limiting *Sheward*'s discussion to non-binding *dicta*.

**vi. Issues Not Decided: The Single-Subject Rule and the Admissibility of Collateral-Benefit Evidence.**

The single-subject rule n49 provides: "No bill shall contain more than one subject, which shall be clearly expressed in its title." The court declined review of this issue because S.B. 80, *in its entirety*, was not challenged. The court also passed on a statute that modified the collateral-source rule. n50 This rule has been defined as "the judicial refusal to credit to the benefit of the wrongdoer money or services received in reparation of the injury caused which emanates from sources other than the wrongdoer." n51 Plaintiff Arbino lacked standing because her insurance contract contained a subrogation clause. n52

**B. The Challenge in *Groch***

In *Groch*, the court revisited the construction statute of repose it found constitutional in *Sedar*, but then unconstitutional when it flip-flopped in *Brennaman*. The S.B. 80 statute provides, in part: "[N]o cause of action based on a product liability claim shall accrue against the manufacturer or supplier of a product later than ten years from the date that the product was delivered to its first purchaser...." n53 Pursuant to S.B. 80, this statute "is purely remedial in operation and shall be applied in a remedial manner." n54

The *Groch* court called *Sedar* a "thorough and concise opinion" in reference to the portion of the decision where the *Sedar* court explained the key difference between a statute of repose and a statute of limitations. A statute of repose does not take away an existing cause of action, but prevents what might otherwise be a cause of action from ever

arising. n55 The *Groch* court rebuked *Brennaman* as an "abbreviated discussion devoid of any in-depth analysis" where a majority simply recited the text of the Ohio constitution and held the legislature to be constitutionally precluded from depriving a claimant of a right to a remedy before the claimant should have known of the injury. n56 *Groch* found *Brennaman* to be the classic example of the "arbitrary administration of justice" that allowed principles of predictability and stability to be sacrificed for the sake of personal judicial whims. n57

Following *Arbino*, the *Groch* court started with a presumption of constitutionality that is enjoyed by all legislation, and the understanding that it is not the court's duty to assess the wisdom of a particular statute. n58 The *Groch* court revisited and approved of *Sedar*'s logic in that a statute of repose bars an action before it ever arises. n59 *Groch* also found that a plaintiff would have viable alternatives available such as, perhaps, through workers' compensation laws, intentional-tort suits, or premises-liability claims. n60

*Groch* then limited the right-to-a-remedy provision to existing, vested rights as defined by state law and found the statute constitutional. n61 With respect to due process and equal protection, n62 the court relied on legislative findings to adequately demonstrate that the statute was sufficiently related to public health, safety, morals, or general welfare. Then, because a cause of action never accrued, there was no property right and no improper taking. n63 At the end of the day, interestingly, *Brennaman* was not overruled. The court hid *Brennaman* on a shelf by limiting it to its particular holding that an outdated statute, former R.C. 2305.131, was unconstitutional. n64

Three other issues from *Groch* are noteworthy. As applied to plaintiff Groch, 2305.10(F) was unconstitutional because it violated the ban on retroactive laws. n65 Since plaintiff Groch was injured on March 3, 2005 and S.B. 80 became effective just over one month later, Groch was given the full two-year limitations time to file his claim. n66 Next, after a long period of uncertainty, entities following workers' compensation subrogation claims finally have some closure as such statutes, n67 from prior legislation, survived constitutional challenges under the takings clause, due process and remedies clauses, and equal protection clause of the Ohio constitution. n68 Third, the issue of the one-subject clause passed on in *Arbino*, was resolved in *Groch*. The one-subject rule n69 provides: "No bill shall contain more than one subject, which shall be clearly expressed in its title." The purposed of the one-subject provision is to attack legislative "logrolling" by disallowing unnatural combinations of provisions in acts, i.e., those dealing with more than one subject. n70 Here, referring to the single-umbrella-subject of "tort reform," the *Groch* court held "the core of the bill...is sufficiently unified to comply with the one-subject rule." n71

**IV. Recent Decisions Applying S.B. 80.**

**A. McClure v. Alexander**

On March 21, 2008, the second district court of appeals upheld a ten-year statute of repose for improvements to real property in *McClure v. Alexander*. A prior version of R.C. 2305.131 had been declared unconstitutional in *Brennaman*. Homeowner McClure brought his action against a contractor's estate ("Alexander") alleging improper construction of an addition to his home 15 years earlier. Alexander argued plaintiff's claims were barred by the ten-year statute of repose for damages based on defective improvements to real property. McClure challenged R.C. 2305.131 as a violation of his constitutional right to a remedy. n72

The statute provides in relevant part: "[N]o cause of action to recover damages...that arises out of a defective and unsafe condition of an improvement to real property...shall accrue against a person who performed services for the improvement to real property...later than ten years from the date of substantial completion of such improvement. n73 The statute provides exceptions if the defendant engaged in fraud or if there is an express warranty beyond the ten-year statute of repose. n74

The court's analysis closely followed the analysis set forth by *Groch*. The court began by acknowledging that the legislature's role is to make policy and the court's role is to adjudicate with a strong presumption of constitutionality. The court then refused to apply *stare decisis* after finding that the current version of R.C. 2305.131 was not

substantially the same as the prior version struck down in *Brennaman*. Turning to the merits, the court found that R.C. 2305.131 did not necessarily deprive a plaintiff of a right to a remedy. For example, prior to the expiration of a different fifteen-year limitations statute, n75 an action on a contract may be available for an owner against an architect or builder. Therefore, *McClure* upheld the statute based on *Groch's* model.

**B. *Faieta v. World Harvest Church*.**

*Faieta v. World Harvest Church*, n76 in contrast to the facial challenges in *Arbino* and *Groch*, reveals how disputes may arise when courts apply real facts to S.B. 80. In *Faieta*, the jury returned verdicts in favor of plaintiffs Michael Faieta, Lacey Faieta, and their minor son, Andrew Faieta, and against the son's teacher Richard Vaughan and his daycare World Harvest Church ("WHC"). n77 The jury awarded compensatory damages of $134,865 and punitive damages of $100,000 against Vaughan. Against WHC, the jury awarded compensatory damages of $764,235 and punitive damages were limited to $5,000,000 plus plaintiffs' attorney fees. Under section 2315.18, Andrew's noneconomic damages to $250,000 despite the jury's determination that Andrew sustained noneconomic damages of $600,000.

The court then turned to the question of whether the limitation in section 2315.21, which caps punitive damages at two times the amount of compensatory damages, is "intended to limit punitive damages based upon the plaintiff's capped or uncapped compensatory damages." n78 The court acknowledged the parties' dispute was the result "of the poor and imprecise drafting of R.C. 2315.21(D)(2)(a)." n79 Since statutory caps apply in derogation of damages as found by a jury, the court limited punitive damages using the uncapped compensatory damages.

As for punitive damages against Vaughan, the question arose whether R.C. 2315.21(D)(2)(b) required a judgment in the amount of zero since Vaughan was an individual with zero net worth. The court found that "application of this poorly drafted provision is fraught with problems." n80 The statute: (1) fails to define "net worth"; (2) provides no guidance as to how to determine a defendant's net worth as the court cannot place the issue before the jury at trial; and (3) fails to address the effect of the reduction of one tortfeasor's punitive-damages liability on the liability of other tortfeasors when there is joint and several liability. Since the statute applies in derogation of the damages found by the jury, the court, again, interpreted the statute narrowly.

For both of these sections, the court commented: "To the extent that the legislature wishes a different result, the legislature is capable of clarifying [the statute]."

**V. Conclusion.**

*Arbino* and *Groch* are certainly landmark decisions. The Ohio legislature was rewarded for its unwavering pertinacity in enacting S.B. 80 after years of prior rejection. *Arbino* and *Groch* should also encourage future legislative efforts as these cases establish that Ohio courts will review challenges to such legislation using a highly deferential standard. In fact, establishing such a standard meant that *Arbino* and *Groch* had to overcome *stare decisis* and distinguish prior decisions finding similar prior statutes unconstitutional. It will remain to be seen how narrowly future courts might carve such distinctions for S.B. 80 or other statutes on the grounds that they are found to be "more than a rehashing" and "sufficiently different" though it is highly unlikely that *Arbino's* refusal to overrule *Brennaman* would ever allow *Brennaman's* cursory approach to be reinstated even if the political composition of the court should shift radically.

*McClure*, having followed the model for analysis handed down by *Groch*, should certainly be greeted with favor should the issue of the construction statute of repose reach the high court in the unlikely event of a split in the appellate districts. Other issues, however, are not so predictable because tort reform will remain a contentious and political issue. *Faieta* reveals how as-applied challenges to S.B. 80 will take some time to resolve and how questions will arise when real facts are applied to certain statutes.

Other challenges to S.B. 80 will likely include questions regarding: (1) the modified collateral benefits rule as

raised in *Arbino*; (2) the post-judgment procedures through which a defendant may challenge an award as excessive under section 2315.19 on the grounds of a violation of the right to a trial by jury; and (3) the requirement that a trial court must bifurcate an action upon proper motion under section 2315.21(B)(1) on the grounds of a violation of the separation-of-powers clause. The most significant impact of *Arbino* and *Groch*, however, might be their effect on other states' courts and legislatures having yet to adopt tort-reform legislation.

Return to Text

n1 *880 N.E.2d 420 (2007).*

n2 *883 N.E.2d 377 (2008).*

n3 2004 Am.Sub.S.B. No. 80, effective April 7, 2005; .

n4 *Id*. at Section 3, 150 Ohio Laws, Part IV, 8024.

n5 *Id*.

n6 *Id*.; *See also* Fiscal Note & Local Impact Statement

n7 The current Ohio supreme court is unanimously Republican and the 1990s court was primarily Democratic. See http://www.sos.state.oh.us/SOS/elections/electResultsMain/1990-1999OfficialElectionResults.aspx

n8 *Arbino, 880 N.E.2d at 427.*

n9 *Morris v. Savoy, 576 N.E.2d 765 (1991).*

n10 *Sorrell v. Thevenir, 633 N.E.2d 504 (1994),* syllabus of the court.

n11 *Galayda v. Lake Hosp. Sys., Inc., 644 N.E.2d 298 (1994).*

n12 *Id.*, paragraph one of the syllabus.

n13 *Zoppo v. Homestead Ins. Co., 644 N.E.2d 397 (1994).*

n14 *Id.* paragraph two of the syllabus.

n15 *639 N.E.2d 425 (1994),* paragraph two of the syllabus.

n16 *551 N.E.2d 938 (1990).*

n17 Former R.C. 2305.131.

n18 *Id.*; *Brennaman, 639 N.E.2d at 428.*

n19 *Sedar, 551 N.E.2d 947* ("The great office of statutes is to remedy defects in the common law as they are developed, and to adapt it to new circumstances.")

n20 *Id*. at 941.

n21 *Id*. at 946.

n22 *State ex rel. Ohio Academy of Trial Lawyers v. Sheward, 715 N.E.2d 1062 (1999).*

n23 Am.Sub.H.B. No. 350, 146 Ohio Laws, Part II, 3867, was passed by the Ohio Senate on September 11, 1996, and by the Ohio House of Representatives on September 26, 1996. The bill was signed into law by former Governor George Voinovich on October 28, 1996, and took effect on January 27, 1997.

n24 *Sheward, 715 N.E.2d at 1067*, paragraphs one and two of the syllabus.

n25 *Arbino, 880 N.E.2d at 426.*

n26 *Id*. at syllabus.

n27 *Groch, 883 N.E.2d at 384.*

n28 *Id. at 382*, syllabus.

n29 R.C. 4123.93 and R.C. 4123.931.

n30 *Groch, 883 N.E.2d at 382*, paragraph one of the syllabus.

n31 R.C. 2315.21.

n32 R.C. 2315.21(D)(2)(b).

n33 *Arbino, 880 N.E.2d at 429.*

n34 *Id. at 445.*

n35 *Id. at 429.*

n36 Section 5, Article I, Ohio Constitution; *See* .

n37 *Arbino, 880 N.E.2d at 431.*

n38 *Id. at 432.*

n39 "[T]he majority opinion employs shallow reasoning and shoddy logic in concluding that juries can meaningfully determine only facts that do not conflict with predetermined assessments of the General Assembly." *Id. at 454.*

n40 *Id. at 453-454.*

n41 Section 16, Article I, Ohio Constitution.

n42 *Arbino, 880 N.E.2d at 432,* citing *Brennaman v. R.M.I. Co., 639 N.E.2d 425 (1994).*

n43 *Arbino, 880 N.E.2d at 433.*

n44 Section 16, Article I, Ohio Constitution.

n45 *Arbino, 880 N.E.2d at 433-434*

n46 Section 2, Article I, Ohio Constitution.

n47 *Arbino, 880 N.E.2d at 436.*

n48 Section 32, Article II, Ohio Constitution.

n49 Section 15(D), Article II, Ohio Constitution.

n50 R.C. 2315.20.

n51 *Arbino, 880 N.E.2d at 439,* quoting *Pryor v. Webber, 263 N.E.2d 235 (1970).*

n52 *Arbino, 880 N.E.2d at 439.*

n53 R.C. 2305.10(C)(1).

n54 R.C. 2305.10(G).

n55 *Groch, 883 N.E.2d at 402*

n56 *Id. at 400.*

n57 *Id. at 401*.

n58 *Id. at 402.*

n59 *Id*.

n60 *Id.*

n61 *Id.*

n62 Section 16, Article I and Section 2, Article I, Ohio Constitution.

n63 Section 19, Article I, Ohio Constitution.

n64 *Groch, 883 N.E.2d at 403.*

n65 Section 28, Article II, Ohio Constitution.

n66 *Groch, 883 N.E.2d at 407-408.*

n67 R.C. 4123.93 and 4123.931 (enacted in prior legislations)

n68 *Groch, 883 N.E.2d at 413.*

n69 Section 15(D), Article II of the Ohio Constitution.

n70 *Groch, 883 N.E.2d at 410* (Logrolling "occurs when legislators combine a disharmonious group of proposals in a single bill so that they may consolidate votes and pass provisions that may not have been acceptable to a majority on their own merits.)

n71 *Groch, 883 N.E.2d at 412.*

n72 Section 16, Article I, of the Ohio Constitution: "All courts shall be open, and every person, for an injury done him in his land, goods, person, or reputation, shall have a remedy by due course of law, and shall have justice administered without denial or delay."

n73 R.C. 2305.131.

n74 R.C. 2305.131(C) and (D).

n75 R.C. 2305.06.

n76 *891 N.E.2d 370 (Ohio Com.Pl. 2008).*

n77 *Id. at 379.*

n78 *Id.*

n79 *Id.*

n80 *Id. at 400.*

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Michael J. Chapman is an attorney with Rendigs, Fry, Kiely & Dennis, L.L.P. Mr. Chapman focuses his practice on product liability, commercial litigation, premises liability, municipal/government law, and construction law. The Rendigs firm is a premier Midwest full-service law firm located in the Cincinnati-Dayton area that provides comprehensive legal counsel and litigation services to a full spectrum of individual and corporate clients. Such clients include individuals, families, closely held corporations, leading insurance firms, major Cincinnati hospitals, construction and architectural firms, physicians, lawyers, investment advisors, manufacturers, and municipalities, as well as trustees and non-profit organizations.

Mr. Chapman received his J.D. and B.A degrees from Indiana University. He is admitted to practice in Ohio and Indiana, including the Northern and Southern Districts of Ohio, Northern and Southern Districts of Indiana, and the U.S. Court of Appeals for the Sixth and Seventh Circuits. For additional information about Mr. Chapman or Rendigs, Fry, Kiely & Dennis, L.L.P., please see the Rendigs website at www.rendigs.com. Mr. Chapman can be contacted directly at mchapman@rendigs.com or through the firm's website.





***Alford on Downing v. Hyland Pharm.***

*2009 Emerging Issues 4037*

Margie Searcy Alford on Downing v. Hyland Pharm., 2008 UT 65

By Margie Alford

December 29, 2008

**SUMMARY:** Toxic tort litigator Margie Searcy Alford reviews the Utah Supreme Courts decision in Downing v. Hyland Pharmacy, a fen-phen case in which the court held that a pharmacy might be liable for negligence for not telling a customer that a drug had been recalled by the FDA. This is an exception to the general rule that a pharmacist is not liable for failing to give warnings about the general side effects of a drug prescribed by a physician.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE: Background**

Defendant Hyland Pharmacy continued to fill plaintiff Downing's prescription for fen-phen even after the weight loss drug was recalled by the U.S. Food and Drug Administration (FDA). The trial court granted a motion for summary judgment for the defendant based in large part on the prior case of *Schaerrer v. Stewart's Plaza Pharmacy, Inc., 2003 UT 43, 79 P.3d 922.*

*Scharrer*, another fen-phen case, held in part that when the prescription was written by a learned intermediary, the doctor, the pharmacist who was just filling the prescription would not be liable for failing to warn about the side effects of the drugs. *Scharrer* was based on products liability claims.

In the *Downing* case, the defendant tried to claim that the *Scharrer* case kept Hyland pharmacists from being liable in negligence when they filed a prescription written by a learned intermediary, a medical doctor.

**Analysis**

The Utah Supreme Court looked at two main issues-the first involving whether the pharmacy could be liable in negligence when it filled prescriptions after the FDA withdrew the drug from the market and the second involving whether the pharmacy was negligent not to warn the customer that the drug had been withdrawn.

The defendant tried to rely in large part on the *Scharrer* case that held a pharmacy did not have to warn about the general side effects of a drug since the drug was prescribed by a learned intermediary. The court held that the learned intermediary rule generally applied in both products liability cases and negligence cases but the court carved out an exception to the rule and said that it only applied to cases involving failure to warn of general side effects of drugs and

*not* to cases where the drug had been withdrawn from the market by the FDA.

In the footnotes the court cited numerous other cases where facts and public policy required exceptions be made to the intermediary rule. None were exactly on point with the *Downing* case but they showed exceptions should be made when facts and public policy mandate for them.

The *Downing* court held that whether or not the defendant was negligent in not warning the patient that the drug had been recalled, was a jury question and not one for which the trial court should have granted the motion for summary judgment. The case was remanded to the trial court for the resolution of the negligence issue.

The court did not mention this, but drugs may frequently be withdrawn from the market by the FDA after they have been prescribed by a doctor. In such a case, the pharmacy is frequently the last one in the line of professionals to warn the patient.

**Conclusion**

In *Downing v. Hyland*, the Utah Supreme Court overturned the lower court's ruling on the defense motion for summary judgment. The court said the issue of whether or not Hyland Pharmacy should have warned the plaintiff that fen-phen had been recalled was a negligence issue to be heard by a jury and not one that could be resolved by a motion for summary judgment.

**Practice Tips**

Look at the standard to which potential defendants will be held. Professionals are generally held to higher standards than nonprofessionals. Pharmacists are held to higher standards than nonprofessional individuals.

Look at the standards to which professionals should be held for each potential cause of action. For example, a defendant may be held to a different standard for a products liability claim than the standard to which he, she, or it may be held in a negligence claim.

Look at exception and limits to the general rule to see if your case fits into one of these or if you have a legal reason why another exception or limitation should be carved out to fit your case. Do the facts and public policy call for another exception?

Attorneys should carefully analyze all cases cited as the law to make sure they really are applicable in their present case. All cases are at least a little different from other prior but similar cases. Best practice dictates that counsel should look at whether these differences will make any difference in the rulings on the case in which they are cited. Try reasoning through your opposing counsel's potential arguments to be better prepared to defend against them.

Be well prepared to distinguish cases. Before arguments, counsel should carefully analyze all cases that may be cited by the opposition and be prepared to state why or why not they should set precedence in the present case. Consider making a chart, notebook or list of all cases that may be cited and why they apply or do not apply to the instant case.

Drug and toxic tort attorneys don't need to have prior experience with a suit involving a particular drug or toxic substance before they consider taking a new case. They need to know the basics on how to handle a toxic tort or drug case and then do extensive research on the toxic substance. See, e.g. *A Guide To Toxic Torts*, *Drug Product Liability*, and *Courtroom Toxicology*.

Carefully research drug cases on the Internet. Research online what data is available through the Exchange with the American Association for Justice and the Federal Drug Administration. Look on the Internet for other helpful sites but be careful about non-peer reviewed and non-scientific sites.

Know your standards and law regarding admissibility of scientific evidence. Best practice dictates that before a

practitioner takes a case he or she knows whether the jurisdiction in which he or she is considering filing suit, follows *Daubert*, *Frye*, some variation of *Daubert* or *Frye*, or some other standard regarding the admissibility of scientific evidence. Do not waste time filing suit if you do not think you can produce admissible.

Before filing suit for a drug or toxic substance, ask yourself if the case should be a class action or part of multidistrict litigation. If so, ask yourself if your client would be better served to be part of a class or to have his or her suit filed individually.

**RELATED LINKS:** See the Downing v. Hyland Pharm. opinion at
- 2008 UT 65

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Margie Searcy Alford is the principal author and editor-in-chief of the five-volume set *A Guide to Toxic Torts* (LexisNexis), a contributing author to the four volume set *Drug Product Liability* (LexisNexis), a contributing author to the two volume set *Alabama Civil Practice Forms* (LexisNexis), and a contributor to many other publications and commentaries.

She served two years as National Chairperson of the American Association for Justice Section on Toxic, Environmental, and Pharmaceutical Tort Law and two years as National Chairperson of the Women Trial Lawyer's Caucus of the American Association for Justice. Also, she was National Chair of the Dioxin Litigation Group for three years.

Margie Searcy Alford practices in the area of serious personal injury with a special focus on toxic torts. Attorney Alford has handled toxic tort cases in sixteen states.

She graduated from The University of Alabama School of Law in 1974. She is a Fellow with the National College of Advocacy and a Trial Warrior for Justice.

Attorney Alford was chosen the most outstanding young career women in Alabama by the Alabama Federation of Business and Professional Women and is in more than a hundred Who's Who type publications. She has served on many boards, committees, and commissions.

8 of 21 DOCUMENTS



***Alford on In re "Agent Orange" Prod. Liab. Litig.***

*2009 Emerging Issues 4036*

Alford on In re "Agent Orange" Prod. Liab. Litig., 517 F.3d 76 (2d. Circ. 2008)

By Margie Alford

July 11, 2008

**SUMMARY:** The U.S. District Court for the Eastern District of New York granted summary judgment in multiple Agent Orange cases based on the government contractor defense. The U.S. Second Circuit Court of Appeals affirmed that and other judgments by the district court. Toxic tort litigator and author Margie Searcy Alford reviews and comments on the courts decision.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE:** Background

The Second Circuit issued its first version of this decision on February 21, 2008 and an errata on March 25, 2008. The errata was issued for sixteen separate cases that first had been filed in various state courts by veterans or their family members for injuries due to exposure to Agent Orange during the Vietnam War.

The cases were mostly for cancers allegedly caused by Agent Orange. The cancers had not manifested themselves until after the deadline for making claims had passed in the first Agent Orange class action in the 1980s.

The state cases were removed to federal courts in their respective states and then moved to the United States District Court for the Eastern District of New York. The court granted the defendants' motion for summary judgment, explaining that the defendants were protected by the government contractor defense. Also, the court limited certain discovery and ruled that the Stevensons, plaintiffs in one of the cases, could not amend their complaint in spite of the fact that no answer had been filed.

Issues on Appeal

Plaintiffs appealed Judge Weinstein's judgment and the errata decision addressed three main issues on appeal. The first was whether the district court was wrong in ruling that the government contractor defense applied. The second issue was whether the court properly limited discovery to prior Agent Orange case discovery plus six additional depositions. The third issue was whether the court had properly held that plaintiffs Stevensons could not amend their complaint.

The Government Contractor Defense

During the Vietnam War, the federal government was afraid it would not be able to obtain enough Agent Orange in the formulation it wanted. So, under the Defense Production Act of 1950 *(50 U.S.C. app. §2061* et seq.) and the regulations issued for it, the government ordered the chemical company defendants to produce Agent Orange in the quantities, formulation, and packaging it specified. Prior Agent Orange cases had held that since the defendants were ordered to meet the government's specifications, that the defendants should have the same protection the government would have had if it had produced the Agent Orange.

The Second Circuit looked at the Federal Tort Claims Act, *28 U.S.C. § 2671* et seq., which allows some suits against the U.S. government and its employees. The court further explored the issue of what criteria had to be met in order for the government contractor defense to apply and held that the three criteria in *Boyle v. United Technologies Corp. , 487 U.S. 500 (1988)* had to be met in order for the government contractor defense to apply in this case.

