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IN THIS ISSUE

Featured Articles

- Courts Dismiss The Idea Of Federal Preemption For Generic Drug Manufacturers: Public Policy Consideration Or Constitutional Violation? 2-6
- Playing Doubles: Managing the Increased Coordination and Cooperation Between State Attorneys General and the Consumer Product Safety Commission and Federal Trade Commission 6-8
- Effective Use of a Regulatory Expert in Product Liability Litigation..... 9-10
- Canada’s Consumer Product Safety Legislation..... 11-14
- The Québec Consumer Protection Act is Changing—Are You Ready? 14-16
- A Cautionary Tale: The Duty To Preserve And Collect Documents Revisited..... 16-18
- ISO 9001 and the Legal Implications of Document Control 18-23
- Economic Loss Doctrine Refresher 23-26

Departments

- Case Notes..... 26-28
- In The Trenches 28-29
- Upcoming ALFA International Events 29

Notes From the Editors

With nearly limitless international trade, travel, and communication, it is clear the world is getting smaller. Unfortunately, for product manufacturers, the regulatory world is getting larger and is also becoming more international. In the U.S., the Consumer Product Safety Improvement Act of 2008 (CPSIA) has resulted in much more stringent enforcement of regulations for imported products. For example, if a product is listed on the Consumer Products Safety Commission’s substantial product hazard list, the product can be seized. If the product was on the list, the importer cannot challenge the finding of a hazard, but only the issue of whether the product is on the list. With increased visibility and communication, the public demands visible response when a product is perceived as unsafe. Since the CPSIA, product inspections and seizures at the U.S. Border have more than doubled.

The CPSIA also significantly increased the maximum possible penalty, from \$8,000 to \$100,000 for knowing violations. The financial consequences make it apparent there is a much greater incentive to implement a more thorough product safety program than ever before, beginning with product research and design and with considerations following through distribution as

to the markets and regulatory bodies for the product as well as the utility and risks.

Likely unknown to most Americans, China has made significant progress in the last couple of years regarding statutes and regulations governing product safety. China has a new tort law effective only as of July 1, 2010 that expressly provides for the right to recover punitive damages against manufacturers and sellers for knowing violations. Moreover, regardless of whether the consumers are in China or in the United States, plaintiff product liability attorneys are plenty ready and willing to represent people against manufacturers in U.S. courts when jurisdiction attaches, where the outcomes are more regularly in a plaintiff’s favor.

For manufacturers that sell products in multiple countries, such that they are subject to multiple regulatory schemes, compliance has always been complex and expensive, and likely increasingly so. Often times an event involving a product may result in a requirement to report to one government or regulatory agency in one country that may not be reportable under another regulatory scheme. It may be tempting, and perhaps less expensive in the short-term, to create a short-term solution under the most immediate regulatory requirement, but a manufacturer may have a more long-term problem with the disparity.

If there is a subsequent accident in a jurisdiction where no corrective action was taken, and it turns out that it is related or similar to the incident reported in the original jurisdiction or would have been prevented by a corrective action in the original jurisdiction, the manufacturer's position will be difficult to defend. To the extent possible, it is best to keep in mind the regulatory scheme for all major jurisdictions where the manufacturer expects a product may be sold, and to the extent possible, design, manufacture, market and sell products with appropriate warnings, instructions, and documentation, consistent with all jurisdictions. Similarly, response to problems will be viewed in a better light the more consistent they are across the product line and markets.

Recognizing the way various regulatory agencies may start working together and coordinate resources, as discussed in Margaret Feinstein and Christopher Allen's article, is wise counsel. Staying current with changes in statutes and regulatory structure in all jurisdictions where products are sold is also important, and there have been big changes around the world recently as discussed below in the articles about the Canada Consumer Product Safety Act.

Prudent manufacturers will monitor news and other media for risk factors that may increase the likelihood of its products being targeted for higher scrutiny. Even if a manufacturer wins every product liability trial, it cannot replace the costs in terms of legal fees, man hours, repair, replacement, and revision of products, and perhaps most importantly public perception.

In today's world of YouTube, Facebook, Twitter, and customer complaint websites addressed at specific products

and/or companies, bad news travels faster than ever before. In fact, the CPSC implemented a publicity campaign that included YouTube and Facebook to increase visibility of the new consumer product safety incident database which is available to the public, government agencies, and companies for searching, review, and submission.