In Boyle, the Supreme Court recognized the government contractor defense as being part of common law. The Supreme Court held that state law could only be "displaced" in cases when: "(1) the United States approved reasonably precise specifications [for the allegedly defectively designed equipment]; (2) the equipment conformed to those specifications; and (3) the [contractor who supplied the equipment] warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States." *Boyle v. United Technologies Corp. , 487 U.S. 500, 512 (1988).*

In this case, the plaintiffs' attorneys made strong arguments that all three criteria had not been met but the plaintiffs' attorneys especially took issue with the warning criteria. In spite of their arguments, the district court held and the Second Circuit affirmed, that all three criteria were met, so the sixteen Agent Orange cases were thrown out on the government contractor defense.

Even though the courts have ruled that warnings were given, this issue is strongly contested by many people who feel the Court was wrong. Some warnings were given about the skin problems that could be caused by Agent Orange but many victims and attorneys believe that no sufficient warnings were given about many of the other damages dioxin could cause. The District Court for the Eastern District of New York and the Second Circuit chose to find that manufacturers had given adequate warnings about what they knew about the dangers of dioxin. Many Agent Orange victims and their family members continue to question why these courts ruled this way.

Discovery Was Properly Limited to Discovery From Over a Hundred Prior Agent Orange Cases

Since the first veterans' case for the use of Agent Orange had been filed in the late 1970s up until the present case, over a hundred Agent Orange cases have been settled or adjudicated. In them many interrogatories were asked and answered, many request for production of documents were made, thousands of documents were produced, and many depositions were taken. All of these discovery documents were eventually made available to the plaintiffs in this case. In addition they were allowed access to six more depositions. The Second Circuit affirmed that the trial court had not abused his discretion in limiting discovery to this prior discovery.

The Trial Court Should Have Allowed Amendment of Plaintiffs' Complaint

The Second Circuit held that the trial court was wrong in barring plaintiffs Stevensons from amending their complaint since no answer had been filed. However, the amendment would not have made any difference because the case was thrown out on the government contractor defense.

Practice Tips

Before Filing, Make Sure The Case Looks Winnable

Best practice dictates that before a practitioner takes a case, that he or she carefully research all prior related cases and all relevant statutes to make sure he or she thinks the case is winnable. Do not give clients false hopes and waste

time on cases that are most likely will not be won unless you know you are battling windmills and are willing to face the consequences. Once over a hundred prior cases such as the Agent Orange cases have been lost, you will most like lose a similar case in front of the same judges.

Study Your Potential Judge

Before filing a case, counsel should carefully research the judges who will mostly likely get the case. Research other opinions written by the judges. Review publications written by the potential judges. In the instant case, Judge Weinstein and the Second Circuit have written extensively and have issued numerous prior opinions on Agent Orange.

If The Case Is One Where The Judge Will Set Your Fee, Know How Your Judge Will Set Your Fee

In the first big Agent Orange lawsuit, Judge Weinstein told all the plaintiffs' attorneys to keep contemporaneous time records. Many plaintiffs' attorneys who usually work on contingency fee contracts are not used to keeping time records and many of the attorneys working on the first Agent Orange class action case did not keep great records. When the case was settled and the fee applications made, Weinstein only allowed payment for approximately twenty-two percent of the time turned in by plaintiffs' attorneys. Some attorneys did not receive any fee.

If an attorney wrote he or she had a phone conference with another attorney, the time was not allowed unless the attorney told what the call was about so that the Court could make a determination among other things as to whether or not the call benefitted the class as a whole. If an attorney wrote he or she did research, the time was not allowed unless more details were given so the Court could determine if among other things, the time benefitted the class as a whole.

Most of the attorneys working on the first big Agent Orange case spent a lot of time studying the literature, but Judge Weinstein did not allow for time-spent reading the scientific literature because he said that we were already being paid at the expert rate so we should already be experts on the literature. The author of this article was one of only a few attorneys who were paid for all of their recorded time. If you are working on a case where the judge will set your fee, make sure you know exactly what your judge will want from you in order to pay you for all of your time. Research prior cases to see what your judge has previously written about fees.

Restate The Words of the Law Throughout Your Case to Reinforce Them in the Minds of The Jurors and Judge

Research your law to know the exact elements you have to prove to succeed with your case. Draft your complaint using the exact wording of what you have to prove to win. Go through all of those elements in voir dire, opening statements, the body of your case, and your closing argument. Allow the judge and jurors to read these elements in order to make sure the necessary points are remembered. Request that your judge give these elements as jury charges. In your written requests, give cites to relevant statutes and cases.

**RELATED LINKS:** See the In re "Agent Orange" Prod. Liab. Litig. Decision at
- 517 F.3d 76 (2nd. Circ. 2008)

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Margie Searcy Alford is the principal author and editor-in-chief of the five-volume set *A Guide to Toxic Torts* (LexisNexis), a contributing author to the four volume set *Drug Product Liability* (LexisNexis), a contributing author to the two volume set *Alabama Civil Practice Forms* (LexisNexis), and a contributor to many other publications and commentaries.

She served two years as National Chairperson of the American Association for Justice Section on Toxic, Environmental, and Pharmaceutical Tort Law and two years as National Chairperson of the Women Trial Lawyer's Caucus of the American Association for Justice. Also, she was National Chair of the Dioxin Litigation Group for three years.

Margie Searcy Alford practices in the area of serious personal injury with a special focus on toxic torts. Attorney Alford has handled toxic tort cases in sixteen states.

She graduated from The University of Alabama School of Law in 1974. She is a Fellow with the National College of Advocacy and a Trial Warrior for Justice.

Attorney Alford was chosen the most outstanding young career women in Alabama by the Alabama Federation of Business and Professional Women and is in more than a hundred Who's Who type publications. She has served on many boards, committees, and commissions.

*Information referenced herein is provided for educational purposes only. For legal advice applicable to the facts of your particular situation, you should obtain the services of a qualified attorney licensed to practice law in your state.*



***Clifford on Johnson v. American Standard***

*2009 Emerging Issues 4041*

Robert C. Clifford on Johnson v. American Standard, 43 Cal. 4th 56 (2008)

By Robert Clifford

July 7, 2008

**SUMMARY:** Robert C. Clifford discusses the implication of *Johnson v. American Standard Inc. (2008) 43 Cal. 4th 56, 74 Cal. Rptr. 3d 108),* where the California Supreme Court adopted the sophisticated user doctrine as a defense to negate a manufacturers duty to warn of a products potential danger when the plaintiff has or should have advance knowledge of a products inherent hazards.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE:** Background -- The Manufacturer's Duty to Warn

Manufacturers generally have a duty to warn consumers of a product's inherent hazards. See *Anderson v. Owens Corning Fiberglas Corp. (1991) 53 Cal. 3d 987, 1002, 281 Cal. Rptr. 528.* The purpose of the requirement is to inform consumers about a product's hazards and faults of which they are unaware so they can refrain from using the product or evade the danger by careful use. Manufacturers, in general, are strictly liable for injuries caused by their failure to warn of the dangers that were known to the scientific community at the time they manufactured and distributed the product.

Although warnings of the hazards of using a product may limit the manufacturer's liability, not all warnings promote user safety. In addition, requiring warnings on all products would be burdensome on manufacturers and it would invite mass consumer disregard and ultimate contempt for the warning process. *Finn v. G.D. Searle & Co. (1984) 35 Cal. 3d 691, 702, 200 Cal. Rptr. 870.* Requiring warnings of obvious or generally known risks could reduce the efficacy of warnings generally.

Introduction

A question of first impression in California was raised in Johnson v. American Standard Inc., where the Supreme Court adopted the sophisticated user doctrine defense to negate a manufacturer's duty to warn of a product's potential danger when the plaintiff has or should have advance knowledge of the product's inherent hazards. The doctrine acts as an exception the manufacturer's general duty to warn consumers.

In Johnson v. American Standard Inc. the plaintiff was a trained and certified heating, ventilation, and air conditioning (HVAC) technician. While he was welding refrigerant lines on an air conditioning unit he was exposed to

phosgene gas, causing him to develop pulmonary fibrosis. He contended that the defendant failed to provide him with a warning that informed users that welding refrigerant lines could result in the creation of phosgene gas.

The Sophisticated User Defense

The sophisticated user defense exempts manufacturers from the usual obligation to provide users with warnings about the product's potential hazards. Because a sophisticated user is charged with knowing the particular product's dangers, the failure to warn about those dangers is not the legal cause of any harm that the product may cause. The rationale supporting the defense is that the failure to provide warnings about risks already known to a sophisticated purchaser usually is not a proximate cause of harm. The user's knowledge of the dangers is the equivalent to prior knowledge. Johnson v. American Standard Inc., citing *Billiar v. Minesota Mining and Mfg. Co., 623 F. 240, 243 (2d Cir.1980).*

Although in some jurisdictions the defense only applies to negligence actions, in California the defense applies equally to strict liability and negligent failure to warn cases. The duty is measured by what is generally known or should have been known to the class of soph9sticaated users, rather than by the individual plaintiff's subjective knowledge.

Application of the Doctrine of Sophisticated User

A product manufacturer is not liable to a sophisticated user of its product for the failure to warn of a potential risk, harm, or danger if the sophisticated user knew or should have known of the risk involved in the use of the product. It would put an undue burden on a manufacturer to determine whether a particular user actually had knowledge of the product's potential danger. A person who is trained or a member of a sophisticated group of users is representing that he or she possesses the level of knowledge and skill associated with that class. In the event a person does not actually possess that knowledge and skill should not impose liability on the manufacturer. The manufacturer should not have the difficult burden of proving a negative-i.e. that a particular user did not have actual knowledge of the danger in using the product.

Even if a user is unaware of a product's danger, it is irrelevant if the danger was objectively obvious. The focus is whether the danger involved in the use of the product was so generally known within the trade of profession that a manufacturer would not have expected to provide a warning. There is no obligation to provide a warning of an obvious danger. See *Simmons v. Rhodes Jamieson, Ltd. (1956) 46 Cal 2d 190,194, 293 P. 2d 26.* Pursuant to the sophisticated user defense, the issue is whether the user knew, or should have known, of the particular risk of harm in using the product and giving rise to an injury.

Establishing That the Plaintiff' is a Sophisticated User

Since the Supreme Court has established the sophisticated user defense, the primary issue in product liability cases will now center upon the issue of whether the plaintiff is in fact a sophisticated user. Ordinarily expert testimony will be necessary by both the plaintiff and the defendant. Usually a person who is in the same technical area as the plaintiff who can testify that members of the group ordinarily would be familiar with the scope of knowledge that a member of the group would have. For example, in Johnson the defendant's expert had 28 years experience as an HVAC technician. He testified that it was widely known among those technicians that when the product is heated it can decompose into toxic byproducts that include phosgene and that the danger created by exposing the refrigerant to high heat and flame was well known within the HVAC technician community to which the plaintiff belonged.

The Sophisticated User Defense in Federal Courts

Federal courts that have applied state law by reason of diversity jurisdiction have applied the sophisticated user as an affirmative defense. The Sixth Circuit in *In re Air Crash Disaster (6th Cir. 1996) 86 F. 3d 498, 522* applied the "sophisticated user" defense in holding that there was no negligence for a manufacturer's failure to warn of danger in aircraft warning system. In In re Related Asbestos Cases (N.D. Cal. 1982) 543 F. Supp.1142, 1151, a federal district

court recognized that the defendants asserted that the Navy was a "sophisticated user" of asbestos products and that the Navy, as an employer, was aware of the dangers of asbestos. The "sophisticated user" defense was also applied in a strict liability case in *Bradco Oil & Gas Co. v. Youngstown Sheet & Tube Co. (5th Cir. 1976) 532 F. 2d 501*.

Defense Practice Tip. Counsel for a manufacturer should be aware that the sophisticated user defense is an affirmative defense and should make certain to plead the defense and be prepared to prove that the plaintiff was in fact a sophisticated user.

Conclusion

One lesson to be learned from the holding of Johnson v. American Standard is that a defendant manufacturer has a significant defense to a claim based upon either a strict liability or an action for negligence based on a claim for failure to warn. However, counsel should make certain to establish that the plaintiff is in fact a sophisticated user. The presentation of expert testimony as to the plaintiff's experience and the fact that a person in his or her occupation would ordinarily be acquainted with the hazards of using the product would normally be required.

**RELATED LINKS:** See the Johnson v. American Standard opinion at
- 43 Cal. 4th 56 (2008)

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Robert C. Clifford serves as a consultant to law firms and as a mediator in insurance and litigation matters. He has been the senior partner of a law firm based in Oakland, California, where he represented major insurance companies in litigation and coverage matters. His expertise in general litigation includes real property disputes, personal injury litigation, insurance matters, contract disputes, will contests and estate matters, and the defense of professional liability claims, including actions against attorneys, accountants, architects and, engineers.

He is a graduate of Stanford University and the Stanford Law School and a former member of the Board of Visitors of the Stanford Law School. He is a member of the American Bar Association and the California State Bar Association and serves on committees relating to insurance and litigation matters.

Mr. Clifford is the author or contributor to several Lexis Nexis Mathew Bender publications including California Uninsured Motorist Law, California Automobile Insurance Law, California Mechanics Lien Law and Construction Industry Practice, and California Insurance Law and Practice.

10 of 21 DOCUMENTS



***Professor J. David Prince Update of Riegel v. Medtronic***

*2008 Emerging Issues 2139*

Professor J. David Prince's Update on Riegel v. Medtronic: U.S. Supreme Court Upholds Federal Preemption of State Tort Claims Against Medical Device Manufacturers

By J. David Prince

April 16, 2008

**SUMMARY:** Professor J. David Prince analyzes the Supreme Courts decision in Riegel v. Medtronic, in which the Court held that state-law tort claims against a manufacturer of an allegedly defective medical device, which had received premarket approval from the FDA, were preempted by the Medical Device Amendments of 1976. Professor Prince is on faculty at William Mitchell College of Law in St. Paul, MN and is Of Counsel to the law firm of Larson King.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE:** In its first significant preemption ruling of 2008, the United States Supreme Court in *Riegel v. Medtronic* n1 voted 8-1 in favor of upholding federal preemption. The Supreme Court's ruling resolved a question that has divided the lower courts for more than a decade: Does the preemption clause in the Medical Device Amendments of 1976 (MDA) n2 bar state common-law tort claims that challenge the safety and effectiveness of a medical device that received premarket approval from the U.S. Food and Drug Administration (FDA)?

Answering in the affirmative, the Supreme Court held that "[s]tate tort law that requires a manufacturer"s [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." n3 In tracing the path of federal regulation over medical devices, the Supreme Court noted that the premarket approval process adopted in 1976 under the MDA "imposed a regime of detailed federal oversight" n4 that is "specific to individual devices" n5 and "is in no sense an exemption from federal safety review-it *is* federal safety review." n6 The Court pointed out that "the FDA may grant premarket approval only after it determines a device offers a reasonable assurance of safety and effectiveness." n7 Allowing Riegel to proceed with his state common-law tort claims n8 would impose on Medtronic "different" or "additional" requirements from those imposed by the FDA premarket approval process and would disrupt the federal regulatory scheme. Thus, the Supreme Court held that Riegel's claims were properly barred by the federal preemption provision in § 360k(a) of the MDA.

**Federal Preemption Doctrine.** The federal preemption doctrine is rooted in the Supremacy Clause of the United States Constitution, which provides that the laws of the United States "shall be the Supreme Law of the Land; . . . anything in the Constitution or laws of any state to the contrary notwithstanding." n9 State law, including common law, which conflicts with federal law is "without effect." n10 State "regulation can be as effectively exerted through an

award of damages as through some form of preventive relief." n11 Thus, state law causes of action must give way when such claims encroach on the objectives that Congress has addressed directly or indirectly through federal statutes or administrative regulations.

Although there is a general presumption against preemption, n12 Congress may indicate its intent to preempt state law either expressly or impliedly. As noted above, one example of express preemption is provided by § 360k(a) of the MDA, which bar states from imposing on medical devices "any requirement which is different from, or in addition to, any requirement applicable under this chapter." n13

**Federal Marketing Approval of Medical Devices.** The FDA's approval process for medical devices is complex. The MDA divides medical devices into three categories, each with separate regulations relating to approval. n14 The most extensive regulation applies to Class III devices that are deemed either: (i) important to sustaining human life or (ii) important in preventing impairment of human health -- but which devices also present a potential unreasonable risk of injury. n15 These devices, like the one involved in *Riegel*, must undergo an extensive premarket approval (PMA) process before they may be marketed, a process designed to assure that the device is both safe and effective.

However, this lengthy and time consuming PMA process can be avoided if the Class III device falls within certain exceptions. One exception allows a manufacturer to show that its product is "substantially equivalent" to devices in existence in 1976 so that the PMA process can be expedited through what is known as "premarket notification" or the "§ 510(k) application." n16

**Prior Preemption Decisions.** The Supreme Court first addressed the issue of whether § 360k(a) of the MDA preempted certain common law products liability claims in the case of *Medtronic, Inc. v. Lohr.* n17 The *Lohr* case involved a Class III device that had been approved under the § 510(k) exception for expediting the premarket notification process. The Supreme Court, in a plurality opinion, held that none of the plaintiff's state claims were preempted by the MDA.

The *Lohr* opinion generated considerable confusion as lower courts attempted to discern its specific holding and to apply it in subsequent cases. Most confusing were cases like *Riegel*, in which plaintiffs were injured by devices that had been approved through the full "safety and effectiveness" scrutiny of the PMA process n18 rather than through the expedited process as in *Lohr*.

A majority of lower courts concluded that the *Lohr* holding applied only to § 510(k) notification, and not to the rigorous PMA process, in which just about every aspect of a medical device is reviewed and specifically approved by the FDA -- and which results in device-specific requirements that preempt most state law claims. n19 The minority view on this issue held that even PMA approval does not constitute the type of specific federal requirement necessary for preemption. n20

**The Supreme Court's Decision in *Riegel v. Medtronic*.** In an 8 -- 1 opinion, the Supreme Court adopted the majority view and held that Riegel's claims were preempted. n21 Writing for the Court, Justice Scalia said that the FDA's "rigorous" premarket approval process entails an average of 1,200 hours of review by the FDA. The agency grants premarket approval only if it finds that there is a "reasonable assurance" of the device's "safety and effectiveness" n22 weighing in the process the "probable benefit to health from the use of the device against any probable risk of injury or illness from such use." n23 Therefore, the FDA's approvals of a device's design and labeling are federal "requirements" within the meaning of the express preemption language of § 360k(a). Riegel's state common-law tort claims would create conflicting state law "requirements" and are thus preempted.

Justice Ginsburg dissented, saying that Congress intended to preempt only conflicting state *regulatory* requirements

and did not intend § 360k(a) to "effect a radical curtailment of state *common-law* suits seeking compensation for injuries caused by defectively designed or labeled medical devices." In an opinion concurring in the result, Justice Stevens agreed with Justice Ginsburg as to Congress's purpose in enacting § 360k(a), but said the actual language of the preemption clause in the statute reached beyond that intended purpose to encompass even common-law "requirements."

**Decision's Impact on Manufacturers' Liability.** The result in *Riegel* will not eliminate all product liability claims against medical device manufacturers. If a medical device is not manufactured in accordance with the specifications, including the proposed labeling, approved by the FDA, a state common-law claim that the device was defective would not be preempted. And the court's holding does not resolve the question of whether § 360k(a) preempts post-sale defect claims -- claims that the device is defective due to information that comes to light only *after* the device receives the FDA's premarket approval.

**Conclusion.** The Supreme Court's decision in *Riegel* is an important step in clarifying the preemptive scope of federal law regulating the safety and effectiveness of medical devices. But *Reigel* does not answer all preemption questions on the issue, nor does it completely eliminate the prospect of lawsuits against device manufacturers whose products are alleged to be defective. Some claims -- particularly manufacturing defect claims -- are clearly not preempted. Likewise, it is not clear whether a claim is preempted when the alleged defect in a medical device reveals itself for the first time *after* the device is put into the market. There are also questions as to what impact there will be on such a claim if the FDA subsequently withdraws its approval of the device or the manufacturer recalls the product. And finally, Congress is likely to continually monitor the balance of interests between medical device manufacturers, on the one hand, and patients who are injured by those devices, on the other. Should Congress decide that the balance has tilted too far in favor of the manufacturers, it may amend the MDA to restrict its preemptive scope. All of these issues will be closely watched as new cases of alleged defective medical devices arise and wind their way through the courts.

Return to Text

n1 . Donna S. Riegel, individually and as administrator of the estate of *Charles R. Riegel v. Medtronic, Inc., 128 S. Ct. 999, 169 L. Ed. 2d 892, 2008 U.S. LEXIS 2013* (U.S. Sup. Ct. February 20, 2008). Charles Riegel was seriously injured when a Medtronic Evergreen balloon catheter burst during an angioplasty procedure, causing a heart block and requiring life support and emergency coronary bypass surgery. Riegel died while his case was on appeal, and his wife was substituted as plaintiff.

n2

[2]. These amendments, added in 1976 to the Federal Food, Drug and Cosmetic Act (FDCA), *21 U.S.C. §§ 301*-95, extended the FDA's authority to include the approval and regulation of medical devices. The preemption provision is found in *21 U.S.C. § 360k(a).*

n3

[3]. *Riegel v. Medtronic, 169 L. Ed. 2d at 903.*

n4

[4]. *169 L. Ed. 2d at 898.*

n5

[5]. *Id, at 902.*

n6

[6]. *Id.*

n7

[7]. *Id*; *see 21 U.S.C. § 360e(d).*

n8

[8]. Riegel filed suit on the grounds that the Medtronic medical device was negligently designed, manufactured, and labeled. He also brought strict liability and breach of express and implied warranty claims.

n9

[9]. U.S. Const. art. VI, cl. 2.

n10

[10]. *Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992).*

n11

[11]. *Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521 (1992).*

n12

[12]. *See Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517-18 (1992)), reh'g denied and cert. denied, 534 U.S. 818 (2001).*

n13

[13]. These amendments, added in 1976 to the Federal Food, Drug and Cosmetic Act (FDCA), *21 U.S.C. §§ 301*-95, extended the FDA's authority to include the approval and regulation of medical devices.

n14

[14]. *21 U.S.C. § 360c(a).*

n15

[15]. *21 U.S.C. § 360c(a)(1)(C).*

n16

[16]. *21 U.S.C. § 360e(b)(1)(B). See Kemp v. Medtronic, Inc., 231 F.3d 216, 221-22 (6th Cir. 2000)* (noting that this limited form of review "averages only 20 hours of review as opposed to some 1200 hours in the PMA process"), *reh'g denied and cert. denied, 534 U.S. 818 (2001).* The other exceptions are for "grandfathered" devices manufactured prior to MDA enactment which may remain on the market, *21 U.S.C. § 360e(b)(1)(A),* and the investigational device exemption, or "IDE," which applies to experimental technology and allows for unapproved devices to be used in human clinical trials to gather data for a PMA, *21 U.S.C. § 360e(a).* An IDE permits a manufacturer to market "a device that otherwise would be required to comply with a performance standard or to have premarket approval for the purpose of conducting investigations of that device." *21 C.F.R. § 812.1.*

n17

[17]. *518 U.S. 470 (1996).*

n18

[18]. *See Kemp v. Medtronic, Inc., 231 F.3d 216, 221 (6th Cir. 2000)* (noting that "[C]ourts of appeals that have confronted the issues of preemption arising under the MDA have struggled mightily with *Lohr's* language in the effort to discern its holding" and granting summary judgment to pacemaker manufacturer on preemption grounds), *reh'g denied and cert. denied, 534 U.S. 818 (2001). Compare Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999)* (facts and legal theories almost indistinguishable, but rejecting express preemption argument), *reh'g and reh'g en banc denied, 180 F.3d 276 (11th Cir. 1999).*

n19

[19]. *See, e.g., Horn v. Thoratec Co., 376 F.3d 163, 179 (3d. Cir. 2004); Martin v. Medtronic, Inc., 254 F.3d 573, 584-85 (5th Cir. 2001); Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090 (6th Cir. 1997), cert. denied, 522 U.S. 1075 (1998); Mitchell v. Collagen Corp., 126 F.3d 902, 913-14 (7th Cir. 1997); Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 431 (E.D. Pa. 2004).*

n20

[20]. *See, e.g., Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1374-75 (11th Cir. 1999), reh'g and reh'g en banc denied, 180 F.3d 276 (11th Cir. 1999); Woods v. Gliatech, Inc., 218 F. Supp. 2d 802, 808 (W.D. Va. 2002); Webster v. Pacesetter, Inc., 171 F. Supp. 2d 1, 19 (D. D.C. 2001).*

n21

[21]. In his complaint, Riegel asserted claims for strict liability, breach of express and implied warranty, and negligent design and manufacturing. The U.S. District Court for the Northern District of New York dismissed the complaint on the ground that such claims were preempted by § 360k(a) of the MDA. This ruling was affirmed by the Second Circuit, and Riegel appealed to the U.S. Supreme Court.

n22

[22]. *21 U.S.C. § 360e(d).*

n23

[23]. *21 U.S.C. § 360c(a)(2)(C).*

**ABOUT THE AUTHOR(S):**

J. David Prince is a Professor of Law at William Mitchell College of Law in St. Paul, Minnesota. In addition to his faculty position at William Mitchell, Professor Prince is Of Counsel to the St. Paul law firm of Larson King, where he focuses his practice on products safety and product liability prevention, mass tort and products liability litigation, appellate advocacy, and alternative dispute resolution.

For additional information regarding Professor Prince, please see http://www.wmitchell.edu/academics/faculty/Prince.asp or www.larsonking.com/attorneydetail.cfm?BioID=35&Edit=1. Professor Prince may be contacted at david.prince@wmitchell.edu or through the Products Liability Prof Blog at http://lawprofessors.typepad.com/products_liability, for which he is a co-editor.

11 of 21 DOCUMENTS



***Alford on Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co.***

*2009 Emerging Issues 4035*

Margie Searcy Alford on Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co., 517 F.3d 104 (2d. Cir. 2008)

By Margie Alford

April 16, 2008

**SUMMARY:** Plaintiffs are citizens of Vietnam who sued for injuries due to alleged exposure to Agent Orange and other chemicals sprayed by the U.S. government during the Vietnam War. The U.S. Second Circuit Court of Appeals affirmed the lower courts decision, which dismissed plaintiffs case for failure to state a claim under the Alien Tort Statute. Toxic tort litigator and author Margie Searcy Alford reviews and comments on the courts decision.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE: Background**

Seeking relief for injuries resulting from exposure to Agent Orange, plaintiffs, Vietnamese nationals, filed suit in the United States District Court for the Eastern District of New York. Plaintiffs alleged that defendant manufacturers were liable for violations of international law norms prohibiting use of poisoned weapons and infliction of unnecessary suffering.

Defendants filed a 12(b)(6) motion, arguing that the plaintiffs had failed to state a valid claim under the Alien Tort Statute (ATS). They argued that Agent Orange was used to defoliate jungles where snipers might hide and to kill enemy food sources but was not made to injure people. They argued it did not violate established international laws against poisoning people and causing unnecessary suffering and thus it did not meet one of the necessary requirements of the ATS.

Among other points, the defendants argued that the ATS does not provide for a court to look at political issues. Defendants argued that under the ATS there is no cause of action for "corporate liability or civil aiding and abetting liability." They argued that the statute of limitations had run and that the case was barred by the government contractor defense since the U.S. government had required the chemical company defendants to manufacture Agent Orange to the government's specifications.

The district court dismissed the plaintiff's ATS claim for failure to state a claim under that statute, granted

summary judgment on plaintiffs' domestic tort law claims, and denied plaintiffs' claim for injunctive relief. Plaintiffs appealed the judgment on these points.

The U.S. Second Circuit Court of Appeals, after dealing with the ATS issue, determined that it did not have to address any of the issues on appeal.

**The Alien Tort Statute Issue**

The Alien Tort Statute, *28 USCS §1350,* provides: "The district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States."

The phrase "law of nations "describes the body of rules that nations in the international community universally abide by or accede to, out of a sense of legal obligation and mutual concern. Three examples of commonly accepted laws of nations are piracy, slavery, and hijacking of planes.

As part of its analysis, the Second Circuit examined *Sosa v. Alvarez-Machain, 542 U.S. 692 (2004).* That case involved U.S. agents going into Mexico to abduct and transport to the U.S. a Mexican national who was charged with the murder and torture of a U.S. agent. According to the court's reading of *Sosa*, "[w]hether an alleged norm of international law can form the basis of an ATS claim will depend upon whether it is (1) defined with a specificity comparable to these familiar paradigms; and (2) based upon a norm of international character accepted by the civilized world."

Plaintiffs argued that the use of Agent Orange "violated customary norms prohibiting use of 'poisoned weapons' and the infliction of unnecessary suffering." The Second Circuit held that since the Agent Orange was intended to defoliate jungles and kill enemy food sources that it did not "violate the customary norms." It was not intended to be a human poison to "inflict unnecessary suffering."

The Second Circuit looked at the history of the use of herbicides. Herbicides did not exist at the time the 1925 Geneva Protocol was written. That Protocol was not ratified by the U.S. until President Nixon sent it to Congress in 1970.

Some in Congress argued that herbicides should be banned since the Geneva Protocol made chemical warfare illegal. The majority opinion in the U.S. Congress was that the use of herbicides was not chemical warfare since the herbicides were not intended to hurt people and since herbicides were not in existence in 1925 when the Protocol was written. Thus, the use of herbicides was held not to violate the "law of nations" so it did not meet one of the mandatory requirements of the alien tort law statute.

**Conclusion**

The court concluded that the plaintiffs' claim failed to satisfy the standard set forth by the Supreme Court in *Sosa* for recognition of a tort in violation of international law and is, therefore, not cognizable under the ATS.

**Practice Tips**

Do Not File Cases Involving Injuries From Exposure To Agent Orange in Vietnam.

Since the late 1970's, attorneys have been filing cases involving injuries from exposure to Agent Orange in Vietnam. All of the more recent cases have been lost. The big class action suit in 1984 was sort of a loss because while it paid out approximately $350,000,000, the amount per injured person was very little. All these cases are being moved

to federal court in the U.S. District Court for the Eastern District of New York, appealed to the Second Circuit, and then sometimes appealed to the Supreme Court. For years, all of these cases have been lost.

Plaintiffs' attorneys want to help injured people. Agent Orange clearly injured people, so many attorneys want to take these cases. Attorneys are not winning these suits and taking such suits gives clients false hopes and expectations, and takes a lot of the attorneys' time and money. Best practice dictates that counsel save time, energy and money for cases that can be won.

Before You Take a Case, Carefully Research The Law and Facts.

Attorneys should carefully research both the law and facts before taking cases to make sure they think they can win the cases. Attorneys who look at all of the related Agent Orange decisions will probably turn down future such cases.

Many personal injury attorneys are not familiar with laws about how to sue under the ATS. This law allows some causes of action to be brought by aliens but bars a number of other actions by aliens, including but not limited to actions for injuries that occur outside the U.S. and its territories even though the product or defendant that caused the injury may be in the U.S. The practitioner should carefully study relevant laws before filing suit for an alien. With more people from other countries such as Mexico, for example, being in the US, the personal injury attorney may need to know more about these laws.

The author of this article was one of the attorneys in the first big Agent Orange class action, the one that paid out approximately $350,000,000. Judge Weinstein made himself clear in the U.S. District Court for the Eastern District of New York that he thought that case was being settled for nuisance value and that he would not otherwise allow the plaintiffs to prevail. Anyone who reads what he has written on this matter should know he is well trenched in his opinions and that these cases do not have future value for plaintiffs under him.

Write Your Complaint Using The Wording In The Relevant Statutes and Cases.

Since the relevant laws and cases set out what you need to prove, research and know the exact wording of what you need to prove. Then, when you put on voir dire, your opening statement, the body of your case, and your closing arguments, use all the same words of the elements that have to be proved. Jurors will remember these things better when they both hear them repeated and see these words on posters, projections, written on paper pads, erasable boards, and so forth. Emphasize and then state again in a different way these important elements.

**RELATED LINKS:** See the Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co. opinion at
- 517 F.3d 104 (2d. Cir. 2008)

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Margie Searcy Alford is the principal author and editor-in-chief of the five-volume set *A Guide to Toxic Torts* (LexisNexis), a contributing author to the four volume set *Drug Product Liability* (LexisNexis), a contributing author to the two volume set *Alabama Civil Practice Forms* (LexisNexis), and a contributor to many other publications and commentaries.

She served two years as National Chairperson of the American Association for Justice Section on Toxic, Environmental, and Pharmaceutical Tort Law and two years as National Chairperson of the Women Trial Lawyer's Caucus of the American Association for Justice. Also, she was National Chair of the Dioxin Litigation Group for three years.

Margie Searcy Alford practices in the area of serious personal injury with a special focus on toxic torts. Attorney Alford has handled toxic tort cases in sixteen states.

She graduated from The University of Alabama School of Law in 1974. She is a Fellow with the National College of Advocacy and a Trial Warrior for Justice.

Attorney Alford was chosen the most outstanding young career women in Alabama by the Alabama Federation of Business and Professional Women and is in more than a hundred Who's Who type publications. She has served on many boards, committees, and commissions

*Information referenced herein is provided for educational purposes only. For legal advice applicable to the facts of your particular situation, you should obtain the services of a qualified attorney licensed to practice law in your state.*

12 of 21 DOCUMENTS



***Erny on Groch v. General Motors Corporation***

*2008 Emerging Issues 2025*

Erny on Groch v. General Motors Corporation

By Frederick M. Erny

March 18, 2008

**SUMMARY:** Frederick M. Erny, a partner with Dinsmore and Shohl, L.L.P. and author of Drug Product Liability, discusses the Ohio Supreme Court's recent case, Groch v. General Motors Corporation, which upholds the constitutionality of the state's ten-year statute of repose on product liaiblity actions against the manufacturers of products.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE:** On February 21, 2008 the Ohio Supreme Court in Groch v. General Motors Corporation, Slip Opinion No. 2008-Ohio-546 (Feb. 21, 2008), ruled that Ohio Revised Code § 2305.10(C)(1), Ohio's new ten year products-liability statute of repose, implemented by Am. Sub. S.B. No. 90 ("S.B. 80") is constitutional. (Opinion available at http://www.supremecourtofohio.gov/rod/docs/pdf/0/2008/2008-Ohio-546.pdf).

In relevant part, § 2305.10(C)(1) provides:

"Except as otherwise provided in divisions (C)(2), (3), (4), (5), (6), and (7), of this section or in Section 2305.19 of the Revised Code, no cause of action based on a product liability claim shall accrue against the manufacturer or supplier of a product later than 10 years from the date that the product was delivered to its first purchaser or first lessee who was not engaged in a business in which the product was used as a component in the production, construction, creation, assembly, or rebuilding of another product."

In Groch, Plaintiff alleged he was injured on March 3, 2005, at a General Motors plant in Toledo, Ohio when a "trim press he was operating came down upon his right arm and wrist." He brought an action in the Lucas County Court of Common Pleas seeking damages from his employer, Defendant General Motors Corporation, for alleged unsafe working conditions based upon the theory of employer-intentional tort. He also sought recovery from Defendants Kard Corporation and Racine Federated, Inc., the manufacturers of the trim press he was using, based upon alleged product defects. Defendants removed the case to the United States District Court for the Northern District of Ohio.

In the district court, the manufacturing defendants asserted that they were immune from liability for any alleged defect based upon a provision of S.B. 80, a tort reform bill that took effect in April, 2005, which provision created a products liability statute of repose in § 2305.10 of the Ohio Revised Code. In response, Plaintiff asked the federal court

to declare the statute of repose (among others) void and unenforceable because it violated various rights guaranteed by the United States and Ohio Constitutions. The federal judge stayed the proceedings in his court and certified nine separate constitutional questions asserted by plaintiff to the Ohio Supreme Court. As it relates to the statute of repose, the district court stated:

"To fully adjudicate this matter and fully determine the rights and liability of each party, this Court needs a determination by the Ohio Supreme Court regarding the constitutionality of the statutes under the Ohio constitution. The Supreme Court of Ohio has not yet had opportunity to issue a decision on the constitutionality of Revised Code § 2305.10, passed as Senate Bill 80, and made effective in April, 2005."

The Ohio Supreme Court accepted review of all nine questions and, in relevant part, in a 6-1 decision, determined that Revised Code § 2305.10(C) does not violate the open-courts provision, the takings clause, the due process remedies clauses, the equal protection clause, or the one subject rule of the Ohio Constitution and is therefore facially constitutional. Syllabus at 1.

The Ohio Supreme Court determined that the new statute of repose prevents a cause of action from accruing if the product that caused an injury was delivered to an end-user more than ten years before the injury occurred. Thus, a cause of action never becomes a vested right, and for most plaintiffs, there is, accordingly, no substantive right affected by the statute.

Nonetheless, the Court determined that Plaintiff's particular situation was different and the retroactive application of the statute of repose to bar his claim against a manufacturer for injuries that he (and other similarly situated plaintiffs) suffered within the two year period before the statute's effective date was unconstitutional as applied. The Court reasoned that Plaintiff's cause of action against the manufacturing defendants accrued on the date of his injury -- March 3, 2005. Under Ohio law in effect when he was injured, Plaintiff had a vested right to seek recovery for his injuries purportedly caused by the manufacturing defendants at any time within two years after his injury. When S.B. 80 took effect on April 7, 2005 (i.e. 34 days later), it retroactively barred the claims of any person who had not already commenced an action against a manufacturer by that date. Thus, application of the statute of repose retroactively against Plaintiff effectively reduced the time available to him to commence his action against the manufacturers from two years to 34 days. The court determined that a 34-day time period was unreasonable [192], and ultimately determined, with reference to other portions of Rev. Code § 2305.10, that a plaintiff "should have no less than two years in which to commence a suit." [195,198]. Thus, with regard to the application to Groch and similarly situated plaintiffs, since provisions of § 2305.10 affect an accrued substantive right by providing an unreasonably short period of time in which to file suit for certain plaintiffs whose injuries occurred before the amendments set forth in S.B. 80 to Rev. Code § 2305.10 became effective, that section is unconstitutionally retroactive under Section 28, Article II of the Ohio constitution which bars the retroactive application of a law when it infringes on the exercise of a substantive right.

Thus, while the Ohio Supreme Court has carved out a limited number of cases from the application of Ohio's new ten-year statute of repose, it determined for all other cases that the applicability of such a statute is constitutionally valid on its face. This will provide yet another strong affirmative defense to manufacturers in Ohio.

This is the second unsuccessful constitutional challenge to the tort-reform provisions of S.B. 80. The first of these occurred through a case filed by Melisa Arbino in a product liability action filed against Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc., and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. in 2006. Her complaint challenged the constitutionality of four separate tort-reform statutes implemented by S.B. 80. n1 She then moved for a partial summary judgment on these challenges asking the court to declare certain provisions of S.B. 80 unconstitutional causing the state of Ohio to intervene in the matter. While her motion was pending, the Judicial Panel on Multi-District Litigation consolidated Ms. Arbino's case with other claims relating to the Ortho-Evra patch before Judge David A. Katz in the United States District Court for the Northern District of Ohio. Judge Katz postponed consideration of Arbino's motion and submitted four certified questions of state law for review to the Ohio Supreme Court, which later accepted three of them. These questions involved the constitutionality of certain portions of Senate

Bill 80 limiting non-economic damages in tort actions (Ohio Rev. Code § 2315.18), governing the admissibility of collateral benefit evidence in tort actions (Ohio Rev. Code § 2315.20), and limiting punitive damages in tort actions (Ohio Rev. Code § 2315.21).

On December 27, 2007, the Ohio Supreme Court, in a 5-2 decision, ruled that two tort-reform measures enacted in S.B. 80 by the General Assembly, capping the amount of non-economic damages that may be awarded to personal injury plaintiffs and placing limits on the amount of punitive damages that may be awarded in tort actions Ohio Rev. Code § 2315.18 and 2315.21, did not violate Ohio's right to a trial by jury, the right to a remedy, the right to an open court, the right to due process of law, the right to equal protection of the laws, or the separation of powers, and therefore found them constitutional on their face. Arbino v. Johnson & Johnson, Slip Opinion No. 2007-Ohio-6948 (Dec. 27, 2007). Syllabus at 1, 2 (Opinion available at http://www.supremecourtofohio.gov/rod/newpdf/0/2007/2007-Ohio-6948.pdf). n2

While tort reformists, both in Ohio and elsewhere, can take great comfort in both of these decisions, the battle is far from over. While the Supreme Court in Arbino rejected a facial constitutional challenge to some provisions of S.B. 80, it remains to be seen whether S.B. 80 will withstand constitutional challenges when applied to specific facts. The Supreme Court's decision in Groch illustrates that it may be open to addressing similar constitutional implications involved with applying these facially constitutional provisions to a particular plaintiff or set of facts.

Return to Text

n1 . Her constitutional challenges involved the right to trial by a jury contained in Section 5, Article I; the right to due process of law, also in Section 16, Article I; the right to equal protection of the laws in Section 2, Article I; the separation of powers contained in Section 33, Article I, specifically the prohibition on the General Assembly exercising general invalid powers; and the single subject rule of Section 15(D), Article II.

n2 . Although it accepted three certified questions, the Court declined to consider Ms. Arbino's challenge to R.C. § 2315.18, governing the admissibility of collateral benefit evidence, because Ms. Arbino lacked standing in that she was not injured by that provision.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Frederick M. Erny is a Partner in the Product Liability Practice Group at Dinsmore & Shohl, LLP in Cincinnati, Ohio. Mr. Erny"s practice primarily entails litigation on behalf of manufacturers or distributors, with particular emphasis in drug and medical device product liability litigation. He is also experienced in the management of both mass tort and products liability litigation for clients on a national level. Mr. Erny has written on drug product liability topics for LexisNexis Matthew Bender Drug Product Liability and instructs at the National Institute of Trial Advocacy"s week-long seminar taught bi-annually at the University of Cincinnati Law School. His bio can be accessed at: http://www.dinslaw.com/attorneys/detail.aspx?attorney=72.

*Information referenced herein is provided for educational purposes only. For legal advice applicable to the facts of your particular situation, you should obtain the services of a qualified attorney licensed to practice law in your state.*

13 of 21 DOCUMENTS



***Alford Isaacson v. Dow Chem. Co.***

*2009 Emerging Issues 4034*

Margie Searcy Alford on Isaacson v. Dow Chem. Co., 517 F.3d 129 (2d. Cir. 2008)

By Margie Alford

March 16, 2008

**SUMMARY:** The U.S. Court of Appeals for the Second Circuit affirmed a decision from the U.S. District Court for the Eastern District of New York, holding that Agent Orange cases were properly in federal court under *42 U.S.C.A. §1442.* Toxic tort litigator and author Margie Searcy Alford reviews and comments on the courts decision.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE: Background**

Agent Orange is an herbicide that was used to defoliate jungles during the Vietnam War. The herbicide's most dangerous component is dioxin, a toxic substance that causes numerous ailments and sometimes death. Numerous chemical companies made Agent Orange for the U. S. government to use during the war. Both civilians and military personnel were exposed to the herbicide and suffered from it.

In the late 1970s, military veterans filed numerous individual suits and class actions against Agent Orange manufacturers. Eventually, these cases were consolidated in the United States District Court for the Eastern District of New York, under Judge Jack Weinstein. In 1984, prior to trial, Judge Weinstein facilitated and approved a settlement for $180 million, which was to include all potential future Agent Orange claims. The fund was exhausted by 1994.

Since the settlement, veterans claiming development of Agent Orange related injuries after the settlement or after exhaustion of the fund have attempted to file other suits. With some exceptions, most of those suits have been dismissed by trial courts.

In this case, plaintiffs filed seven state court actions in Illinois, Missouri, New Jersey, New York, and Texas, alleging violations of their respective state laws. These actions were mostly for Agent Orange related illnesses and injuries that manifested themselves after the settlement of the prior class action suit. The cases were removed to federal courts in their respective states. The Judicial Panel on Multidistrict Litigation transferred the cases to the United States District Court for the Eastern District of New York (where the first Agent Orange class action had been settled).

The district court first dismissed the cases because it determined that they were attacking the 1984 settlement. On appeal, the United States Court of Appeals for the Second Circuit vacated the order of dismissal and remanded, finding

that the plaintiffs were not bound by the prior settlement. The Second Circuit also held that the district court properly had subject matter jurisdiction over the cases.

The United States Supreme Court affirmed the judgment vacating the order of dismissal, but vacated and remanded on the issue of federal jurisdiction. The Second Circuit then remanded the case back to the district court for analysis of federal jurisdiction.

With the case back at district court, the defendants moved for summary judgment and the plaintiffs moved to remand the actions to state court. The court granted defendants' motion for summary judgment and denied plaintiff Isaacson's motion to remand. The court found that federal jurisdiction for Isaacson was proper under the federal officer removal statute, *28 U.S.C. § 1442.* Later, the court denied all remaining plaintiff motions to remand.

Plaintiffs appealed the district court's order finding removal jurisdiction and order denying motions to remand.

**Three-Prong Test Applied to Defendants**

The Second Circuit Court of Appeals reviewed, de novo, the district court's denial of the motions to remand. This court held that in accordance with *Jefferson County v. Acker, 527 U.S. 423, 431, 119 S. Ct. 2069, 144 L. Ed. 2d 408 (1991),* it would have to apply a three-pronged test to defendants to determine if removal was proper under *28 U.S.C. § 1442:*

Defendants must show that they are persons within the meaning of the statute who acted under color of a federal officer.

Defendants must show that they performed the actions for which they are being sued under the color of a federal office.

Defendants must raise a colorable federal defense.

The Manufacturers Were Persons Acting Under Color of a Federal Officer

Plaintiffs contended that defendant chemical companies do not qualify as persons under Section 1442 because they are not natural persons. Another panel of the Second Circuit, in the case *In re Methyl Tertiary Butyl Esther ("MTBE") Prods. Liab. Litig., 488 F. 3d 112, 124 (2d Cir. 2007),* determined that corporate persons qualify as "persons" under Section 1442. The court explained that it presumed, under *1 U.S.C. §1,* that "the term 'person' includes corporations 'unless the context indicates otherwise.'" Therefore, the court found that the defendants were persons within the meaning of Section 1442.

The court cited the U.S. Supreme Court's explanation in *Watson v. Phillip Morris Cos., 551 U.S. 142 (2007)* of what satisfies the "acting under" portion of the first prong of the Section 1442 test: "an entity 'act[s] under' a federal officer when it 'assist[s], or . . . help[s] carry out, the duties or tasks of the federal superior.'" *Isaacson v. Dow Chem. Co., 517 F.3d 129, 136-137 (2008).* The court then concluded that the defendants in this case, in providing Agent Orange to the federal government during the Vietnam War, assisted and helped it carry out duties or tasks of officers at the Department of Defense.

The court therefore concluded that the defendants met the first prong of the Section 1442 test and were persons within the meaning of the statute who acted under color of a federal officer.

**The Manufacturers Acted Under Color of a Federal Office**

The court also concluded that the defendants acted (i.e. produced Agent Orange, containing the toxin dioxin) while they were performing their duties under color of a federal office (i.e. while under contract with the government), dismissing arguments by plaintiffs that Agent Orange was an off-the-shelf product and that because defendants

voluntarily bid for the government contracts their actions were not under color of federal office.

**The Manufacturers Raised a Colorable Federal Defense**

Lastly, the court concluded that the defendants raised a colorable federal defense, the government contractor defense, rejecting plaintiff's argument that the court must determine that a defense is an immunity defense before it can conclude that it is a colorable federal defense.

**Conclusion and Comments**

The Second Circuit, finding that the defendants met all three prongs of the federal officer removal statute, affirmed the orders of the district court denying the plaintiffs' motions to remand.

Before these cases were filed, the author of this Commentary participated in several meetings with some of the plaintiffs' attorneys involved in these cases, when they discussed how to keep this case out of U.S. District Court for the Eastern District of New York. The author of this commentary declined to be involved with these cases because she thought there was a strong possibility the cases would end up in that court where she felt they could not be won.

Best practice dictates that before filing suit, the practitioner carefully study the judges who may end up with the potential case and what his or her track record has been on the issues similar to the ones involved in the case. Counsel should examine previous cases with related issues to get some idea of how their case will be decided. If, as in this case, a potential judge has written law books, counsel should be familiar with the judge's books.