The reports submitted must discuss the product and identify the manufacturer as well as the harm suffered. The manufacturer will receive a copy of the report, but the CPSC must publish the report within ten business days thereafter. In many instances, this is certainly not enough time for a manufacturer to evaluate the credibility of the report, discover any additional significant facts about the product including any modifications, misuse, misrepresentations, etc. before it is subject to distribution and review by the public and potential plaintiffs and their attorneys.

Staying current with the evolution of product liability law and regulations in all relevant jurisdictions and developing products with an overview of compliance and responsiveness that is consistent in all jurisdictions is the most defensible strategy. If a suit does develop, the ability to document the process and how it was intended to comport with public safety and regulatory goals will be a manufacturer's best evidence.

- Robert Smith & Colleen Murnane

Courts Dismiss The Idea Of Federal Preemption For Generic Drug Manufacturers: Public Policy Consideration Or Constitutional Violation?

By Stanton E. Shuler, Jr., Esq. and Lauren Fajoni Bartlett, Esq.

Background

In *Wyeth v. Levine*, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009), the United States Supreme Court held that preemption does not apply to state tort actions in cases involving innovator drug manufacturers. By a 6-3 vote, the Court affirmed the lower court's decision that the plaintiff could pursue claims that defendant failed to provide adequate warnings even though the Food and Drug Administration ("FDA") had previously deemed these warnings adequate. However, the Court did not address whether preemption applied to failure to warn claims brought against generic drug manufacturers.

Since the *Levine* decision, a majority of lower courts addressing the latter issue have deprived generic manufactur-

ers of the preemption defense. This move to deny preemption to generic drug manufacturers ignores congressional intent and deference to agency, and it impinges upon the constitutional notion of separation of powers.

Regulatory Framework

In 1938, Congress enacted the Food, Drug, and Cosmetic Act ("FDCA") in order to regulate the safe and effective design, manufacture, sale and labeling of pharmaceuticals and medical devices. Due in large part to the growing cost of health care, in 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, which quickly moved generic drugs into mainstream production. Today, "seven in ten prescrip-

tions filled in this country are now for generic drugs.” *Mensing v. Wyeth*, 588 F.3d 603, 607 (8th Cir. 2009).

The original goal of the Hatch-Waxman Act was to help lower the cost of health care by easing the burden on generic drug manufacturers so that more Americans would be able to afford a wider array of prescription medications. These same public policy considerations remain a top priority for the legislative and executive branches more than 25 years later. Indeed, the debate over affordable health care reached its pinnacle in March of 2010, when Congress passed President Obama’s health care reform package.

Basis for Preemption

Given Congress’ interest in providing affordable health care, considerable deference must be given to both the intent of the Legislature when passing regulatory laws and the agencies to which Congress has delegated its power to regulate. An example of this is Congress’ delegation of power to the FDA to regulate the manufacturing, labeling, sale and distribution of drugs and medical devices pursuant to the FDCA.

When Congress has made clear its intent to regulate an industry, either directly or through a designated agency, the judiciary must enforce the laws as written. Historically, the judiciary has been mindful of the separation of powers principle in cases of express preemption, although it tends to take more liberties in the area of implied preemption. In the latter instance, a close eye must be kept on constitutional notions of federalism and separation of powers in order to ensure that the judiciary does not ignore Congress’ intent in order to further its own agenda on matters where the two diverge. Recent decisions that consider the issue of federal preemption in the context of generic drugs demonstrate the blurred line between law enforcement and regulation.

Wyeth v. Levine

In 2009, the United States Supreme Court considered whether federal law preempted state law product liability claims against manufacturers of reference listed drugs whose products had been cleared by the FDA through the New Drug Application (“NDA”) process. *See Levine*, supra. The Court observed that Congress places the onus on the manufacturer, not the FDA, to monitor the effects of their products on human health and to disclose later discovered risks through the Changes Being Effected (“CBE”) process. *See id.* at 1198; 21 CFR § 201.80(e); 21 CFR § 314.80(b); and 73 Fed.Reg. 49605. The Court concluded that since state tort actions are one of the best ways to ensure that innovator-

manufacturers adequately monitor the market, Congress did not intend to preempt state court actions involving innovator liability. Of course, while *Levine* recognizes that the CBE process is the mechanism by which innovator-manufacturers effect a labeling change, the opinion is silent on the issue of whether this process is equally available to generic drug manufacturers. *See id.* at 1196; 21 CFR § 314.70(c)(6)(iii).