Most plaintiff attorneys do what they do because they want to help injured people but they cannot help everyone who is injured. We cannot afford to stay in business if we continue to do that. Sometimes the law prevents us from righting wrongs. Before you take a case and after you have researched the relevant cases, statutes, courts and judges, decide if the risk is worth taking. The practitioner should be careful not to give the client false hopes. That being said, this author salutes the brave and honorable attorneys who fight difficult cases because taking them on is the right thing to do.

**RELATED LINKS:** See the Isaacson v. Dow Chem. Co. opinion at

- 517 F.3d 129 (2d. Cir. 2008)

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Margie Searcy Alford is the principal author and editor-in-chief of the five-volume set *A Guide to Toxic Torts* (LexisNexis), a contributing author to the four volume set *Drug Product Liability* (LexisNexis), a contributing author to the two volume set *Alabama Civil Practice Forms* (LexisNexis), and a contributor to many other publications and commentaries.

She served two years as National Chairperson of the American Association for Justice Section on Toxic, Environmental, and Pharmaceutical Tort Law and two years as National Chairperson of the Women Trial Lawyer's Caucus of the American Association for Justice. Also, she was National Chair of the Dioxin Litigation Group for three years.

Margie Searcy Alford practices in the area of serious personal injury with a special focus on toxic torts. Attorney Alford has handled toxic tort cases in sixteen states.

She graduated from The University of Alabama School of Law in 1974. She is a Fellow with the National College of Advocacy and a Trial Warrior for Justice.

Attorney Alford was chosen the most outstanding young career women in Alabama by the Alabama Federation of Business and Professional Women and is in more than a hundred Who's Who type publications. She has served on many boards, committees, and commissions

*Information referenced herein is provided for educational purposes only. For legal advice applicable to the facts of your particular situation, you should obtain the services of a qualified attorney licensed to practice law in your state.*

14 of 21 DOCUMENTS



***Alford on Griffin v. Unocal and Dealing with Statutes of Limitations***

*2008 Emerging Issues 1985*

Alford on Griffin v. Unocal and Dealing with Statutes of Limitations

By Margie Searcy Alford

March 3, 2008

**SUMMARY:** For almost twenty-nine years, AL law dictated that the states two-year statute of limitations for toxic torts cases ran from the date of last exposure to toxic substances. In Griffin v. Unocal Corp., the AL Supreme Court overrules Garrett v. Raytheon Co. (and its progeny) and adopts a discovery rule for toxic tort cases in AL.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE:** Overview

For almost twenty-nine years, Alabama law dictated that the state's two-year statute of limitations for toxic torts cases ran from the date of last exposure to toxic substances. This "last exposure rule," as set forth in *Garrett v. Raytheon Co., 368 So. 2d 516, 520-521 (Ala. 1979)*, was frequently harsh on potential plaintiffs who did not show signs of injury or illness within the two years after their last exposure. In Griffin v. Unocal Corp., the Alabama Supreme Court overrules Garrett (and its progeny) and adopts a "discovery rule" for toxic tort cases in *Alabama. Griffin v. Unocal Corp., 2008 Ala. LEXIS 19* (Ala. Jan. 25, 2008). Under this new rule, which will be applied proactively, the statute of limitations runs from the date a "manifest, present injury" occurs.

Analysis

Last Exposure Rule for Toxic Tort Cases, Prior to Griffin. In 1979 the Alabama high court "defined [the] 'date of injury' for statute of limitations purposes to be the day on which the plaintiff was last exposed to the damages n1 which injured her." *Garrett v. Raytheon Co., 368 So. 2d 516, 520-521 (Ala. 1979).* In response to the court's adoption of the last exposure rule in Garrett, the Alabama Legislature enacted Act No. 79-468, Ala. Acts 1979, which provided for a discovery rule in toxic tort cases. Code of Ala. §§ 6-5-500 through 6-5-504. However, that act was voided when the Alabama Supreme Court held the 10-year rule of repose in § 6-5-502(c) to be unconstitutional. *Lankford v. Sullivan, Long & Hagerty, 416 So. 2d 996, 1001 (Ala. 1982).*

Separate, Statutory Discovery Rule for Asbestos Cases. The Alabama Legislature enacted Acts 1980, No. 80-566, which provides a discovery rule for asbestos cases only. Code of Ala. § 6-2-30. This rule has remained in effect, to date. It provides in part:

A civil action for any injury to the person or rights of another resulting from exposure to asbestos, including asbestos-containing products, shall be deemed to accrue on the first date the injured party, through reasonable diligence, should have reason to discover the injury giving rise to such civil action. Code of Ala. § 6-2-30(b).

Justice Harwood's Dissent in Cline v. Ashland: A Prelude to Griffin. In Cline v. Ashland, the Alabama Supreme Court affirmed (without opinion) a circuit court summary judgment based on the last exposure rule. *Cline v. Ashland, Inc., 970 So. 2d 755 (Ala. 2007).* Justice Harwood wrote a lengthy dissent to the no-opinion decision, in which he made a case against affirming the last exposure rule. Cline, at 761 (Ala. 2007).

Background of the Griffin case. The plaintiff's husband in Griffin was exposed to defendants' chemicals (including benzene and others) over many years while working in a tire plant. *Griffin v. Unocal Corp., 2008 Ala. LEXIS 19,* at *1-*2 (Ala. Jan. 25, 2008). About ten years after the date of last exposure, he was diagnosed with acute myelogenous leukemia; he died five months later. Griffin, at *2 (Ala. Jan. 25, 2008). Plaintiff filed a wrongful death suit, alleging that the chemical exposure caused her husband's cancer. The trial court granted defendants' motions to dismiss (which argued that plaintiff's action was time-barred based on the Garrett last exposure rule), and plaintiff appealed. Griffin, at *3 (Ala. Jan. 25, 2008).

NEW Discovery Rule, As Adopted in Griffin. The issue under consideration in the Griffin case was "whether 'the date of last exposure rule [is] still the law in Alabama.'" Griffin, at *3 (Ala. Jan. 25, 2008). The Alabama Supreme Court answered: "it is not, because we hereby overrule Garrett and its progeny." Griffin, at *3 (Ala. Jan. 25, 2008). The Court, as it explains below, adopted and attached (as an appendix) Justice Harwood's dissent from the Cline decision:

We do so for the reasons set forth in Justice Harwood's scholarly dissent to this Court's no-opinion affirmance in Cline v. Ashland, Inc., [citation omitted], which is attached as an appendix to this opinion. We hereby adopt the reasoning of that dissent as the opinion of the Court in this case.

In particular, as Justice Harwood stated, "a cause of action accrues only when there has occurred a manifest, present injury." [citation omitted] (emphasis added). We need not repeat Justice Harwood's accurate description of the meaning of the word "manifest" in this context. Further, as Justice Harwood advocated in his dissenting opinion in Cline, the new accrual rule of toxic-substance-exposure cases will be applied prospectively, except in this case, where it will apply retroactively. Griffin, as the prevailing party in bringing about a change in the law, should be rewarded for her efforts. Griffin, at *3-*4 (Ala. Jan. 25, 2008).

As evident from the last quoted sentence above, the court reversed the trial court judgment and remanded the case for further proceedings consistent with their opinion. Griffin, at *4 (Ala. Jan. 25, 2008).

In the appendix (a.k.a. Justice Harwood's Cline Dissent), Justice Harwood defines the terms "accrued" and "manifest", which are used in the discovery rule standard he stated:

The proper construction of the term "accrued" in § 6-2-30(a) in the context of toxic-substance-exposure cases should honor the rule that a cause of action accrues only when there has occurred a manifest, present injury. I understand "manifest" in this context to mean an injury manifested by observable signs or symptoms or the existence of which is medically identifiable. "Manifest" in this sense does not mean that the injured person must be personally aware of the injury or must know its cause or origin. All that is required is that there be in fact a physical injury manifested, even if the injured person is ignorant of it for some period after its development. Griffin, at *55 (Ala. Jan. 25, 2008).

Justice Harwood also describes the "Catch-22" situation in which plaintiffs would remain if the last exposure rule is not rejected:

A person exposed to a toxic substance having the potential to cause disease on a delayed basis, but who has suffered no manifest, present injury within two years thereafter, may not file an action within that two-year period. [citations omitted] If, after two years, that same person in fact suffers an injury from the exposure and files an action,

the action will be dismissed on the basis that it should have been filed earlier. Thus, no matter when the person attempts to file the action, it is either too soon or too late. This is a classic Catch-22, [footnote omitted] and one that would seem to violate Art. 1, § 13, Ala. Const. 1901, which provides, in pertinent part, "that every person for any injury done him .. shall have a remedy by due process of law." Griffin, at *51 (Ala. Jan. 25, 2008).

In another highlight of the appendix, Justice Harwood also explains that he believes that Garrett was wrongly decided in the first place and that the doctrine of stare decisis is not reason enough to avoid correcting the mistake. Griffin, at *39-*55 (Ala. Jan. 25, 2008).

Conclusion. In Griffin v. Unocal Corp., the Alabama Supreme Court overruled Garrett v. Raytheon Co. and adopted a discovery rule for toxic tort cases, thereby putting an end to almost twenty-nine years of the last exposure rule in Alabama. The new rule, which states that "a cause of action accrues only when there has occurred a manifest, present injury," will be applied retroactively to the Griffin case and proactively to all other cases. This landmark decision changes the playing field for toxic tort litigation in Alabama by permitting plaintiffs to pursue actions that they might not have been able to pursue under the former rule. Nevertheless, statutes of limitations can still pose problems for plaintiffs in Alabama and in other jurisdictions. See the following sections for advice on how to deal with problems raised by statutes of limitations.

Practice Tips

Warning to Alabama Plaintiff Attorneys. Best practice dictates that a practitioner should review any cases he or she has turned down due to statute of limitations obstacles. The review should examine whether the cases could be brought under the new Alabama discovery rule. Failure to do so might have dire malpractice consequences.

Practice Tip for Plaintiffs in Alabama (and Other Discovery Rule Jurisdictions): Order all medical records before filing suit. Counsel should order all relevant medical records before filing suit, to determine when the plaintiff's disease was first discovered; or in Alabama, "medically identifiable." *Griffin v. Unocal Corp., 2008 Ala. LEXIS 19,* at *55 (Ala. Jan. 25, 2008).

Practice Tip for Plaintiffs: Consider Filing Suit in Other Jurisdictions. There are several reasons why a lawsuit in a jurisdiction (state or federal) outside of your own just might be the solution to your statute of limitation problem:

(1) Other jurisdictions may have a longer statute of limitations. Determine if your plaintiff's claim may be brought in one of these other jurisdictions. For example, if a toxic tort case is barred in Alabama, perhaps a jurisdiction where the product was manufactured or where the defendant has its main office has a longer statute of limitations.

Case Example: In unreported cases, this author filed a toxic pesticide suits in Texas, where the pesticide had been manufactured. The suits were filed for clients who had been exposed to the substance in Alabama, where the statute of limitations had already run before the clients retained this author. At the time, a number of related cases were already pending in Alabama. Defendants agreed that if the Texas cases were transferred to Alabama, where discovery would be consolidated for all the related cases, Defendants would not use the statute of limitations defense in Alabama.

Also, determine if your plaintiff can bring suit under a federal statute with a discovery rule that is broader than the rule in your jurisdiction. For example, the Comprehensive Environmental, Response, Compensation and Liability Act (CERCLA), provides for a discovery rule that is broader than Alabama's rule (and perhaps other state laws). *42 U.S.C.S. § 9658(b)(4).*

(2) Some states discovery rules hold that the statute of limitations does not begin to run until the plaintiff knows or should have known that the defendant's product may have caused the injury or illness. See, e.g., *Betts v. Manville Personal Trust, 225 Ill. App 3d. 882, 588 N.E.2d 1193, 167 Ill. Dec. 1063 (1992); Moll v. Abbott Labs., 444 Mich. 1, 506 N.W.2d 816 (1993).*

If you are in a state that lacks this requirement, such as Alabama, determine if your plaintiff's claim may be brought in one of these states.

(3) Some states require that the plaintiff knew of the existence of a cause of action before the statute of limitation begins to run. See, e.g., *Soutiere v. Betzdearborn, Inc., 2002 U.S. Dist. LEXIS 4538,* at *18-*29 (D. Vt. Jan. 28, 2002; *Sopko v. Dowell Schlumberger, Inc., 21 P.3d 1265, 1270-1271 (Alaska 2001); Enertron Indus. v. Mack, 242 N.J. Super. 83, 576 A.2d 28 (App. Div. 1990).*

If you are in a state that lacks this requirement, such as Alabama, determine if your plaintiff's claim may be brought in one of these states.

(4) Some states recognize that early symptoms may be "too isolated or

inconsequential" for the plaintiff to recognize that he or she is injured. See e.g., *Bartlett v. Moore Bus. Forms, Inc., 2000 U.S. Dist. LEXIS 8686,* at *14-*15 (N.D.N.Y. March 30, 2000).

If you are in a state that lacks this consideration, such as Alabama, determine if your plaintiff's claim may be brought in one of these other states.

(5) While most states limit plaintiffs to one law suit for injuries due to particular toxic substances from one or a group of defendants, some states recognize the difference between immediate and long-term illnesses or injuries and allow separate suits for diseases that manifest themselves years apart. See, e.g., *Peterson v. Instapak Corp., 690 F. Supp 697 (N.D. Ill. 1988); Anderson v. Sybron Corp., 165 Ga. App. 566, 299 S.E. 2d 160 (1982).* See also *Wilson v. Johns-Manville Sales Corp., 684 F.2d 111 (D.C. Cir. 1982)* (plaintiff developed asbestosis but did not sue; later he developed mesothelioma and was allowed to sue).

Best practice dictates that the practitioner should consider: 1) whether a cause of action can be split, and 2) whether his or her client should avoid signing a release that bars the client from bringing a suit for future injury or illness.

For more discussion on splitting causes of action, see A Guide to Toxic Torts, § 9.01[5]. See also Restatement (Second) of Judgments §§ 24--26 (1982).

Practice Tip for Plaintiffs. Determine if a statute of limitations problem may be overcome by adding your plaintiff to a class action suit that has already been filed.

Practice Tip for Plaintiffs and Defendants: Remember That Sometimes the State High Court Makes Mistakes. While prior case law and statutes generally govern future cases, remember that the state high court will occasionally admit that it made a mistake in a prior decision. In light of a high court holding like the one in Griffin, the practitioner should remember that he or she may argue that a prior decision was wrongly decided.

Additional References

For a more detailed discussion of how to overcome statute of limitations problems in toxic tort cases, see A Guide to Toxic Torts, Chapter 9.

Return to Text

n1 . Arguably, the court meant toxins rather than "damages."

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Margie Searcy Alford is the Principal Author and Editor-in-chief of the five-volume set A Guide to Toxic Torts (LexisNexis), and a contributing author to the four-volume set Drug Product Liability (LexisNexis), the two-volume set Alabama Civil Practice Forms (LexisNexis), and many other publications.

Margie Searcy Alford practices in the area of serious personal injury with a special focus on toxic torts. Attorney Alford has handled toxic tort cases in sixteen states.

She served two years as National Chairperson of the American Association for Justice Section on Toxic, Environmental, and Pharmaceutical Tort Law and two years as National Chairperson of the Women Trial Lawyer?s Caucus of the American Association of Justice. She was National head of the Dioxin Litigation Group for three years.

Attorney Alford was chosen the most outstanding young career women in Alabama by the Alabama Federation of Business and Professional Women and is in more than a hundred Who?s Who type publications. She has served on many boards, committees, and commissions.

She graduated from The University of Alabama School of Law in 1974. She is a Fellow with the National College of Advocacy and a Trial Warrior for Justice.

15 of 21 DOCUMENTS



***Alford on Adams v. Cooper Indus.***

*2009 Emerging Issues 4032*

Margie Searcy Alford on Adams v. Cooper Indus., 2008 U.S. Dist. LEXIS 9349 (E.D. Ky., February 5, 2008)

By Margie Alford

February 24, 2008

**SUMMARY:** Some of the best toxic tort plaintiffs attorneys in the nation lose four bellwether cases when the judge determines that they have not offered proof of chemical exposure sufficient to cause plaintiffs injuries. Toxic tort litigator and author Margie Searcy Alford reviews the judge's ruling on these motions and offers practical tips relating to proof and expert testimony in toxic tort cases.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE: Background**

This case, *Adams v. Cooper Indus.*, No. 03-476-JBC, is one of several arising out of alleged contamination (of dioxin, polychlorinated biphenyl, and other toxins) released from the former National Electric Coil plant in Dayhoit, Harlan County, Kentucky. In 1989, state officials discovered contamination in groundwater wells adjacent to the plant.

Defendant Cooper Industries, upon learning of contaminated wells, paid for and installed pipes to bring residents clean water from alternative sources. In the early 1990s, the EPA began cleaning up the area and numerous plaintiffs filled suit in the U.S. District Court for the Eastern District of Kentucky. The first wave of cases (a consolidation of actions known as the *Robinett* litigation) was settled in 1996.

Additional plaintiffs filed a class action, *Lankford v. Cooper Indus*., No. 97-CI-00670 (Harlan Cir. Ct. 1997), but the class was eventually decertified and many of the former class members settled their cases. Pursuant to that settlement agreement, the statute of limitations was tolled until April 1, 2004 for those people who fit the class description but did not settle at that time.

Suits were filed for hundreds of remaining plaintiffs who were represented by some of the top plaintiffs' toxic tort attorneys in the country. This action and another, *Moody v. Cooper Indus*., No. 03-158-JBC , were filed in the E.D. Ky. District Court in 2003. The *Moody* action was later consolidated with this action.

Four plaintiffs in this action were chosen as bellwethers.

**Issues Addressed by This Decision**

During the *Daubert* hearing, plaintiffs' experts offered testimony and affidavits and plaintiffs produced Rule 26 expert reports. None of the reports contained evidence of the levels of exposure the plaintiffs had to the toxins. Nor did any contain evidence that the plaintiffs had been exposed to sufficient quantities of the toxins to produce the illnesses that they claimed. The court therefore found the evidence offered by a number of the plaintiffs' experts not credible.

After the *Daubert* hearing, plaintiffs motioned the court to reconsider three resulting orders, which excluding testimony and evidence by various plaintiffs' experts. Plaintiffs also submitted three new expert declarations to their pleadings.

Defendants filed motions to strike plaintiffs' new declarations and for summary judgment on the four bellwether cases.

This decision, *Adams v. Cooper Indus., 2008 U.S. Dist. LEXIS 9349* (E.D. Ky., February 5, 2008), by Chief Judge Jennifer B. Coffman, addresses the aforementioned motions by defendants and plaintiffs.

**Defendants' Motion to Strike Plaintiff's Evidence**

In order to bolster their evidence on the issue of levels of exposure, the plaintiffs attached declarations to their pleadings. These declarations were from plaintiffs' experts Dr. Kramer, Dr. Orris, and Dr. Rodgers, each of whom had already given Rule 26 statements, depositions, and affidavits. The new declarations were supposedly provided to clear up "misunderstandings" by the court.

However, the court determined that the declarations contained new evidence that should have been previously presented. Dr. Rodger's declaration included new calculations to evaluate blood data and Dr. Kramer's offered a new opinion regarding levels of toxins in the blood. The court held that "[f]airness does not require that the plaintiffs be afforded a second chance to shore up their case before the court may consider the defendants' motion for summary judgment." Thus, defendants' motion to strike was granted.

**Plaintiffs' Motion for Reconsideration of Prior Orders**

The plaintiffs filled a motion to reconsider three prior orders that excluded certain plaintiff experts and their testimony, studies, and findings. One order excluded the causation testimony and opinions of plaintiffs' experts Orris, Miller, and Rodgers; another order excluded the testimony and opinions of plaintiffs' expert Sawyer; a third order excluded the testimony of Dr. Kramer's studies pursuant to Fed. R. Evid 403. Under federal law there is no motion to reconsider but the court treated these motions as motions "to alter or amend a judgment under Fed. R. Civ. P. 59(e) in accordance with *Trident Int'l Corp v. Kentucky, 395 F. Supp. 2d 521 (E.D. Ky. 2005).*" *Adams v. Cooper Indus., 2008 U.S. Dist. LEXIS 9349*, *17 (E.D. Ky., February 5, 2008). The court stated that a plaintiff moving for reconsideration "may not simply ' reargue its prior position in the hope that the court will change its mind.' " *Adams v. Cooper Indus., 2008 U.S. Dist. LEXIS 9349*, *18 (E.D. Ky., February 5, 2008). The court held that the plaintiffs failed to present evidence of clear error by the court in its prior rulings. Also, plaintiffs presented no newly discovered evidence and did not demonstrate manifest injustice due to the court's prior rulings. Thus, plaintiffs' motion for reconsideration of all three orders was denied.

**Defendants' Motion for Summary Judgment**

Before the defendants' motion for summary judgment was filed, plaintiffs had not proved causation. Furthermore, the court excluded the plaintiffs' causation experts as unreliable. Thus, the court granted summary judgment for defendants. Plaintiffs essentially could not get a "second shot" at trying to provide evidence of causation.

**Practice Tips Relating to Proof and Expert Testimony in Toxic Tort Cases**

Do not just assume that the other attorneys on your side of the case will cover certain issues.

This case involved some of the best plaintiffs' toxic tort lawyers in the country. When working with a large group of plaintiffs' attorneys, best practice dictates that the attorneys make sure that all the necessary elements of the case are covered. Do not think that just because many good attorneys and experts are involved, that all the elements necessary to prove the case are being covered.

Know the standards for admissibility of scientific evidence that are applicable in your case.

Many jurisdictions vary in their admissibility standards for scientific evidence. Before filing a case, you should know whether you need to follow Fed. R. Evid. 702 and *Daubert* and its progeny; or *Frye* and its progeny; or some other standard.

Look at the scientific literature before taking a case.

Before you take a case, make sure there is enough valid scientific evidence for your experts to rely upon. Failure to do may have dire consequences.

The author of this commentary won the first Agent Orange case (for use of the chemical in the United States), the first multiple chemical sensitivity case, and the first organophosphate case involving a certain reaction; but she could not have done so if there had not been significant scientific literature to back up her experts. Research the scientific literature before taking a case.

Do not rely solely on scientific literature from the U.S.

Many valid scientific studies have been written in languages other than English. The author this commentary won the above-mentioned organophosphate case using a series of studies that she had translated from German. She won another case due in part to the use of Swedish studies. Both of these cases did not have sufficient scientific evidence in English. You may not always feel the need to look at foreign language studies if there is sufficient English literature, but do look at the foreign studies to be thorough.

Only retain experts who can meet *Daubert* or *Frye* challenges.

Do not hire experts unless after careful investigation you are confident that they have the experience and credentials to get around a Rule 702/*Daubert* or *Frye* challenge. Google your potential expert's name. Ask who else has had experiences with your potential expert. Ask potential experts whether they have ever been prohibited from testifying because of a *Daubert* or *Frye* challenge. Research your potential expert using: resources at Legal > Area of Law -- By Topic > Products Liability & Toxic Torts > Research Experts on www.lexis.com; IDEX at https://idex.lexisnexis.com; and Courtlink at https://courtlink.lexisnexis.com.

First test potential experts on a few clients.

If you are working on a case where you have many plaintiffs and you are considering using a particular expert, you may want to test how that expert will do by having the expert first evaluate a small number of plaintiffs. Evaluate among other things whether he or she can get by a Rule 702/*Daubert* or *Frye* challenge. You can sometimes save a lot of time and money by following this tip. If there are numerous expensive tests that your experts are considering doing, have the tests done on a smaller group to plaintiffs to see which tests produce the most dramatic evidence of the illnesses and injuries the toxins have caused.

Be prepared with evidence to defeat motions for summary judgment.

One lesson to be learned is that in most toxic tort cases, the defendants will file a motion for summary judgment. Best practice dictates that the plaintiffs' attorneys should in their depositions and Rule 26 statements include proof of all the elements necessary to prove the case. This proof should include but not be limited to the fact that each plaintiff was

exposed to the defendants' toxins in sufficient levels to produce the resulting illness or injury in the time in which the illness or injury manifested itself.

Know your judge.

Best practice dictates that you study your judge. Talk to other attorneys who have practiced in front of him or her. Study as many of his or her prior decisions, articles, books, etc. as possible to find out what he or she likes. Make sure you know any pet peeves he or she has. Research your judges on Courtlink at https://courtlink.lexisnexis.com.

When you are considering whether to take a case, carefully look at the judge who may decide the case. Some judges lean so far one way or the other that it is hard to get a fair trial in their courts. In such cases, look for ways to file your suit in a different jurisdiction or in front of a different judge. A plaintiff may have been exposed to a toxin in one location but the potential defendant may have its headquarters or the plant where it manufactured the toxin in a different jurisdiction with better potential judges for the case.

Quote exact wording from the relevant laws.

Before filing suit carefully research the constitution, statutes, and case law in the jurisdiction where you are considering filing suit.

Create your complaint using the exact words of the relevant law.

During voir dire tell the potential juror what the relevant laws are. Use exact wording. The jurors will remember these things better if they can both see and hear these laws. Hearing and seeing things multiple times also increases jury retention. Question the jurors in voir dire about whether or not they can follow each individual law as you go through them one at a time. Get a commitment from them to follow the law. *See Rules of the Road* by Friedman, R. and Malone, P., Trial Guides, 2006, for a good expansion on this tip.

Use the exact wording of these laws in your Rule 26 expert witness reports.

Shape your presentation of evidence in the body of your case to fit the exact wording of the laws in your jurisdiction. Get your witnesses when possible to use this wording for all elements you have to prove.

Request your judge to give jury charges using the exact wording of the laws that you have emphasized since the beginning of the case.

Consider the Risks of Using Bellwether Cases.

When counsel represents a large number of plaintiffs, he or she may want to pick out a few of the most compelling clients and try their cases first. One problem with doing so however, may be that if counsel loses these cases, settling the rest of the cases may be harder. In addition, counsel may learn hard and difficult lessons on their best cases-the ones that should have been more successful and productive than the others.

**RELATED LINKS:** See the Adams v. Cooper Indus. opinion at
- 2008 U.S. Dist. LEXIS 9349

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Margie Searcy Alford is the principal author and editor-in-chief of the five-volume set *A Guide to Toxic Torts* (LexisNexis), a contributing author to the four volume set *Drug Product Liability* (LexisNexis), a contributing author to

the two volume set *Alabama Civil Practice Forms* (LexisNexis), and a contributor to many other publications and commentaries.

She served two years as National Chairperson of the American Association for Justice Section on Toxic, Environmental, and Pharmaceutical Tort Law and two years as National Chairperson of the Women Trial Lawyer's Caucus of the American Association for Justice. Also, she was National Chair of the Dioxin Litigation Group for three years.

Margie Searcy Alford practices in the area of serious personal injury with a special focus on toxic torts. Attorney Alford has handled toxic tort cases in sixteen states.

She graduated from The University of Alabama School of Law in 1974. She is a Fellow with the National College of Advocacy and a Trial Warrior for Justice.

Attorney Alford was chosen the most outstanding young career women in Alabama by the Alabama Federation of Business and Professional Women and is in more than a hundred Who's Who type publications. She has served on many boards, committees, and commissions.

16 of 21 DOCUMENTS



***Levine on Insurance Coverage Implications of Lead-Tainted Product Recalls***

*2008 Emerging Issues 1911*

Levine on Insurance Coverage Implications of Lead-Tainted Product Recalls

By Michael S. Levine

February 12, 2008

**SUMMARY:** Michael S. Levine, a senior associate in the McLean, Virginia office of Hunton & Williams LLP, practices in the firm's insurance and reinsurance group. He discusses the recent rash of product recalls due to the presence of lead in the products, which has the potential to implicate multiple lines of insurance coverage, including commercial property, general liability, recall coverage, and the liability coverage of directors and officers.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE:** Introduction

The recent rash of product recalls due to the presence of lead in the products has the potential to implicate multiple lines of insurance coverage, including commercial property, general liability, recall coverage, and the liability coverage of directors and officers.

Commercial Property

Commercial property policies typically cover damage to a policyholder's own insured property, subject to requirements, such as that the damaged property be tangible property and that the damage be physical in nature. But, courts differ on what constitutes tangible property and what constitutes a physical loss; thus, whether coverage is available for recall damages under a commercial property policy may be subject to debate.

Certain aspects of the commercial property policy are less susceptible to such debate, however, such as certain exclusions, which plainly bar coverage where damage to insured property is the result of certain characteristics of the property, as opposed to damage caused by external forces.

General Liability

General liability policies, in contrast, typically cover damages that a policyholder becomes legally obligated to pay because of bodily injury or property damage, to which the insurance applies, caused by the policyholder's product, subject to some exclusions and assuming the company has purchased the "products-completed operations" option offered by most CGL insurers. But courts differ regarding the scope of consequential damages covered under the CGL insuring agreement, including the extent of coverage when some recalled products did not actually cause injury or

damage. In a product recall situation, a policyholder might incur a variety of expenses, including costs for examination, transportation, destruction, analysis, decontamination of plant sites, storage space and cancellation charges, additional storage capacities, notification to customers and end users, replacement, and advertising measures, as well as lost profits. Whether any of these sums are covered depends on the circumstances of the case and court interpretations of the CGL policy language.

In the famous Tylenol recall, for example, Johnson & Johnson sued its excess insurers for reimbursement of expenses resulting from the recall of 31,000,000 bottles of Tylenol. In that case, McNeilab v. North River Ins. Co., a federal judge in New Jersey held that the excess insurers were not liable for any of the costs associated with the recall noting, "Johnson & Johnson, which at one time carried recall coverage, [and who] knew such coverage could be purchased, [but] elected not to purchase it because the cost was prohibitive, and now claims that it enjoys recall coverage anyway." n1

Product Recall Coverage

The third type of coverage that will likely be implicated by the lead product recalls is product recall coverage. Product recall insurance expressly provides coverage for those expenses that occur before the defectiveness of a product or food item has resulted in injury or damage to a third party. While companies are often concerned about the costs associated with defective product liability claims or lawsuits, the logistical expenses of a recall itself may be overlooked. Large product recalls can be enormously expensive. By some estimates it is five to ten times more expensive to recall a product than it is to manufacture the product. And these estimates do not include other costs that may accompany a recall, such as damage to a company's reputation and market share.

Product recall coverage tends to be industry and product specific. Policies insuring against recall costs have been available in the food and cosmetic industry for many years. In other markets, such as the automotive and original equipment manufacturing markets, coverage may be harder to find. In addition, product-recall coverage can be tailored to a company's specific concerns, such as "malicious tampering" situations (the Tylenol case).

D&O

Lastly, product recalls may implicate coverage under Directors' and Officers' liability insurance, to the extent a recall can be tied, or allegedly is tied, to decisions at the corporate level. Similarly, where a recall results in a drop in company value, shareholders may assert claims against corporate management triggering defense and/or indemnity under various aspects of the D&O policy.

Potential coverage issues

The seemingly endless series of lead-related product recalls inevitably will lead to product makers, distributors, and retailers turning to their insurance companies for recovery of alleged property losses stemming from the recall, as well as a defense to and indemnification for the anticipated lawsuits.

Issues Under First-Party Property Coverages

First-party property policies typically provide coverage, pursuant to their terms, provisions, conditions and exclusions, for "direct physical loss of or damage to Covered Property at the premises.. caused by or resulting from any Covered Cause of Loss." n2 Under these property policies, a "Covered Cause of Loss" encompasses all risks that are not specifically excluded or otherwise limited under the policy. n3 Nevertheless, first-party property insurers have substantial grounds on which to reject coverage for the lead-related claims.

Inherent Vice/Latent Defect. Coverage for the lead recalls may implicate, and may be excluded by, the first-party property policy's inherent vice/latent defect exclusion. The inherent vice/latent defect exclusion typically precludes coverage for "rust, corrosion, fungus, decay, deterioration, hidden or latent defect or any quality in property that causes

it to damage or destroy itself." n4

The inherent vice/latent defect exclusion operates to bar coverage where property damage results, not from an external force, but from something inherent in the damaged property itself. The exclusion was relied upon by insurers with good success in claims seeking recovery for Y2K-related upgrades and remediation in order to avoid Y2K-related date recognition problems.

In GTE Corp. v. Allendale Mut. Ins. Co., for example, a Washington appellate court examined the inherent vice/latent defect exclusion and applied the exclusion as a bar to coverage. The court defined "inherent vice" as "any existing defects, diseases, decay or the inherent nature of the commodity which will cause it to deteriorate with a lapse of time." n5 The court further explained that "inherent vice," in an insurance contract, means a "cause of loss not covered by the policy, does not relate to an extraneous cause but to a loss entirely from internal decomposition or some quality which brings about its own injury or destruction. The vice must be inherent in the property for which recovery is sought." n6

Parallels to the GTE decision can be drawn in the case of the lead product recalls. Indeed, the problems alleged to exist with toys and other products containing lead stem not from an external force, but from the chemical composition of the products themselves. Thus, the inherent vice/latent defect exclusion should operate as a bar to coverage for lead-related claims under first-party property policies.

Defective Design. Coverage under first-party property policies may also be barred by those policies' defective design exclusions, which typically bar coverage for loss resulting from the defective design of a product. Such defective design exclusions typically preclude coverage for "[f]aulty, inadequate or defective . . . [d]esign, specifications, workmanship, repair, construction, renovation, remodeling, grading, [or] compaction." n7

Courts analyzing the defective design exclusion have applied the exclusion as a bar to coverage in situations analogous to the lead product recalls, where products have functioned as designed but nevertheless caused damage. For example, one court found, in the context of a Y2K remediation, that the exclusion applied to preclude coverage where systems performed exactly as designed, but nevertheless could not anticipate date recognition problems. n8

The failure of products containing lead to safely serve their intended purpose is similar to a financial accounting software's inability to both perform its intended financial function while recognizing dates into the next millennium. To the extent these products cannot safely serve their purpose, it may be that the products were not properly designed. If that proves to be the case, coverage will be precluded by the design defect exclusion.

Sue & Labor. In addition to affording coverage for the actual loss or destruction of property, most first-party property policies also afford coverage to the insured for amounts spent by the insured to mitigate further loss once a covered loss has occurred. This coverage is typically found in "Sue & Labor" or "protection of property" provisions. A typical Sue & Labor provision may provide as follows:

In case of actual or imminent loss or damage by a peril insured against, it shall, without prejudice to this insurance, be lawful and necessary for the Insured, their factors, servants, or assigns to sue, labor, and travel for, in, and about the defense, safeguard, and the recovery of the property or any part of the property insured hereunder; nor, in the event of loss or damage, shall the acts of the Insured or this Company in recovering, saving, and preserving the insured property be considered a waiver or an acceptance of abandonment. This Company shall contribute to the expenses so incurred according to the rate and quantity of the sum herein insured. n9

Similarly, the protection of property clause typically provides that the insured shall:

Take all reasonable steps to protect the Covered Property from further damage, and keep a record of your expenses necessary to protect the Covered Property, for consideration in the settlement of the claim. This will not increase the Limit of Insurance. However, we will not pay for any subsequent loss or damage resulting from a cause of loss that is

not a Covered Cause of Loss. Also, if feasible, set the damaged property aside and in the best possible order for examination. n10

Incumbent upon recovering under a property policy's "Sue & Labor" provision, however, is the prerequisite that the mitigated loss be a covered loss. Where the mitigated loss would not be covered, amounts spent to mitigate that loss likewise are not covered. This prerequisite stems from the fundamental purpose of Sue & Labor coverage, which is to ensure that the insured take reasonable steps to minimize the insurer's potential exposure. Where the insured does so and incurs expenses in the process, that money is recoverable from the insurer in the form of a Sue & Labor recovery. It follows, therefore, that where an insured incurs costs merely to mitigate its own potential liability, the expenses are not covered.

This distinction is illustrated in the context of the Tylenol recall. n11 In McNeilab, a federal district court in New Jersey refused to permit a Sue & Labor-type recovery for amounts spent recalling the Extra Strength Tylenol. n12 McNeilab claimed that the recall costs were covered under its liability insurance policy because the recall mitigated the insurer's exposure for a liability that would have resulted from the tainted drug had it not been recalled. n13 The district court rejected McNeilab's argument, finding that McNeilab was under a duty to recall the drug and that had it refused to recall the drug, the refusal would have been intentional conduct, which is not insurable. The court concluded, therefore, that the benefit of the recall inured to the insured by minimizing its own uninsurable liability. Consequently, the cost of the recall was unrecoverable. n14

McNeilab is consistent with decisions applying Sue & Labor and protection of property provisions under first-party property policies. For example, in White Star S.S. Co. v. N. British & Mercantile Ins. Co., n15 the court held that the purpose of the "protection of property" provision is twofold, stating that the purpose of such clauses:

. . . is to encourage and bind the assured to take steps to prevent a threatened loss for which the underwriter would be liable if it occurred, and when a loss does occur to take steps to diminish the amount of the loss. n16

That purpose has not changed. n17 Thus, in order for there to be coverage for the cost of mitigating a loss resulting from the recall of lead laden toys, the loss must be one that is covered under the policy. n18 Consistent with that purpose, where the loss is not covered under the policy, there can be no coverage for amounts spent by the policyholder to mitigate that loss.

As McNeilab and the other cases addressing "Sue & Labor" and "protection of property" provisions demonstrate, the purpose and requirements of the "Sue & Labor" and "protection of property" provisions will likely prohibit coverage for the mitigation of losses arising out of the recent lead recalls. This should be the case because, as illustrated above, there has been no actual physical damage to the recalled product. Rather, to the extent the products are unsafe, that condition likely stems from the design of the product itself or some other inherent vice. Any steps taken by the product manufacturers to mitigate potential loss therefore stands to benefit the manufacturer, not its insurer. Consequently, the cost of those steps cannot be covered.

Economic Losses. Product manufacturers may also seek first-party coverage for so-called "economic losses" stemming from the recalls, such as claims for lost profits or a loss of market value. These losses may be alleged to have been caused by actual damage to the property n19 or merely by the perceived diminution in a product's market appeal, or stigma. n20 These economic losses are generally not recoverable, however, because they are intangible damages that do not constitute or flow directly from the physical loss or damage to tangible property. n21

Issues Under Third-Party General Liability Coverages

With the list of lead laden products subject to recall growing, the number of lead-related injuries allegedly caused by these products is expected to be significant. Insurers, therefore, should expect to see a significant number of claims under third-party liability coverages arising out of the lead product recalls.

General liability insurance typically covers "those sums an insured becomes legally obligated to pay as damages because of 'bodily injury' or 'property damage'" sustained by a third-party. n22 Incorporated into the general liability policy are, among other things, the concepts of "direct loss" and "proximate cause" meaning that a third-party claimant must prove that the insured is legally responsible to the claimant's direct losses. n23 Just as in the first-party context, there are a number of reasons why claims arising out of the lead product recalls may not be covered under contracts for third-party liability insurance.

No Occurrence. Lead product recall claims must allege an "occurrence" in order to implicate coverage under third-party liability policies. General liability policies, typically define an "occurrence" as an "accident, including continuous or repeated exposure to substantially the same generally harmful conditions." n24 Thus, in order to invoke coverage under a general liability policy, there must be an alleged "accident." n25

Unlike the term "occurrence," however, the term "accident" is undefined in most general liability policies. Courts, therefore, have afforded the term its plain and ordinary meaning and defined the term, as it is used in the definition of an "occurrence," as an unexpected or unintended event. n26 In the context of lead product claims, the issue turns on whether the injuries allegedly resulting from the use of these products were unexpected and unintended.

Although manufacturers and distributors will attempt to argue that the injuries giving rise to these claims were unexpected and unintended, the argument may fail. Indeed, for decades, manufactures have known of the potentially harmful side effects from exposure to lead. Further, it is entirely likely that manufacturers knew or should have known that certain of their products, or components used in their products, contained unsafe levels of lead.

In contrast, many general liability policies support the existence of an "occurrence" where the injury is the result of a "continuous or repeated exposure to substantially the same general harmful conditions." In the context of a lead product exposure claim, allegations of injury or harm resulting from a continuous or repeated use of or exposure to the product containing lead may therefore constitute an "occurrence." Still, however, the continuous or repeated exposure must not be expected or intended (i.e., it still must be an "accident"). Countervailing arguments, therefore, still exist.

In addition to raising issues as to whether an "occurrence" exists at all, exposure to lead in the recently recalled products raises significant issues regarding the number of occurrences that might exist. For instance, does each recalled product or each exposure constitute a separate occurrence? This issue, which is largely dependent both upon the specific wording of each insurance contract and applicable state law, could have a substantial impact on an insurer's potential exposure for lead product related claims. This, in turn, underscores the need for a proper and thorough choice-of-law analysis prior to initiating any coverage litigation.

Known Loss And The Fortuity Doctrine. Coverage for lead product-related injuries also may be barred by the fortuity doctrine. The doctrine operates to preclude coverage for losses that were either in progress or known to have existed prior to the inception of the insurance policy. n27 The doctrine is premised on the fact that insurance policies are contracts based upon some contingency or act to occur in the future.

This issue was discussed by the Fifth Circuit Court of Appeals in RLI Ins. Co. v. Maxxon Southwest, Inc., where the court held that coverage cannot exist for claims that the insured reasonably should have expected to result from its years of alleged price fixing and manipulation. n28 In RLI, the court explained that "insurance coverage is precluded where the insured is or should be aware of an ongoing progressive or known loss at the time the policy is purchased." n29 The RLI court, therefore, court granted summary judgment for the insurer after concluding that the insured should have expected that its actions prior to the policy period might give rise to liability during the policy period. n30

A strong parallel can be drawn to claims resulting from the marketing and sale of products containing lead long after the relevant scientific and trade communities recognized and, indeed accepted, the potential hazards associated with exposure to lead. If this is proven to be true, it may be that the manufacturers of the recalled products sufficiently knew or objectively should have known about the potential harm that could result prior to the effective date of coverage,

thereby rendering any resulting loss non fortuitous.

Damages. Coverage also may be limited if not altogether precluded under third-party liability policies to the extent that claims resulting from exposure to lead in the recalled products do not seek recovery because of "bodily injury" or do not seek legal "damages." These limitations are born out of the contract language itself, which typically provides, that the insurer only "will pay those sums that the insured becomes legally obligated to pay as damages because of 'bodily injury'. . . ." n31

This issue is likely to arise most often in cases where claimants are seeking an award of money for future medical monitoring. Indeed, prior experience in lead paint and other lead-related litigation suggests that a number of lead product claimants will seek recovery not only for actual and future medical costs arising from injuries allegedly sustained as the result of exposure to lead, but they are also will seek amounts for testing to detect injuries that have not yet manifested but which might manifest in the future. n32 The recovery of these so-called "medical monitoring" costs can be quite costly to defendants and their insurers, since medical monitoring often involves monitoring a large number of individuals over an extended period of time.

Central to determining whether medical monitoring costs constitute covered damages is whether the amounts sought are because of "bodily injury" or "property damage." Similarly, whether the amounts constitute covered damages will turn on whether the amounts are viewed as compensation for past injury or merely just preventative of future injury. n33 While amounts for the former purpose generally are considered covered "damages," amounts paid for the latter typically are not. n34

In HPF v. General Star Indem. Co., for example, the plaintiffs sought coverage for medical monitoring costs of all persons who used HPF's herbal Phen-Fen products. n35 The Illinois Appellate Court reversed a finding of coverage after concluding that the claim for medical monitoring costs did not constitute a suit because of "bodily injury" or "property damage." n36 Rather, the court viewed the costs of medical monitoring as nothing more than a "prayer for relief" designed to examine the product's effect. n37

As with requests for medical monitoring costs in the context of Phen-Fen, requests for medical monitoring arising out of products containing lead also should be barred, since the amounts are not because of actual "bodily injury" or "property damage" but, rather, they are merely prophylactic against future possible injury, which has not yet occurred and, in fact, may never occur. n38 Medical monitoring costs, therefore, do not likely constitute covered damages.

Advertising Injury. Policyholders may also contend that lead product recall claims implicate personal and advertising injury coverage to the extent that the lead product claims allege a failure to adequately warn consumers of the products' lead content or potentially harmful side effects. Such a contention would likely be erroneous.

General liability policies typically provide coverage for "damages because of 'personal and advertising injury'." However, "personal and advertising injury" coverage is very narrow, and typically affords coverage only for certain enumerated offenses, including:

* * *

a. False arrest, detention or imprisonment;

b. Malicious prosecution;

c. The wrongful eviction from, wrongful entry into, or invasion of the right of private occupancy of a room, dwelling or premises that a person occupies, committed by or on behalf of its owner, landlord or lessor;

d. Oral or written publication of material that slanders or libels a person or organization or disparages a person's or organization's goods, products or services;

e. Oral or written publication of material that violates a person's right of privacy;

f. The use of another's advertising idea in your "advertisement"; or

g. Infringing upon another's copyright, trade dress or slogan in "advertisement". n39

* * *

The narrowly tailored definition of "personal and advertising injury" does not include coverage for damages related to failures to adequately warn of a product's harmful effects. Therefore, a typical general liability policy's "personal and advertising injury" coverage should provide no coverage for lead product claims.

Business Risk Exclusions. General liability policies also contain certain exclusions which specifically bar coverage for damage to the insured's work or product. These "your product" and "your work" exclusions are often referred to as "business risk" exclusions and, as the name suggests, may operate to bar coverage for recall-related claims where the damage is limited to the recalled product.

The purpose of the "business risks" exclusions is to protect insurers from becoming guarantors or sureties of their insureds' products. n40 For that reason, the exclusions make clear that there can be no coverage where the claimed injury or damage is the result of the insured's faulty product. n41 In contrast, general liability policies often provide coverage for loss falling within the Products-Completed Operations Hazard -- a policy definition that segregates claims arising out of an insured's product or work, but which is distinct from damage to that product or work. General liability policies that afford coverage for claims within the Products-Competed Operations hazard often do so pursuant to a policy sub limit or aggregate limit. On the other hand, some policies specifically exclude coverage for claims meeting the Products-Completed Operations Hazard definition. In these instances, courts have applied the same broad construction to the scope of the excluded claims as they have to the scope of claims included within the Hazard. n42

Sistership Exclusion. General liability policies also contain an exclusion (exclusion "n"), also called the "sistership exclusion, which specifically bars coverage for recalls. The exclusion provides that coverage is barred for:

"Damages claimed by you or others for the loss of use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal of:

(1) "your product";

(2) "your work";or

(3) "impaired property,

if such product, work or property is withdrawn or recalled from the market of from use by any person or organization because of a known or suspected defect, deficiency, inadequacy or dangerous condition in it.

But, the "sistership" exclusion bars coverage only for the costs incurred when a policyholder recalls a product that, it is suspected, may cause injury or damage. As one court observed:

The sistership clause was developed to protect insurers against liability for the cost of recalls. The clause's name, in fact, reflects this purpose. Following an accident involving a defective airplane, the airplane manufacturer became obligated to recall the airplane's sisterships in order to correct the common defect that caused the crash of the first airplane. Insurance companies . . . developed the "sistership" clause to make clear that, while they intended to pay for damages caused by a product that failed, they did not intend to pay for the costs of recalling products containing a similar defect that had not yet failed. n43

Similarly, the sistership exclusion does not bar coverage where the policyholder has not withdrawn the product and

its product has caused damage to the property of others:

The effect of . . . [the sistership exclusion] is to exclude claims for damages caused by the purchaser's withdrawal of the insured's products from use due to a deficiency in them. Such a result does not affect other possible instances of product liability, such as those in which damage occurs to a person, or to property other than the product of the insured itself. n44

Courts construing the sistership exclusion have held that the exclusion has two general requirements: (1) the withdrawal must be made by the policyholder, and (2) the withdrawal must take place before actual injury or damage arises. In Stonewall Insurance Co. v. Asbestos Claims Management Corp., for instance, a federal appeals court found that the sistership exclusion did not apply under New York and Texas law because the policyholder had "not itself withdrawn or removed its products from the market." n45 The court also held that the exclusion did not apply because property other than the policyholder's product had been damaged. n46

In contrast, the sistership exclusion has been applied to preclude coverage for classic product recalls. For example, in McNeilab, the court relied on the exclusion, in part, to deny coverage for the Tylenol recall. n47 Similarly, an Ohio appellate court held that the exclusion would bar coverage for the costs associated with the recall of cookie mix containing packets of spoiled peanut butter, even though the peanut butter had not damaged the cookie mix in any way. n48

Recall Coverage

In recent years, more insurers have entered the market with specially crafted product recall coverages, either as stand-alone policies or as endorsements to other coverage lines. Although available since the 1980s, however, may companies have chosen to forgo such coverage. Why? Perhaps because these insureds believe the risk of recall is too small, or perhaps they feel their R&D efforts are too strong for a recall to ever become necessary, or perhaps they feel the premium associated with the coverage is too high. Whatever the reason, courts are cognizant of the availability of such coverage, and have noted that where an insured consciously chooses to forgo such coverage, it should not expect recovery for recall related expenses. This was seen in the Tylenol coverage litigation, where the district court commented that "Johnson & Johnson, which at one time carried recall coverage, knew such coverage could be purchased, elected not to purchase it because the cost was prohibitive, and now claims that it enjoys recall coverage anyway. n49

What Does Recall Coverage Cover?

Accidental Contamination or impairment of the insured's product during production or distribution

Product Tampering (such as the Tylenol tampering of the 1980s)

Product Extortion, such as the threat to commit product tampering in order to extort monies from manufacturers or distributors

Recall Costs, which may include the costs of advertising, transportation, employee overtime, costs to suppliers, distributors and retailers, and costs to destroy the recalled product.

Consultant and Expert Fees incurred in connection with the recall decision and logistical planning

Lost Profits for certain periods of time resulting from the recall

Product Restoration & Rehabilitation Costs incurred after the recall in order to restore the insured company's reputation and market share Possible Coverage Issues

What Losses Are Covered?

Questions may arise as to what constitutes a covered "recall." This issue arose in the Sokol litigation, where the court held that coverage would not be available under a product recall endorsement to the insured's CGL policy because the recall was initiated by a third party, not the insured or a government entity, as the policy terms required. n50

Questions may also arise concerning the nature of the problem with the product -- some being covered and others not.

What Costs Are Covered?

Costs must be reasonable

May be limited by time or amount

Costs limited to particular activities or purposes -- some of which are less clear than others, such as rehabilitation of reputation -- may require scrutiny

Who Is The Insured?

Is coverage limited to the policyholder, or do certain "downstream" entities also qualify?

Impaired Property

Does coverage extend to instances where the defective product is incorporated into the product of a third party?

Does it matter that the defective product is not removable? Loss Mitigation

Insured must exercise due care and diligence

Overlap With Other Coverages

Which coverage is "primary"?

What are the "other insurance" implications?

What are the additional insured implications?

Directors & Officers Liability Coverage

In addition to property and casualty coverages, Directors and Officers liability coverage also may be implicated by the lead product recalls.

Shareholders in large companies don't like to see their products being recalled. It's not good for profits. This was the case following the announcement of the Vioxx recall, where Merck's shares plunged 27 percent from $45 to a low of $30. n51 This drop in share price translated into $32 billion in shareholder losses. n52 As a result of the shareholder losses, two shareholder suits were filed within weeks of the recall. One case was filed on behalf of stockholders, while the other case was filed on behalf of 39,000 Merck employees holding company stock in their 401(k) plans. n53 Both suits stood to implicate Merk's D&O coverage.

D&O policies generally provide coverage for "Loss" arising from "Claims" made within the policy period for "Wrongful Acts" committed by directors and officers. In addition to the terms, conditions, provisions and exclusions contained in the policy, D&O insurance is subject to statutory authorization that prohibits coverage for willful or intentional wrongdoing, fraud or knowing violation of law. n54

Modern D&O policies typically provide three separate coverages within one policy. The first coverage, Insuring

Agreement A, reimburses the individual directors and officers for losses for which they are not indemnified by their corporation. The second coverage, Insuring Agreement B, reimburses the corporation for amounts which it is lawfully permitted or required to expend in indemnifying its officers and directors for their losses. And the third coverage, Insuring Agreement C, provides coverage for claims made against the organization as a result of wrongful acts committed or allegedly committed by the organization's directors, officers or other insured individuals.

Under today's securities laws, manufacturers of recalled products may be liable to their shareholders and other investors for failing to provide full and accurate disclosure of "material information" regarding the recalled products or the processes leading to the recall. It follows, then, that the continuing onslaught of lead product related recalls may also invoke coverage from directors and officers policies in addition to traditional first and third-party coverages.

Conclusion

There are many more issues likely to arise under contracts for insurance as a result of the lead product recalls. Only time and the language of the insurance contracts will dictate how they play out.

Return to Text

n1 . *McNeilab v. North River Ins. Co., 645 F.Supp. 525, 528 (D.N.J. 1986).*

n2

[2]. International Organization for Standardization (ISO) Form BP 00 02 12 99, Business Owners Special Property Manual (following this link will bring you to a search box for the ISO Forms, simply copy and paste the form number into the box to view the desired form).

n3

[3]. See id.

n4

[4]. International Organization for Standardization (ISO) Form BP 00 02 12 99, Business Owners Special Property Manual (following this link will bring you to a search box for the ISO Forms, simply copy and paste the form number into the box to view the desired form)..

n5

[5]. *GTE Corp. v. Allendale Mut. Ins. Co., 372 F.3d 598, 611 (3d Cir. 2004)* (quoting *Port of Seattle v. Lexington Ins. Co., 48 P.3d 334 (Wash. Ct. App. 2002).*

n6

[6]. Id. at 611.

n7

[7]. International Organization for Standardization (ISO) Form BP 00 02 12 99, Business Owners Special Property Manual (following this link will bring you to a search box for the ISO Forms, simply copy and paste the form number into the box to view the desired form)..

n8

[8]. *GTE Corp., 372 F.3d at 609.*

n9

[9]. *Id. at 608.*

n10

[10]. International Organization for Standardization (ISO) Form BP 00 02 12 99, Business Owners Special Property Manual (following this link will bring you to a search box for the ISO Forms, simply copy and paste the form number into the box to view the desired form).

n11

[11]. *McNeilab, Inc. v. N. River Ins. Co., 645 F. Supp. 525 (D. N.J. 1986),* aff'd, *831 F.2d 287 (3d Cir. 1987)* (affirming trial court holding without opinion).

n12

[12]. *Id. at 553.*

n13

[13]. Although McNeilab involved a liability insurance policy, which typically does not contain a Sue & Labor or protection of property provision, the court addressed the concept of Sue & Labor recovery under common law principles.

n14

[14]. Id. (holding that Sue & Labor recovery only is available where the mitigation of loss benefits the insurer).

n15

[15]. *White Star S.S. Co. v. N. British & Mercantile Ins. Co., 48 F. Supp. 808 (E.D. Mich. 1943).*

n16

[16]. *Id. at 813* (emphasis added); see also *Reliance Ins. Co. v. The Yacht Escapade, 280 F.2d 482, 488, n.11 (5th Cir. 1960)* (assured's obligation to mitigate loss is keyed to the existence of liability on the underwriter for the loss).

n17

[17]. E.g., *Wolstein v. Yorkshire Ins. Co., Ltd., 985 P.2d 400, 410-11 (Wash. Ct. App. 1999)* (purpose of the "Sue & Labor" clause remains to reimburse expenses incurred for the benefit of the insurer in mitigating a covered loss; but there is no benefit to the insurer in mitigating a loss that is not covered under the policy).

n18

[18]. Id.

n19

[19]. E.g., *Auto-Owners Ins. Co. v. Carl Brazell Builders, Inc., 588 S.E.2d 112, 113 (S.C. 2003)* (homeowners claimed that contaminants from aerial bombing practice during World War II caused a loss of market value).

n20

[20]. E.g., *Siegle v. Progressive Consumers Ins. Co., 819 So. 2d 732, 736 (Fla. 2002)* (plaintiff sought recovery for "loss due to a 'stigma on resale resulting from market psychology'").

n21

[21]. *White v. Mock, 2004 Ida. LEXIS 134* (Idaho, July 7, 2004); *Auto-Owners Ins. Co., 588 S.E.2d at 116* (finding that the diminished value of tangible property does not constitute property damage within the meaning of a general liability which defines property damage as physical injury).

n22

[22]. International Organization for Standardization (ISO) Form CG 00 01 07 98, Commercial General Liability Coverage Form (following this link will bring you to a search box for the ISO Forms, simply copy and paste the form number into the box to view the desired form).

n23

[23]. *Kemmerer v. State Farm Ins. Co., 2004 U.S. Dist. LEXIS 2645,* *8 -- *13 (E.D. Pa., Jan. 16, 2004) (coverage precluded for a personal property damage claim where the insured failed to rebut the insurer's expert report, which suggested there were many sources of mold growth, including non-covered sources).

n24

[24]. International Organization for Standardization (ISO) Form CG 00 01 07 98, Commercial General Liability Coverage Form (following this link will bring you to a search box for the ISO Forms, simply copy and paste the form number into the box to view the desired form).

n25

[25]. *Erie Ins. Exch. v. Colony Dev. Corp., 2003 Ohio 7232, P31 -- P33, 2003 Ohio App. LEXIS 6518,* **15-**16 (Ohio Ct. App. Dec. 31, 2003).

n26

[26]. *Westfield Nat. Ins. Co. v. Cont'l Cmty. Bank & Trust Co., 804 N.E.2d 601, 605* (Ill. App. Ct. Dec. 23, 2003); *Nas Sur. Group v. Precision Wood Prod., Inc., 271 F. Supp.2d 776, 781 n.4 (M.D.N.C. 2003).*

n27

[27]. Richard L. Fruehauf, The Cost of Knowledge: Making Sense of "Nonfortuity" Defenses in Environmental Liability Insurance Coverage Disputes, *84 Va. L. Rev. 107 (1998).*

n28

[28]. *RLI Ins. Co. v. Maxxon Southwest, Inc., No. 03-10660, 2004 U.S. App. LEXIS 18500* *9 (5th Cir. Sept. 1, 2004).

n29

[29]. Id.

n30

[30]. Id.

n31

[31]. Barnaby J. Feder, Vioxx Recall May Bring Flood of Suits to Merck, N.Y. Times, Oct. 5, 2004.

n32

[32]. Missouri Woman Sues Vioxx Maker for Daughter's Death, Assoc. Press State & Local Wire, Oct. 3, 2004.

n33

[33]. *Braswell v. Faircloth, 387 S.E.2d 707, 710 (S.C. Ct. App. 1989)* (finding that removal costs are preventative in nature and not covered by a general liability policy).

n34

[34]. *Cincinnati Ins. Co. v. Milliken and Co., 857 F.2d 979, 980-981 (4th Cir. 1988)* (finding that general liability policies do not cover equitable relief and that the term "damages" in a general liability policy means legal damages).

n35

[35]. *HPF, L.L.C. v. General Star Indem. Co., 788 N.E.2d 753 (Ill. Ct. App. 2003).*

n36

[36]. See *id. at 758* (citing *Crawford Lab., Inc. v. St. Paul Ins. Co., 715 N.E.2d 653 (Ill. Ct. App. 1999).*

n37

[37]. Id.

n38

[38]. *Ellett Bros., Inc. v. U.S. Fid. & Guar. Co., 275 F.3d 384, 387-388 (4th Cir. 2001).*

n39

[39]. Barnaby J. Feder, Vioxx Recall May Bring Flood of Suits to Merck, N.Y. Times, Oct. 5, 2004.

n40

[40]. *Hartford Accident & Indem. Co. v. A.P. Reale & Sons, Inc., 644 N.Y.S.2d 442, 443 (N.Y. 1996); Zandri Constr. Co., Inc. v. Firemen's Ins. Co., 440 N.Y.S.2d 353, 355 (N.Y. 1981).*

n41

[41]. *Id. at 355.*

n42

[42]. See e.g., *Beretta U.S.A. Corp. v. Federal Ins. Co., No. 00-2387, 17 Fed. Appx. 250,* *254, *2001 U.S. App. LEXIS 19798,* **9 (4th Cir. Sept. 6, 2001); *Brazas Sporting Arms, Inc. v. American Empire Lines Ins. Co., 220 F.3d 1 (1st Cir. 2000).*

n43

[43]. *Forest City Dillon, Inc. v. Aetna Cas. & Sur. Co., 852 F.2d 168, 173 (6th Cir. 1988).*

n44

[44]. *Commercial Union Assurance Co. v. Glass-Lined Pipe Co., 372 So.2d 1305, 1309 (Ala. 1979).*

n45

[45]. *73 F.3d 1178, 1211 (2d Cir. 1995),* modified, *85 F.3d 49 (2nd Cir. 1996).*

n46

[46]. *73 F.3d at 1211.*

n47

[47]. *645 F.Supp. 525, 540 (D.N.J. 1986),* aff'd without opinion, *831 F.2d 287 (3rd Cir. 1987).*

n48

[48]. *Sokol and Co. v. Atlantic Mut. Ins. Co., 430 F.3d 417, 424 (7th Cir. 2005)* (applying Illinois law).

n49

[49]. *McNeilab, 645 F.Supp. at 528.*

n50

[50]. See *Sokol, 430 F.3d 417, 424.*

n51

[51]. Barnaby J. Feder, Vioxx Recall May Bring Flood of Suits to Merck, N.Y. Times, Oct. 5, 2004.

n52

[52]. Tim O'Brien, Vioxx Becomes a Class Act, N.J.L.J., Oct. 19, 2004.

n53

[53]. Id.

n54

[54]. E.g., Cal. Ins. Code § 533 (2004); Cal. Civ. Code § 1668 (2004); *Allstate Ins. Co. v. Hansten, 765 F. Supp. 614, 616 (N.D. Cal. 1991); Boyd v. Travelers Indem. Co., No. 93-15859, 1995 U.S. App. LEXIS 321* at *5 (9th Cir. Jan. 6, 1995); *St. Paul Fire & Marine Ins. Co. v. Weiner, 606 F.2d 864, 870 (9th Cir. 1979); Eglin Nat'l Bank v. Home Indem. Co., 583 F.2d 1281, 1284 (5th Cir. 1978); Cmty Nat'l Bank v. Fid. & Deposit Co., 563 F.2d 1319 (9th Cir. 1977).*

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Michael S. Levine is a senior associate in the McLean, Virginia office of Hunton & Williams LLP, where he is a member of the firms insurance and reinsurance practice group. Mr. Levine regularly represents and counsels insurers and reinsurers in connection with complex insurance coverage and extra-contractual disputes. The opinions expressed in this article are solely those of the author and may not necessarily reflect those of Hunton & Williams or its clients.

17 of 21 DOCUMENTS



***Tainted Toys from China: Keeping Prod. Liability Litigation Inside U.S. Borders***

*2008 Emerging Issues 1701*

Carboy on Tainted Toys from China: Keeping Products Liability Litigation Inside U.S. Borders

By Andrew J. Carboy

December 28, 2007

**SUMMARY:** For product liability attorneys, the difficulties began immediately when they learned of virtually insurmountable barriers to reaching Chinese defendants through the courts in China. Prominent attorney Andrew Carboy addresses these hurdles and recommends pursuing Chinese toy recall litigation in the U.S. courts by focusing on the domestic importers, wholesalers, and retailers of the tainted toys.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE:** The Year of the Recall. Product liability attorneys will remember 2007 for its waves of imported toy recalls. By October 2007, excluding the recall of 1.5 million "Thomas the Train" toys, n1 at least 1.7 million items, decorated or coated with lead paint, were pulled from retail shelves. n2 Most of these toys originated in China. Parents' fears ratcheted higher on November 7th, when the United States Consumer Product Safety Commission ("CPSC") announced a recall of 4.2 million units of a hit toy known as "Aqua Dots." Unlike the millions of other Chinese toys targeted earlier, Aqua Dots, small plastic beads that fuse when moistened, contained not lead paint, but a powerful toxin. The CPSC explained, "the coating on the beads that causes the beads to stick to each other when water is added contains a chemical that can turn toxic when many are ingested. Children who swallow the beads can become comatose, develop respiratory depression, or have seizures." n3

In 2006, China exported a staggering 22 billion toys, or 60% of the world's total. n4 Errors in manufacturing on this scale reverberate across the globe. The influx of millions of toys, manufactured abroad and contaminated with lead or other toxins, is a threat that needs to be addressed meaningfully.

The outlook for protection of children from lead hazards in toys is especially troubling when one considers the tremendous progress the United States realized in its three-decade war on lead contamination. Lead is capable of causing a variety of injuries. n5 In 1977, the CPSC issued a final ban on "lead-containing paint and on toys and furniture coated with such paint." n6 In 1995, the Food and Drug Administration banned lead solder from canning. In 1996, after years of increasing restriction, lead was banned from most U.S. gasoline. Lead emissions in American motor vehicles plummeted to 4.8 million pounds in 1989 from 208 million pounds in 1979. The average American blood lead level declined from 12.8 ug/dL in 1976 to 2.8 ug/dL in 1991.

The responses to date from the United States and Chinese governments to this significant and still emerging crisis

do little to reassure consumers who may recognize it as the biggest setback in this nation's campaign against lead hazards.

This fall, at the peak of the latest round of toy recalls, the CPSC, the watchdog agency entrusted with consumer protection, actually fought Congressional efforts to increase its budget, staff, and enforcement powers. At the same time, skepticism remains regarding the efforts of the Chinese government to improve toy safety and quality control as its recent corrective efforts are followed by additional recalls.

On October 24th, Nancy A. Nord, Acting Chairman of the CPSC, wrote to the Senate Committee on Commerce to oppose legislation, drafted in the context of the lead paint recalls that would: (i) strengthen enforcement of federal consumer protection laws; (ii) increase fines and impose criminal penalties for violations of those same laws; and (iii) protect whistle blowing employees of offending manufacturers. These measures, among others, wrote Chairman Nord, "could have the unintended consequence of hampering, rather than furthering, consumer product safety." n7 Chairman Nord's response prompted calls for her resignation.

One week earlier, the Chinese government announced sponsorship of "training courses for toy makers on product quality and safety." Representatives from the Ministry of Commerce, the General Administration of Quality Supervision, and local authorities from Guangdong, Jiangsu, and Anhui provinces organized the programs. "Trainees, numbering more than 2,600, came from 1,800-plus Chinese toy manufacturing enterprises, or one-fifth of the country's total." n8

The November 7th Aqua Dots recall, which eclipsed this impressive-sounding initiative, was relegated to a footnote in the American media. Moreover, the Chinese announcement seemed to blame American interests for the problem:

China has been in the spotlight amid a spate of export recalls, the recent one by the U.S. toy maker Mattel, which this summer staged three separate recalls of Chinese-made products, 87 percent of which were found to have loose magnets -- a design defect by Mattel itself -- and 13 percent of which contained excessive lead. n9

Significant Obstacles to Reaching Chinese Defendants. Given the weak responses of the governments on both sides of the Pacific, it may be tempting to view the American tort system as de facto regulation, a potentially effective means to address the threat. There are, however, several considerations to address. As U.S. District Judge Jack Weinstein has noted, in the context of class actions and the economics of bringing them, as opposed to individual claims, the primary concern of tort law is compensation and not regulation:

Punishment of defendants who cause harm and deterrence of future harmful conduct is a by-product of the traditional tort system, but it should not independently furnish the rationale for private civil litigation..Thus, while the class action is deemed procedural and distinct from substantive considerations for most purposes, it may become. . . the only practicable way to secure a remedy.

*In re Agent Orange Product Liability Litigation, 597 F. Supp. 740, 842 (E.D.N.Y. 1984).*

Moreover, as described below, the identity of the toy manufacturers is often unclear. If a plaintiff decides to bring a lawsuit concerning imported Chinese toys, does plaintiff's attorney really need to identify and track down a shadowy manufacturing concern half a world away? Having done that, and named the Chinese concern as a defendant, must the plaintiff then navigate the legal system of a country that, to some, appears unconcerned with regulation and remains hostile to foreign (U.S.) claims? In most instances, the answer would appear to be "no," thankfully.

Nevertheless, there are daunting factual and legal obstacles to pursuing a claim in the United States courts against a defendant operating in the People's Republic of China.

From a practical standpoint, it may be difficult or impossible to identify the corporate origin of a Chinese product.

There are reports of unlabelled and mislabeled products. Several different factories may produce similar items that are repackaged and sold under a single brand name in the United States. The CPSC itself, which routinely notifies the Chinese government when Chinese products are recalled from American stores, recognizes this identification problem in its official recall policy. The policy states that "many voluntary recalls announced by U.S.-based retailers and importers do not publicly identify the Chinese manufacturer. If the Commission knows the name and address of the Chinese manufacturer, the Commission will provide it with notice of the voluntary recall." n10 It is difficult to imagine such ambiguity and confusion surrounding a recall of a product manufactured anywhere in the United States or in the European Union.

The interests of the Chinese government in manufacturing cannot be overlooked either. Although divestiture makes it less true today than a decade ago, the People's Liberation Army ("PLA") owns and operates a significant number of non-military factories in China, some 8,000-10,000 at last estimate. n11 If the PLA operates the factory producing the toy at issue in the case, then the real party-in-interest is the Chinese government itself!

Of course, if and when a Chinese defendant answers and appears in a lawsuit, such confusion is fodder for a product identification defense. Establishing a company's responsibility for a particular product, usually feasible in litigation against domestic defendants, may become convoluted or, worse, may be without support altogether.

China is party to the Hague Convention on Service Abroad of Judicial and Extra-Judicial Documents in Civil and Commercial Matters. Service of legal papers, compliant with translation requirements, may be effected through the Department of Judicial Assistance and Foreign Affairs Ministry of Justice of the People's Republic of China, located in Beijing. n12

After completion of service pursuant to the Hague Convention, in and of itself a lengthy and costly process, the practitioner's headaches are just beginning. The pursuit of discovery will be expensive and perilous. China views discovery not only as an adversarial process, but as a breach of its sovereignty.

According to the Bureau of Consular Affairs of the U.S. Department of State:

Taking evidence in China for use in foreign courts is problematic. China does not recognize the right of persons to take depositions, and any effort to do so could result in the detention and/or arrest of U.S. participants. n13

The State Department continues, "China could well deem taking depositions by American attorneys or other persons in China, as a violation of China's judicial sovereignty. Such action could result in the arrest, detention, expulsion, or deportation of the American attorneys and other participants." n14 The State Department advises that use of letters rogatory in China often proves futile, with preliminary responses taking one year or more. Although the U.S. government advises that it may be useful to retain local Chinese counsel for this endeavor, it also warns:

Chinese law offices are within the jurisdiction and authority of the Ministry of Justice. Under the Ministry of Justice is the Department of Public Notaries and Lawyers, which in turn establishes the legal advisory offices at the provincial and local levels. All lawyers and public notaries in China are part of this system, and as such are employees of the State. Lawyers in the Chinese system therefore do not necessarily assume the advocacy role expected of lawyers in the United States, but rather have obligations to the State.. . n15

Fight Your Case at Home: Follow the Distribution Chain and Target Domestic Importers, Wholesalers, and Retailers. The way to navigate directly through a tort claim involving a Chinese product may very well be to steer clear of distant shores and to travel "domestically." Large, publicly traded American corporations are the beneficiaries of these cheap, unregulated imports. Traditional tort law imposes a duty of care not only upon manufacturers, but also places equivalent obligations upon the entire chain of distribution. Sharing equally in the liability of a ghostly Chinese toy manufacturer are the importers, wholesalers, and retailers, from the small town drugstore, with a single toy shelf, to so-called "big box" superstores.

These domestic defendants are no less culpable than their foreign suppliers; however, they are usually solvent, stable, and readily identified and served. The theories of liability against such defendants, including strict liability, negligence, and breaches of warranty, are well established in American tort law. Many jurisdictions have expansive consumer protection statutes enabling private causes of action.

Medical Monitoring as a Possible Remedy. Expanded tort remedies in the area of medical monitoring may present new opportunities for attorneys representing children who play with toxic imports. In recent years, courts have certified medical monitoring classes for those exposed to lead hazards. A West Virginia court certifying such a class, in claims against the operators of a smelting operation, noted lead's status "as a probable human carcinogen" and a cause of "permanent neurological effects," particularly in children. n16

Monitoring those potentially exposed to lead is appropriate, among other reasons, because the "latency..for diseases from heavy metal exposure can be decades. Waiting for such a disease to manifest before bringing a claim could create statute of limitations issues." n17 So pervasive is the concern for injury from increased lead levels in the environment that plaintiff's counsel was not required to present evidence of any individuals with increased lead levels in their blood or increased levels of any toxins in their blood during the trial of the West Virginia case, which culminated in a plaintiffs' verdict. Instead, the court permitted class counsel to present evidence consisting of measurements of toxins in the environment and the modeling of potential exposures.

At least one other jurisdiction recognizing medical monitoring for those exposed to lead rejects the need for evidence of injury or even blood lead levels. In reversing a denial of certification of a medical monitoring class (children potentially exposed to lead from another smelting plant), the Supreme Court of Missouri rejected consideration of individual issues, including:

-- age at which exposure occurred:

-- the nature of the exposure;

-- the time period over which the exposure occurred;

-- the blood lead level;

-- whether the individuals are presently suffering from any lead related injuries; and

-- whether there is any need for a particular individual to be monitored.

*Meyer ex rel. Coplin v. Fluor Corp., 220 S.W.3d 712* (Mo., 2007)

These factors were "primarily relevant to a personal injury action, not a medical monitoring claim for which there is no necessity of establishing a present physical injury." Id. "The significance and extent of toxic exposure is primarily an issue of common proof. Under this theory of liability, the individual factors identified by the circuit court are not particularly relevant because the need for monitoring is based on a common threshold of exposure." Id.

What is striking is the Court's definition of "injury" in the context of medical monitoring:

"the injury underlying a medical monitoring claim is the invasion of a legally protected interest. Just as an individual has a legally protected interest in avoiding physical injury, so too does an individual have an interest in avoiding expensive medical evaluations caused by the tortious conduct of others."

Here, the thousands of children who have been exposed to lead while playing with tainted Chinese-manufactured toys have likewise suffered an invasion of their legally protected interests, as did the plaintiffs in Meyer, and they may be entitled to seek the same remedy-medical monitoring.

Conclusion. Due to the multiple, and virtually insurmountable, problems of suing Chinese toy manufacturers in the U.S. courts, American attorneys contemplating products liability actions involving lead-tainted (or otherwise defective) Chinese-manufactured toys, should focus on bringing actions in the U.S. Courts against the American importers, wholesalers, and retailers of the Chinese-manufactured toys. Armed with evolving damage remedies and a well-established body of tort liability theories, attorneys representing children in such actions may not only realize compensation for their clients, but may also deter the influx of cheap and dangerous toys into the

United States.

Return to Text

n1 . June 2007; distributor RC2 Corp.

n2

[2]. United States Consumer Product Safety Commission.

n3

[3]. CPSC, November 7, 2007 Aqua Dots Recall Announcement.

n4

[4]. Source: Embassy of the People's Republic of China.

n5

[5]. "When absorbed into the human body, lead affects the blood, kidneys and nervous system. Lead's effects on the nervous system are particularly serious and can cause learning disabilities, hyperactivity, decreased hearing, mental retardation and possible death. Lead is particularly hazardous to children between six months and six years of age because their neurological system and organs are still developing." *In re Lead Paint Litigation, 191 N.J. 405, 414 (N.J. 2007)* citing Childhood Lead Poisoning in New Jersey: Annual Report.

n6

[6]. Press Release: CPSC Announces Final Ban on Lead Paint, September 2, 1977; see also *16 CFR 1303.4*, Banned hazardous products.

n7

[7]. October 24, 2007 letter of CPSC Chairman Nord to Hon. Daniel K. Inouye, Chairman of the Senate Committee on Commerce concerning S. 2045.

n8

[8]. October 19, 2007 announcement of the Embassy of the People's Republic of China in Washington, D.C.

n9

[9]. Id.

n10

[10]. Source: CPSC policy entitled "Chinese Government Notification of Recalls."

n11

[11]. Source: Department of Defense Annual Report of the Military Power of the People's Republic of China 2006, at p. 18, describing "extra-budget revenue of the PLA."

n12

[12]. Source: U.S. Department of State, Bureau of Consular Affairs.

n13

[13]. Source: State Department, "China Judicial Assistance," citing Diplomatic Note No. 88 dated April 14, 1988. "For a U.S. consular officer to receive or witness statements made under oath or affirmation in China in

contravention of Chinese law would not conform to the provisions of the U.S.-China bilateral consular convention." It must be noted, however, that the State Department also explains, "China deposited its instruments of accession to the Hague Evidence Convention December 8, 1997. The United States declared its acceptance of China's accession to the Convention in June 1998. The Convention entered into force between the United States and the PRC in August 1998. The United States is seeking clarification from the Government of the People's Republic of China concerning how the Hague Evidence Convention will be applied in China." http://travel.state.gov/law/info/judicial/judicial_694.html.

n14

[14]. http://travel.state.gov/law/info/judicial/judicial_694.html

n15

[15]. http://travel.state.gov/law/info/judicial/judicial_694.html

n16

[16]. Perrine, et al. v. E.I. DuPont De Nemours and Company, et al., in the Circuit Court of Harrison County, West Virginia 04-C-296-2.

n17

[17]. Id.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Andrew J. Carboy is a member of Sullivan Papain Block McGrath & Cannavo P.C., a New York City plaintiffs firm practicing in all areas of tort law. He has served or serves as plaintiffs counsel in the World Trade Center Disaster Site Litigation, prosecuting claims for respiratory illnesses sustained by hundreds of rescue and recovery workers; litigation against the Port Authority arising from New York Citys first terrorist incident, the 1993 World Trade Center bombing; and the New York Hemophilia litigation. He also represents plaintiffs in a variety of environmental contamination cases, including a 2006 lawsuit brought on behalf of over 700 members of a New Jersey Native American community against Ford Motor Company, and an action brought by a Long Island school district for damages resulting from a gasoline spill. Mr. Carboys representation also involves cases of defective drugs, medical devices, and other products. He can be contacted at ACarboy@triallaw1.com or through his firms website, http://www.triallaw1.com/intro.jsp.

*Information referenced herein is provided for educational purposes only. For legal advice applicable to the facts of your particular situation, you should obtain the services of a qualified attorney licensed to practice law in your state.*





***Clifford on In Re Tobacco Cases II***

*2008 Emerging Issues 1660*

Clifford on In Re Tobacco Cases II

By Robert C. Clifford

December 20, 2007

**SUMMARY:** *In re Tobacco Cases II, 41 Cal. 4th 1257 (Cal. 2007)* considered the issue of whether the Federal Cigarette Labeling Act *(15 USCS § 1331* et seq.) preempted plaintiffs Cal Bus & Prof Code § 17200 unfair competition lawsuit against certain cigarette manufacturers. *Overruling Mangini v. R.J. Reynolds Tobacco Co., 7 Cal. 4th 1057 (Cal. 1994),* the California Supreme Court held that the Cigarette Labeling Act did indeed preempt the action.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE:** *INTRODUCTION. In re Tobacco Cases II, 41 Cal. 4th 1257 (Cal. 2007)* considered the issue of federal preemption of state law. Federal preemption is derived from the Supremacy Clause, article VI of the U.S. Constitution. The Clause specifically grants Congress the power to pass legislation that preempts (i.e., supercedes) state and local laws addressing the same subject matter. In other words, the doctrine precludes a state from enacting a law inconsistent with a federal law.

The California Supreme Court in In re Tobacco Cases II noted that the United States Supreme Court has explained that federal preemption arises in three circumstances: First, Congress can define explicitly the extent to which its enactments preempt state law. Preemption fundamentally is a question of Congressional intent, and when Congress has made its intent known through explicit statutory language, the courts' task is an easy one. Second, in the absence of explicit statutory language, state law is preempted where it regulates conduct in a field that Congress intended the federal government to occupy exclusively. Finally, state law is pre-empted to the extent that it actually conflicts with federal law. *In re Tobacco Cases II, 41 Cal. 4th 1257, 1265 (Cal. 2007).*

ANALYSIS. The federal statute at issue here was the Cigarette Labeling and Advertising Act (*15 USCS § 1331* et seq.), which requires tobacco companies to include warnings about the dangers of tobacco use on their cigarette packages. Significantly, the Act also contains explicit preemption language: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter." (*15 USCS § 1334(b).*)

In In re Tobacco Cases II, plaintiffs brought a class action lawsuit against certain tobacco companies, alleging that the companies had violated California's Unfair Competition Law (UCL) (Cal Bus & Prof Code § 17200, et seq.) and Cal Pen Code § 308 by devising and displaying cigarette advertisements that encouraged minors to smoke. The tobacco

companies opposed the lawsuit and contended that the federal Cigarette Labeling and Advertising Act (*15 USCS § 1331* et seq.) preempted the lawsuit.

I. Unfair Competition Law Backround

The UCL authorizes civil suits for "unfair competition" (Cal Bus & Prof Code § 17204) which it defines to include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising. It governs anti-competitive business practices as well as injuries to consumers, and has as a major purpose the preservation of fair business competition. The principal prong in the test to determine if the unfair competition law is applicable is whether the defendant engaged in a business act or practice consisting of ether (a) an unlawful act or practice, or (b) a fraudulent act or practice, or (c) an unfair act or practice, or (d) unfair or false advertising, that caused the plaintiff to suffer injury in fact. (See 1-2 MB Practice Guide: CA Unfair Comp & Bus Torts 2.04.)

II. Court's Preemption Evaluation

The California Supreme Court noted that the plaintiffs were essentially seeking to impose on the defendant tobacco companies a duty not to advertise in a way that could encourage minors to smoke. The Court further noted that the duty plaintiffs were seeking to impose necessarily and inherently was based upon concerns about smoking and health. Consequently, plaintiff's unfair competition action would be preempted by the Federal Cigarette Labeling Act pursuant to the U.S. Supreme Court's decision in *Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (U.S. 2001),* unless it fell within an exception recognized by Lorillard. Significantly, Lorillard noted that " . . . the State may prohibit inchoate offenses that attach to criminal conduct, such as solicitation, conspiracy, and attempt." *In re Tobacco Cases II, 41 Cal. 4th 1257, 1274 (Cal. 2007)* citing *Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 552 (U.S. 2001).*

Here, the plaintiffs alleged that defendant's advertisements were aimed at minors and encouraged the minors to obtain cigarettes in violation of Cal Pen Code § 308, which prohibits selling or otherwise furnishing tobacco to minors. Although the Court observed that when enacted in 1891, Cal Pen Code § 308 was not based on health concerns, but rather on concerns about immoral activities. However, the Court further noted that the legislative history of recent amendments to that statute demonstrates that it is now unquestionably based in large part, if not entirely, on health concerns. Recent legislative hearings detailed major health problems caused by youth smoking as justification for stiffening penalties for minor purchases. *In re Tobacco Cases II, 41 Cal. 4th 1257, 1273 (Cal. 2007).* Consequently, the scales tipped in favor of preemption.

Furthermore, the Court concluded that classifying the defendant's legal advertisements as aiding and abetting a criminal violation of Cal Pen Code § 308 would run afoul of First Amendment protection for commercial speech. *In re Tobacco Cases II, 41 Cal. 4th 1257, 1275 (Cal. 2007).* Therefore, plaintiffs failed to establish that their UCL action fell within Lorilard's criminal conduct exception and plaintiffs could not escape the Federal Cigarette Labeling and Advertising Act's preemptive force.

CONCLUSION. Significantly, the California Supreme Court found that "the unfair competition law is a law of general application and it is not based on concerns about smoking and health." *In re Tobacco Cases II, 41 Cal. 4th 1257, 1272 (Cal. 2007).* The fatal component to the plaintiffs' UCL claim was the plaintiffs' reliance on the defendants' purported aiding and abetting violations of Cal Pen Code § 308. The Court went on to note that "[t]he FCLAA [Federal Cigarette Labeling and Advertising Act] does not preempt that law on its face; nor would the FCLAA preempt a claim under that law, that sought to impose only content-neutral restrictions on cigarette advertising -- such as a requirement that the advertising not contain false statements of fact -- that were unrelated to concerns about smoking and health." *In re Tobacco Cases II, 41 Cal. 4th 1257, 1272 (Cal. 2007).*

While this language appears to leave the door open to future UCL claims that target the tobacco companies' advertising practices, it is unlikely that such claims would be any more viable since they would inevitably be related to concerns about smoking and health, which in turn would render them subject to the preemptive effect of the FCLAA (

*15 USCS § 1331* et seq.).

Cross References. For further information regarding Unfair Competition claims under Cal Bus & Prof Code § 17200 et seq., see 1-2 MB Practice Guide: CA Unfair Comp & Bus Torts 2.syn.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Robert C. Clifford serves as a consultant to law firms and as a mediator in insurance and litigation matters. He has been the senior partner of a law firm based in Oakland, California, where he represented major insurance companies in litigation and coverage matters. His expertise in general litigation included real property disputes, personal injury litigation, insurance matters, contract disputes, will contests and estate matters and the defense of professional liability claims, including actions against attorneys, accountants, architects and, engineers.

He is a graduate of Stanford University and the Stanford Law School and a former member of the Board of Visitors of the Stanford Law School. He is a member of the American Bar Association and the California State Bar Association and serves on committees relating to insurance and litigation matters.

Mr. Clifford is the author or contributor to several Lexis Nexis Mathew Bender publications including California Uninsured Motorist Law, California Automobile Insurance Law, California Mechanics Lien Law and Construction Industry Practice, California Insurance Law and Practice.

19 of 21 DOCUMENTS



***Professor Steenson on the Pet Food Recall Litigation***

*2008 Emerging Issues 1628*

Professor Steenson on the Pet Food Recall Litigation

By Michael K. Steenson

December 19, 2007

**SUMMARY:** The recall of approximately 60 million packets of pet food sold by Menu Foods, Inc. in March 2007 had staggering financial repercussions for Menu Foods and resulted in injury or death to thousands of dogs and cats. Professor Steenson takes a look at the legal issues raised in the recall litigation, particularly the difficult issue of damages and the valuation of companion animals.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE:** In March of 2007, the Food and Drug Administration announced that Menu Foods, Inc., a Canadian private-label pet food manufacturer, was recalling all its "cuts and gravy" dog and cat food that was produced at its Kansas facility between December 3, 2006 and March 6, 2007. n1

The products are packaged in cans and pouches under numerous brand names and are marketed nationwide by many pet food retailers-including Ahold USA Inc., Kroger Company, Safeway, Wal-Mart Stores, Inc., PetSmart, Inc., and Pet Valu, Inc. There were also recalls by other companies, including Hill's Pet Nutrition, Nestle Purina Pet Care Company, P & G Pet Care, and Del Monte products.

The FDA identified melamine and melamine-related compounds as the problem ingredient in the pet food. n2 Melamine is used as a fertilizer in Asia and for industrial and commercial uses, including the manufacture of kitchen utensils and plates. A subsequent study commissioned by the American Association of Veterinary Laboratory Diagnosticians, which was designed and implemented by Michigan State University toxicologists, found that more than 300 dogs and cats may have died earlier this year as a result of eating contaminated pet food. The cause of these deaths was melamine coupled with cyanuric acid, which together can cause renal failure in animals. n3

The pet food recall has had a significant economic impact on Menu Foods, including a significant reduction in sales. The company reported that "cuts and gravy" pet food accounted for almost half the company's business in 2006 and that the company's sales in the second quarter of 2007 were off 44% from the prior year. n4 While Menu Foods subsequently resumed shipment of "cuts and gravy" pet food to most of its private label customers, the full impact of the recall is still being assessed. In March, the company indicated that the recall could cost $25 million to $35 million. n5 The recall involved approximately 60 million cans/packets of pet food, n6 and the number of pets affected could run into the thousands. n7

Consolidated Class Action Filings. In the wake of the recall, a number of class action lawsuits were filed against Menu Foods and related companies, as well as against other manufacturers and sellers of pet food. Since the laws in most states support only relatively minimal damage awards for the injury or death of an individual animal, these suits were structured as class actions in order to seek recovery of cumulative damages for the multiple injuries and deaths that occurred throughout the country.

Finding that thirteen actions pending in eight districts involved common questions of fact, and that centralization would "serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation," the Panel on Multidistrict Litigation transferred the pet food suits to the District of New Jersey. n8 Other tag-along actions have also been transferred. n9 Menu Foods and its customers have started a mediation process with counsel for the plaintiffs in the litigation. n10

Theories of Liability. The suits allege various theories of liability, ranging from negligence to strict liability, breach of warranty, breach of contract, unjust enrichment, common law fraud, and various statutory violations, including consumer fraud, deceptive trade practices, false advertising, and unlawful trade practices. Strict liability claims include both manufacturing defect and failure to warn claims. The negligence allegations include negligence in "supplying, exporting, importing, manufacturing, distributing, marketing and/or selling" the pet food products, and in failing to implement adequate quality control and adequate testing" of the pet food sold by the defendants, as well as negligence in the design, manufacture, production, marketing, distribution, and sale of the pet food. A res ipsa loquitur allegation may also be added.

Alleged Statutory Violations. In light of the damage limitations discussed below, the various statutory violations asserted in the cases are likely to become particularly important. For example, in Krosschell v. Menu Foods Income Fund, n11 originally filed in the United States District Court for the District of Minnesota on April 27, 2007, the plaintiff alleges four Minnesota statutory violations. The first is that the defendants' actions violated Minnesota's Consumer Fraud Act, which prohibits the "act, use or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been mislead, deceived, or damaged thereby." n12

The second alleged statutory claim is that the defendants committed a deceptive trade practice in violation of the Deceptive Trade Practices Act, which provides that a person "engages in a deceptive trade practice when that person, in the course of business . . . [r]epresents that goods or services have . . . characteristics, ingredients, uses, benefits . . . that they do not have . . . or represents that goods or services are of a particular standard, quality, or grade . . . if they are of another." n13

The third claim for statutory violation is that the defendants committed an unlawful trade practice in violation of Minnesota law, which provides that "[n]o person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise." n14

The fourth statutory claim alleges false advertising, which is defined by statute to include advertising of any sort that contains any material assertion, representation or statement of fact which is untrue, deceptive, or misleading." n15

The particular importance of these statutory claims is that a proven violation gives rise to a private remedy, including the right to "recover damages, together with costs and disbursements, including costs of investigation and reasonable attorney's fees." n16 In the context of the pet food recall litigation, it is not unreasonable to predict that the recovery of costs and fees may be significant in relationship to the actual damages.

Unjust Enrichment and Warranty Claims. The plaintiffs' unjust enrichment theory alleges that the defendants "charged consumers for the pet food products that endangered the lives of their pets and have therefore received benefits that they have unjustly retained at the expense of the plaintiff and class members."

The express warranty claims are based on allegations that the defendants expressly warranted their pet food products to be suitable and safe for pet consumption. The implied warranty allegations assert that the defendants impliedly warranted that the pet food was fit for the ordinary purpose for which it was intended, including to safely nourish pets without risk of death or illness to them.

Damages. Perhaps the most perplexing issue arising in connection with the pet food recall litigation concerns the damages to which the plaintiffs can recover. There has been significant expansion of animal rights law in recent years, n17 including focused attention on the issue of what damages pet owners are entitled to recover in cases involving injury to or death of their pets. n18 Because animals, including pets, are considered personal property, the base standard for damages in those cases is the fair market value of the pet. n19 Of course, in many cases, that value is minimal. Some courts have altered their approaches, however, and permitted broader recovery, including permitting the recovery of reasonable veterinary expenses, even if those expenses exceed the pet's market value. Some courts have even permitted recovery of the actual or extrinsic value of the pet. n20

In cases where limiting damages to market value is unjust, most jurisdictions take the position that the measure of damages is the actual value to the owner. n21 Even critics of expanded damages agree that this may be the most prudent and fairest approach to the issue of valuation of injury to or death of a pet. n22

The most difficult issue is whether pet owners will be entitled to recover damages for the emotional harm associated with injury to or loss of their pets. While most courts are sympathetic to plaintiffs' claims of emotional harm for the loss of a pet, they typically deny damages for those claims. This issue was considered by the Virginia Supreme Court in Kondaurov v. Kerdasha: n23

It is beyond debate that animals, particularly dogs and cats, when kept as pets and companions, occupy a position in human affections far removed from livestock. Especially in the case of owners who are disabled, aged or lonely, an emotional bond may exist with a pet resembling that between parent and child, and the loss of such an animal may give rise to grief approaching that attending the loss of a family member.

Despite the Court's sympathy towards the claim, it nonetheless denied recovery on the ground that allowing recovery of damages for emotional harm involving the injury or death of a pet would be a "sweeping change in the law."

Of those states that do recognize the right of recovery for emotional harm when a pet is injured or killed, they all impose specific limitations on that right. The most liberal statutory approach is in Tennessee, which allows recovery for death of or injury to a pet "caused by the unlawful and intentional, or negligent, act of another or the animal of another." n24 However, the statute limits recovery in such cases to $5,000 in noneconomic damages. These damages are "limited to compensation for the loss of the reasonably expected society, companionship, love and affection of the pet." n25 In general, attempts to introduce legislation in other states to permit recovery of damages for noneconomic harm have been unsuccessful. n26

Conclusion. The most difficult issue facing plaintiffs in the class action suits arising out of the pet food recall litigation centers around the amount of damages recoverable as a result of the defendants' alleged misconduct. Current estimates are that more than 300 dogs and cats may have died earlier this year because of the tainted pet food subject to the recall. However, given that most states only allow pet owners to recover "fair market value" as damages for the injury or death of a pet, the amount of damages in this litigation could be severely limited in the absence of a theory by the plaintiffs to overcome this damages limitation.

Return to Text

n1 . http://www.fda.gov/bbs/topics/NEWS/2007/NEW01590.html.

n2

[2]. http://www.fda.gov/cvm/MenuFoodRecallFAQ.htm.

n3

[3]. http://www.sciam.com/article.cfm?id=correction-tainted-pet-fo.

n4

[4]. http://www.bloomberg.com/apps/news?pid=20601082&sid=aKc95WcV_aOA&refer=canada.

n5

[5]. http://www.bloomberg.com/apps/news?pid=20601082&sid=aKc95WcV_aOA&refer=canada.

n6

[6]. http://www.avma.org/onlnews/javma/mar07/x070320.asp.

n7

[7]. http://www.consumeraffairs.com/news04/2007/04/pet_food_recall21.html.

n8

[8]. See *In re Pet Food Products Liability Litigation, 499 F. Supp. 2d 1346* (J.P.M.L. June 19, 2007).

n9

[9]. See http://docs.justia.com/cases/federal/district-courts/minnesota/mndce/0:2007cv01808/90656/26/ for a compilation. The tag-along actions are governed by Multidistrict Litigation Rule 7.4.

n10

[10]. Statement of Menu Foods Regarding Mediation, Sept. 28, 2007, http://www.menufoods.com/recall/statement100107.htm.

n11

[11]. http://docs.justia.com/cases/federal/district-courts/minnesota/mndce/0:2007cv02108/91110/1/

n12

[12]. Minn. Stat. § 325F.69, subd. 1.

n13

[13]. Minn. Stat. § 325D.44 (5), (7).

n14

[14]. Minn. Stat. § 325D.13.

n15

[15]. Minn. Stat. § 325F.67.

n16

[16]. Minn. Stat. § 8.31, subd. 3a.

n17

[17]. Richard L. Cupp Jr., A Dubious Grail: Seeking Tort Law Expansion and Limited Personhood as Stepping Stones Toward Abolishing Animals' Property Status, *60 SMU L. Rev. 3 (2007).*

n18

[18]. See Elaine T. Byszewski, Valuing Companion Animals in Wrongful Death Cases: A Survey of Current Court and Legislative Action and a Suggestion for Valuing Pecuniary Loss of Companionship, *9 Animal L. 215, 225 (2003);* Geordie Duckler, The Economic Value of Companion Animals: A Legal and Anthropological Argument for Special Valuation, *8 Animal L. 199 (2002);* Lynn A. Epstein, Resolving Confusion in Pet Owner Tort Cases: Recognizing Pets' Anthropomorphic Qualities Under a Property Classification, *26 S. Ill. U. L. J. 31 (2001);* Susan J. Hankin, Not a Living Room Sofa: Changing the Legal Status of Companion Animals, *4 Rutgers J. L. & Pub. Pol'y 314 (2007);* Rebecca J. Huss, Valuing Man's and Woman's Best Friend, *86 Marq. L. Rev. 47 (2002);* Margit Livingston, The Calculus of Animal Valuation: Crafting a Viable Remedy, *82 Neb. L. Rev. 783 (2004);* William C. Root, Note, "Man's Best Friend": Property or Family Member? An Examination of the Legal Classification of Companion Animals and Its Impact on Damages Recoverable for Their Wrongful Death or Injury, *47 Vill. L. Rev. 423 (2002);* Victor E. Schwartz and Emily J. Laird, Non-Economic Damages in Pet Litigation: The Serious Need to Preserve a Rational Rule, *33 Pepp. L. Rev. 227 (2006);* Debra Squires-Lee, Note, In Defense of Floyd: Appropriately Valuing Companion Animals in Tort, *70 N.Y.U. L. Rev. 1059, 1087 (1995);* Sonia S. Waisman & Barbara R. Newell, Recovery of "Non-Economic" Damages for Wrongful Killing or Injury of Companion Animals: A Judicial and Legislative Trend, *7 Animal L. 45, 60 (2001).*

n19

[19]. Victor E. Schwartz and Emily J. Laird, Non-Economic Damages in Pet Litigation: The Serious Need to Preserve a Rational Rule, *33 Pepp. L. Rev. 227, 232 (2006).*

n20

[20]. Susan J. Hankin, Not a Living Room Sofa: Changing the Legal Status of Companion Animals, *4 Rutgers J. L. & Pub. Pol'y 314, 321 (2007).*

n21

[21]. *Burgess v. Shampooch Pet Industries, Inc., 131 P.3d 1248, 1252 (Kan. Ct. App. 2006),* quoting *Anzalone v. Kragness , 826 N.E.2d 472 (Ill. Ct. App. 2005);* see Restatement (Second) of Torts § 911, comment e (1965).

n22

[22]. Victor E. Schwartz and Emily J. Laird, Non-Economic Damages in Pet Litigation: The Serious Need to Preserve a Rational Rule, *33 Pepp. L. Rev. 227, 242 (2006).*

n23

[23]. *629 S.E.2d 181, 186-187 (Va. 2006).*

n24

[24]. Tenn. Code Ann. § 44-17-403 (a)(1).

n25

[25]. Id. § 44-17-403 (d).

n26

[26]. Victor E. Schwartz and Emily J. Laird, Non-Economic Damages in Pet Litigation: The Serious Need to Preserve a Rational Rule, *33 Pepp. L. Rev. 227, 247-248 (2006).*

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Michael K. Steenson is the Margaret H. and James E. Kelly Professor of Law at William Mitchell College of Law in St. Paul, Minnesota. Professor Steenson wishes to acknowledge and thank Joe Sayler for his excellent research assistance on this project. For additional information regarding Professor Steenson or the William Mitchell College of Law, please see http://www.wmitchell.edu/.

Professor Steenson may also be contacted through the Products Liability Prof Blog at http://lawprofessors.typepad.com/productsliability, for which he is one of the co-authors.

20 of 21 DOCUMENTS



***Prince on Riegel v. Medtronic: Federal Preemption and Medical Devices***

*2008 Emerging Issues 1626*

Professor J. David Prince on Riegel v. Medtronic: Federal Preemption and Medical Devices

By J. David Prince

December 19, 2007

**SUMMARY:** Professor Prince examines the issues of federal preemption and a plaintiff's right to sue a medical device manufacturer under state law. Both issues are currently before the United States Supreme Court in Riegel v. Medtronic. Professor Prince takes a look at the issues raised by the parties, as well as the parties' oral arguments before the Supreme Court, and predicts an outcome for the case.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE:** Can patients sue companies for injuries related to the design and labeling of complex medical devices when the U.S. Food and Drug Administration (FDA) has approved those products for use? Or are claims based on state statutes and common law preempted if the manufacturer has complied with federal laws and regulations in making and marketing the device? The U.S. Supreme Court will resolve these issues this term when it renders an opinion in Riegel v. Medtronic.

Background. Charles Riegel was seriously injured when a balloon catheter manufactured by Medtronic burst during an angioplasty procedure. He sued claiming that the device was negligently designed, manufactured, and labeled. Riegel also brought strict liability and breach of express and implied warranty claims. A federal district court ruled that most of his claims were preempted n1 by § 360k of the Medical Device Amendments (MDA), n2 and that ruling was affirmed on appeal. n3

Business interests have supported Medtronic, saying that a ruling in this case for Riegel would upset the delicate balance achieved by the FDA's approval process and place medical device manufacturers in the untenable position of trying to respond to inconsistencies in safety standards imposed by state juries. But plaintiffs' attorneys say a ruling for Medtronic could prevent patients from being able to recover for injuries caused by defective medical devices.

Federal Preemption Doctrine. The federal preemption doctrine is rooted in the Supremacy Clause of the United States Constitution, which provides that the laws of the United States "shall be the Supreme Law of the Land; . . . anything in the Constitution or laws of any state to the contrary notwithstanding." n4 State law, including common law, which conflicts with federal law is "without effect." n5 State "regulation can be as effectively exerted through an award of damages as through some form of preventive relief." n6 Thus, state law causes of action must give way when such claims encroach on the objectives that Congress has addressed directly or indirectly through federal statutes or

administrative regulations.

Although there is a general presumption against preemption, n7 Congress may indicate its intent to preempt state law either expressly or impliedly. One example of express preemption is provided by § 360k of the MDA, which bars states from imposing on medical devices "any requirement which is different from, or in addition to, any requirement applicable under this chapter."

Federal Approval of Medical Devices. The FDA's approval process for medical devices is complex. The MDA divides medical devices into three categories, each with separate regulations relating to approval. n8 The most extensive regulations apply to Class III devices that are deemed either: (i) important to sustaining human life or (ii) important in preventing impairment of human health-but which devices also present a potential unreasonable risk of injury. n9 These devices, like the one involved in Riegel, must undergo an involved premarket approval (PMA) process before they may be marketed, a process designed to assure that the device is both safe and effective.

However, Class III devices that fall within certain exceptions are exempt from the time-consuming PMA process. One exception allows a manufacturer to show that its product is "substantially equivalent" to devices in existence in 1976 so that the PMA process can be expedited through what is known as "premarket notification" or the "§ 510(k) application." n10

Preemption Under MDA. The Supreme Court first addressed whether the MDA preempts certain common law products liability claims in Medtronic, Inc. v. Lohr, n11 a case involving a Class III device that had been approved under the § 510(k) premarket notification process, meaning that it was "substantially equivalent" to a pre-1976 device. The court, in a plurality opinion, held that none of the plaintiff's claims were preempted by the MDA.

The Lohr opinion generated considerable confusion as lower courts attempted to discern its specific holding and to apply it in subsequent cases, including cases like Riegel, in which plaintiffs were injured by devices that had been approved through the full "safety and effectiveness" scrutiny of the PMA process. n12

Since Lohr, a majority of courts has concluded that the holding applies only to § 510(k) notification, and not to the rigorous PMA process in which just about every aspect of a medical device is reviewed and specifically approved by the FDA-and which results in device-specific requirements that preempt most state law claims. n13 A minority of courts has reached the opposite conclusion, holding that even PMA approval does not constitute the type of specific federal requirement necessary for preemption. n14

As to the types of claims preempted, the cases have generally concluded that design defect claims in connection with PMA-approved devices, whether sounding in negligence, strict liability or breach of implied warranty, are preempted, n15 as are failure to warn claims. n16 However, manufacturing defect claims usually avoid preemption, n17 as do breach of express warranty claims. n18

Oral Argument in Riegel v. Medtronic. In her argument before the court on December 4, 2007, Riegel's lawyer argued that device manufacturers should not be able to obtain PMA approval and avoid liability if the approved device later proves to have problems. In contrast, Medtronic's lawyer argued that the expert judgments of the FDA, and not the verdicts of state juries, are better suited to determine what is safe and effective in terms of a device's design, as well as what constitutes adequate labeling and warnings for a device. The solicitor general's lawyer, arguing as amicus on behalf of the FDA, emphasized that the agency itself believes that PMA approval should result in preemption.

Questions from the bench seemed to indicate that Justices Roberts, Scalia, Kennedy, and Breyer all favor preemption, with Souter leaning in that direction. They are likely to be joined by Justice Thomas, who favored preemption even in Lohr. Justice Ginsburg's questioning indicated that she holds the opposite view. She is likely to be joined by Justice Stevens, given his past record in state tort claim preemption cases. Justice Alito, a Bush appointee, did not participate enough in the oral arguments to provide a basis for predicting how he will vote on the issue.

My prediction is that the court will rule 6 -- 3 or 7 -- 2 in favor of Medtronic and uphold federal preemption in this case.

Return to Text

n1 . *2002 U.S. Dist. LEXIS 28145* (N.D.N.Y. March 18, 2002). The negligent manufacturing and breach of express warranty claims survived dismissal on preemption grounds but Medtronic later moved on other grounds for summary judgment on those two remaining claims, and the trial court granted that motion.

n2

[2]. *21 U.S.C. § 360k*. These amendments were added in 1976 to the Federal Food, Drug and Cosmetic Act (FDCA), *21 USCS § 301*, and extended the FDA's authority to include the approval and regulation of medical devices.

n3

[3]. *451 F.3d 104 (2nd Cir. 2006).*

n4

[4]. U.S. Const. art. VI, cl. 2.

n5

[5]. *Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992).*

n6

[6]. *Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521 (1992).*

n7

[7]. See *Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517-518 (1992).*

n8

[8]. *21 U.S.C. § 360c(a)*.

n9

[9]. *21 USCS § 360c (a)(1)(C)*.

n10

[10]. *21 U.S.C. § 360e(b)(1)(B)*. See *Kemp v. Medtronic, Inc., 231 F.3d 216, 221-222 (6th Cir. 2000)* (noting that this limited form of review "averages only 20 hours of review as opposed to some 1,200 hours in the PMA process"), reh'g denied and cert. denied, *534 U.S. 818 (2001).* The other exceptions are for "grandfathered" devices manufactured prior to MDA enactment that may remain on the market, *21 U.S.C. § 360e(b)(1)(A)*, and the investigational device exemption, or "IDE," which applies to experimental technology and allows for unapproved devices to be used in human clinical trials to gather data for a PMA, *21 U.S.C. § 360e(a)*. An IDE permits a manufacturer to market "a device that otherwise would be required to comply with a performance standard or to have premarket approval for the purpose of conducting investigations of that device." *21 C.F.R. § 812.1*.

n11

[11]. *Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).*

n12

[12]. See *Kemp v. Medtronic, Inc., 231 F.3d 216, 221 (6th Cir. 2000)* (noting that "[C]ourts of appeals that have confronted the issues of preemption arising under the MDA have struggled mightily with Lohr's language in the effort to discern its holding" and granting summary judgment to pacemaker manufacturer on preemption grounds), reh'g denied and cert. denied, *534 U.S. 818 (2001).* Compare *Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999)* (facts and legal theories almost indistinguishable, but rejecting express preemption argument), reh'g and reh'g en banc denied, *180 F.3d 276 (11th Cir. 1999).*

n13

[13]. See, e.g., *Horn v. Thoratec Co., 376 F.3d 163, 179 (3d. Cir. 2004); Martin v. Medtronic, Inc., 254 F.3d 573, 584-585 (5th Cir. 2001); Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090 (6th Cir. 1997),* cert. denied, *522 U.S. 1075 (1998); Mitchell v. Collagen Corp., 126 F.3d 902, 913-914 (7th Cir. 1997); Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 431 (E.D. Pa. 2004).*

n14

[14]. See, e.g., *Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1374-1375 (11th Cir. 1999),* reh'g and reh'g en banc denied, *180 F.3d 276 (11th Cir. 1999); Woods v. Gliatech, Inc., 218 F. Supp. 2d 802, 808 (W.D. Va. 2002); Webster v. Pacesetter, Inc., 171 F. Supp. 2d 1, 19 (D. D.C. 2001).*

n15

[15]. See, e.g., *Kemp v. Medtronic, Inc., 231 F.3d 216, 229 (6th Cir. 2000),* reh'g denied and cert. denied, *534 U.S. 818 (2001); Lewis v. Intermedics Intraocular, 19 F. Supp. 2d 625 (E.D. La. 1998); Martin v. Medtronic, Inc., 254 F.3d 573, 584 (5th Cir. 2001),* cert. denied, *534 U.S. 1078 (2002); Mitchell v. Collagen Corp., 126 F.3d 902, 915 (7th Cir. 1997).*

n16

[16]. See, e.g., *Brooks v. Howmedica, Inc., 273 F.3d 785, 796-798 (8th Cir. 2001),* cert. denied, *535 U.S. 1056 (2002); Lindquist v. Tambrands, Inc., 721 F. Supp. 1058 (D. Minn. 1989); Cornelison v. Tambrands, Inc., 710 F. Supp. 706, 709 (D. Minn. 1989).*

n17

[17]. See, e.g., *Chambers v. Osteonics Corp., 109 F.3d 1243, 1248-1249 (7th Cir. 1997); Chmielewski v. Stryker Sales Corp., 966 F. Supp. 839, 843 (D. Minn. 1997); Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 432-433 (E.D. Pa. 2004); Easterling v. Cardiac Pacemakers, Inc., 986 F. Supp. 366, 375 (E.D. La. 1997).*

n18

[18]. See, e.g., *Mitchell v. Collagen Corp., 126 F.3d 902, 915 (7th Cir. 1997),* cert. denied, *523 U.S. 1020 (1998).*

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

J. David Prince is a Professor of Law at William Mitchell College of Law in St. Paul, Minnesota. In addition to his faculty position at William Mitchell, Professor Prince is Of Counsel to the St. Paul law firm of Larson King, where he focuses his practice on products safety and product liability prevention, mass tort and products liability litigation, appellate advocacy, and alternative dispute resolution. In connection with the writing of this Commentary, Professor Prince wishes to acknowledge and thank the assistance of Sarah L. Brew, a partner in the Minneapolis law firm of Greene Espel, for sharing her extensive knowledge of preemption law.

For additional information regarding Professor Prince, please see http://www.wmitchell.edu/academics/faculty/Prince.asp or www.larsonking.com/attorneydetail.cfm?BioID=35&Edit=1.

Professor Prince may be contacted at david.prince@wmitchell.edu or through the Products Liability Prof Blog at http://lawprofessors.typepad.com/products_liability, for which he is a co-editor.

21 of 21 DOCUMENTS



***Eades on E.I. du Pont v. Strong***

*2008 Emerging Issues 947*

Eades on E.I. du Pont v. Strong (admission of speculative and prejudicial evidence overturns $15.5 million toxic tort jury verdict)

By Ronald W. Eades

November 15, 2007

**SUMMARY:** In *E. I. du Pont de Nemours & Co. v. Strong, 2007 Miss. LEXIS 574 (Miss. 2007),* the Mississippi Supreme Court reversed and remanded a $15.5 million jury award in a toxic tort case due to the trial courts erroneous admission of certain prejudicial, irrelevant and speculative evidence. This Emerging Issues Analysis discusses those evidentiary rulings and provides related practice tips.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ARTICLE:** Overview

In *E. I. Dupont de Nemours & Co. v. Strong, 2007 Miss. LEXIS 574 (Miss. 2007),* the Mississippi Supreme Court reversed and remanded a $15.5 million jury verdict in a toxic tort case due to the trial court's erroneous admission of certain evidence. Specifically, the Court found that the trial court erred in admitting affidavits from plaintiff's physicians that conflicted with their deposition testimony, and, in admitting expert testimony stating that large corporations such as the defendant often intimidate regulatory agencies. Finally, the Court also held that the trial court erred in admitting testimony about another, unrelated on-the-job injury that plaintiff sustained. In contrast, the dissent believed that the errors were not significant enough to require reversal, and contended that this decision represented yet another example of the Court overturning a large jury verdict that had been entered against a corporate defendant.

Analysis

A. Physicians' Affidavits

Two of the plaintiff's physicians gave depositions that were introduced at trial. In addition, the plaintiff was allowed, over objection, to introduce additional affidavits from these physicians several days after the trial began. The critical issue raised by the affidavits concerned the issue of causation of the multiple myeloma plaintiff suffered. In the depositions, the physicians stated that there was no known cause of multiple myeloma. However, in their affidavits, the physicians stated that they had no opinion as to the cause of multiple myeloma. The defendants objected to the introduction of the affidavits on the grounds that they conflicted with the physicians' deposition testimony. Additionally, the defendants complained that they were not given notice that the affidavits would be offered at trial.

On appeal, plaintiff contended that the affidavits were admissible under Miss. R. Evid. Rule 804(b)(5), the state's hearsay catch-all exception that permits the admission of certain statements made by witnesses that are unavailable for trial. However,the Mississippi Supreme Court disagreed and ruled that the plaintiff improperly introduced the affidavits in an attempt to tailor the doctors' prior deposition testimony on the issue of causation. The Court held that the affidavits were highly prejudicial and that plaintiff failed to give the defendant adequate notice of his intent to introduce the affidavits at trial. *E. I. Dupont de Nemours & Co. v. Strong, 2007 Miss. LEXIS 574 (Miss. 2007).*

The dissent responded to this issue by noting that the affidavits did not alter the physicians' deposition testimony. In addition, it appeared to the dissent that the affidavits actually helped the defense. The dissent did not think there was any way that the affidavits could have been seen as highly prejudicial. *E. I. Dupont de Nemours & Co. v. Strong, 2007 Miss. LEXIS 574 (Miss. 2007).*

The majority's opinion appears to focus on the issue of insufficient notice, leaving the question of whether the affidavits would have been admissible under Miss. R. Evid. Rule 804(b)(5) if plaintiff had provided the defendant with notice prior to trial. However, the Court did not state how many days' notice would be required to constitute sufficient notice, and the statute is equally silent on this issue, simply stating that the proponent of the evidence " . . . makes known to the adverse party sufficiently in advance of the trial or hearing to provide the adverse party with a fair opportunity to prepare to meet it, his intention to offer the statement and the particulars of it, including the name and address of the declarant." Miss. R. Evid. Rule 804(b)(5).

Another issue the Court did not address was whether plaintiff's physicians were truly unavailable under Miss. R. Evid. Rule 804(a). Under the statute, a declarant is unavailable when he or she:

(1) Is exempted by ruling of the court on the ground of privilege from testifying concerning the subject matter of his statement; or

(2) Persists in refusing to testify concerning the subject matter of his statement despite an order of the court to do so; or

(3) Testifies to a lack of memory of the subject matter of his statement; or

(4) Is unable to be present or to testify at the hearing because of death or then existing physical or mental illness or infirmity; or

(5) Is absent from the hearing and the proponent of his statement has been unable to procure his attendance (or in the case of a hearsay exception under subdivision (b)(2), (3), or (4), his attendance or testimony) by process or other reasonable means; or

(6) In the case of a child, because of the substantial likelihood that the emotional or psychological health of the witness would be substantially impaired if the child had to testify in the physical presence of the accused.

Practice Tip. Based on the foregoing, counsel seeking to offer an unavailable declarant's affidavit (or other potential hearsay statement) at trial in Mississippi should provide the opposing party with notice at the first possible opportunity, and well in advance of trial. Counsel must also establish that the declarant is truly "unavailable" within the meaning of Miss. R. Evid. Rule 804(a).

B. Speculative Testimony Concerning Intimidation

During the trial, the court allowed plaintiff's expert witness to testify that large corporations are likely to engage in conduct to intimidate those that work for regulatory agencies that oversee those corporations. The Mississippi Supreme Court found that admission of this evidence was error. The court found that this testimony was speculative and hypothetical, and could not show that this defendant had actually engaged in that conduct. In addition, the Court opined

that the jury could be misled into thinking that the evidence showed that this defendant engaged in that type of intimidating conduct. The Court found support for its holding in the comments to Miss. R. Evid. Rule 702, which provide in pertinent part that "[t]he use of the hypothetical question has been justly criticized." *E. I. Dupont de Nemours & Co. v. Strong, 2007 Miss. LEXIS 574 (Miss. 2007)*, at p. 12.

The dissent noted that the evidence at issue concerned a one-sentence answer to a question. The witness was being asked how this defendant had managed to "get away with the egregious underreporting that . . . research uncovered." *E. I. Dupont de Nemours & Co. v. Strong, 2007 Miss. LEXIS 574 (Miss. 2007)*, at p. 24. The dissent noted that there was "voluminous evidence indicating regulatory violations" by this defendant. Any error in the admission of this speculation would not have been prejudicial. *E. I. Dupont de Nemours & Co. v. Strong, 2007 Miss. LEXIS 574 (Miss. 2007)*, at p. 26.

Practice Tip: Counsel should avoid posing questions to experts which invite them to speculate, hypothesize, or otherwise make broad generalizations about how a party usually acts.

C. Evidence of Other Injuries

During the course of trial, a plaintiff's witness was allowed to testify to other injuries that were not related to the injury suffered by the plaintiff. The Court held that the admission of this irrelevant evidence was error. *E. I. Dupont de Nemours & Co. v. Strong, 2007 Miss. LEXIS 574 (Miss. 2007)*, at pp. 14-15.

The dissent noted that the testimony concerning the other injury should be viewed in the context in which it was offered. The witness was testifying concerning release of toxic gases and the injury suffered illustrated that the witness had personal knowledge of the facts at issue. The dissent also noted that even if the admission of the evidence was error, it was only two pages of the witnesses 46 pages of testimony and was of only "minimal" prejudicial effect. *E. I. Dupont de Nemours & Co. v. Strong, 2007 Miss. LEXIS 574 (Miss. 2007)*, at pp. 24.

D. Dissent's Main Complaint

A reading of the dissent reveals that Justice Diaz believes that the errors found by the Court's opinion were not sufficiently substantial to warrant reversal of the case. The final portion of the dissent, however, further reveals the dissenting justice's main concern.

In the final portion of the dissent, Justice Diaz lists cases where the Mississippi Supreme Court had reversed substantial judgments that had been awarded against large defendants. The Justice felt that this practice revealed a troubling trend. "Today's case is yet another example of this Court's willingness to overturn a jury verdict when individuals have been awarded large damages against corporate defendants. In the last two years, this Court has been asked to consider at least eight cases involving large damage awards in favor of individual plaintiffs, and seven of these cases have been reversed." *E. I. Dupont de Nemours & Co. v. Strong, 2007 Miss. LEXIS 574 (Miss. 2007)*, at pp. 27-28. Justice Diaz's concern was that, "we must defer to the finders of fact and stop substituting this Court's judgment for that of the jury." *E. I. Dupont de Nemours & Co. v. Strong, 2007 Miss. LEXIS 574 (Miss. 2007)*, at pp. 27-28.

Conclusion

The Court's opinion reversed the verdict and judgment of the trial court based upon what it found to be a series of evidentiary errors. Traditional evidence law grants substantial discretion in the trial judge over evidentiary rulings. However, that same evidence law places the final decision for admissibility in the hands of the highest court of the state.

Counsel faced with similar evidentiary predictaments in the future can reduce their chances of reversal on appeal if they provide sufficient notice of their intent to introduce an unavailable declarant's out-of-court statements at trial, and limit their expert's testimony to opinions and conlcusions that are derived from the expert's investigation and analysis of objective factors. Asking the expert to speculate as to why the defendant got away with something -- or asking similar

questions that invite speculation or generalizations -- should be avoided.

Additional References

For a discussion of the role of the judge in deciding evidentiary issues, see 1-104 *Weinstein's Federal Evidence § 104.10*.

For a discussion of the appropriate role of the jury in evaluating the evidence, see 1-104 *Weinstein's Federal Evidence § 104.60*.

For a discussion of the review of evidence decision at the appellate level, see Thomas A. Moore, Evidence in Negligence Cases § 22.3.

**PDF LINK:** Click here for enhanced PDF of this Emerging Issues Analysis at no additional charge

**ABOUT THE AUTHOR(S):**

Ronald W. Eades is a Professor of Law at the Louis D. Brandeis School of Law, University of Louisville. He also holds the title of Distinguished University Scholar. He received his B.A. degree in 1970 from Rhodes College in Memphis, Tennessee. He received his J.D. from the University of Memphis in 1973, and an LL.M. from the Harvard Law School in 1977.

Professor Eades teaches in the torts and evidence areas. He is the author of numerous works in those same areas. He is, for example, the author of Jury Instructions on Products Liability (LexisNexis); Jury Instructions on Damages in Tort Actions (LexisNexis); Jury Instructions on Medical Issues (LexisNexis); Jury Instructions on Automobile Actions (LexisNexis); Jury Instructions in Commercial Litigation (LexisNexis); and Jury Instructions in Real Estate Litigation (LexisNexis).

Professor Eades has also been active in the research and development of evidence law. He has served on the Kentucky State Evidence Rules Review Commission. In service on that commission, he has had the opportunity to testify before the Kentucky General Assembly House Judiciary Committee concerning rules of evidence.

In the academic areas, Professor Eades has been an active teacher. He has also been active in the development of technology resources for legal education. He served as a Fellow for the Center for Computer Assisted Legal Instruction where he wrote computer lessons in tort law for law students. He also serves on the Editorial Board and the Governing Board for the Center for Computer Assisted Legal Instruction.