Post-Levine Era

Following *Levine*, the United States District Court for the Northern District of Illinois was among the first courts to consider federal preemption in the context of generic manufacturers. In *Stacel v. Teva Pharmaceuticals, USA, et al.*, 620 F.Supp.2d 899 (N.D.Ill. 2009), the plaintiff sued Teva when she allegedly developed drug-induced lupus after taking minocycline, a generic form of Minocin®. She alleged that Teva had information showing that minocycline may cause lupus but did not include this information in its package insert. Teva filed a motion to dismiss asserting that plaintiff’s state law claims are preempted under the FDCA and Hatch-Waxman Amendments. The court relied on both the Code of Federal Regulations and *Levine* as its basis for denying Teva’s motion, although it recognized that *Levine* is distinguishable because it did not involve a generic manufacturer. Nevertheless, the court found compelling the fact that Teva, like the manufacturer in *Levine*, could not point to any instances where the FDA had sanctioned a manufacturer for strengthening its warning label.



While *Stacel* may have been among the first to apply *Levine* to generic drug manufacturers, it certainly wasn’t the last. Recently, both the Fifth and Eighth Circuits have found that state failure-to-warn claims brought against generic drug manufacturers are not preempted by federal law, although it is clear that these decisions were result driven. In *Mensing v. Wyeth*, 588 F.3d 603, 608 (8th Cir. 2009), the court specifically declined to decide the issue of whether a generic manufacturer unilaterally could have requested a labeling change, finding, instead, that it at least should have tried. After more in depth analysis, the court in *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), likewise concluded that the FDA imposes an independent duty on manufacturers of generic drugs to request a labeling change where necessary, even if the reference listed drug manufacturer has not submitted a CBE change notice. Of course, whether the FDA subsequently mandates the label change remains within the sole discretion of the FDA. Other courts reaching similar conclusions include *Munroe v. Barr Labs., Inc.*, 670 F.Supp.2d 1299 (N.D.Fla. 2009) (no preemption); *Bartlett v. Mutual Pharm. Co.*, 659 F.Supp.2d 279 (D.N.H. 2009) (no preemp-

tion); and *Schrock v. Wyeth, Inc.*, 601 F.Supp.2d 1262 (W.D.Okla. 2009) (no preemption).

Not all courts have been so willing to extend *Levine* to generic manufacturers. For instance, the Northern District of California, the Western District of Kentucky and the Southern District of Florida are among those in favor of preemption. See *Gaeta v. Perrigo Pharm. Co.*, 672 F.Supp.2d 1017 (N.D.Cal. Nov.24, 2009) (state law failure-to-warn claims are preempted); *Smith v. Wyeth*, 2009 WL 425032 (W.D.Ky. Feb.20, 2009) (court aware of the *Levine* decision, but nevertheless determined that plaintiff's failure-to-warn claims against generic drug manufacturer were preempted); *Morris v. Wyeth*, 642 F.Supp.2d 677 (W.D.Ky.2009) (FDA regulations preempted state failure-to-warn claims notwithstanding *Levine*); *Wilson v. Pliva*, 640 F.Supp.2d 879 (W.D.Ky.2009) (same); and *Masterson v. Apotex Corp.*, 2008 WL 3262690 (S.D.Fla. Aug.7, 2008) (finding preemption because a state law that requires a generic manufacturer to request a label change when no such requirement can be found in the FDA regulations necessarily would require courts to speculate about what the FDA might have done before it can make a liability determination). Notwithstanding this line of cases, the majority view and growing trend is to find claims against generic drug manufacturers not preempted. Today, the prevailing view is that generic manufacturers have an affirmative duty to avail themselves of the CBE process notwithstanding the FDA's contrary expression of intent over the past decade.

While *Levine* walks a fine line between fulfilling the judiciary's role as enforcer of the laws and encroaching on the legislature's role as lawmaker, state and federal laws requiring an innovator-drug manufacturer to monitor the field and submit labeling changes as necessary can coexist. However, courts that impose a similar duty on generic drug manufacturers may go too far. In *Levine*, the Supreme Court was particularly bothered by the fact that the defendant manufacturers were unable to highlight any instances where the FDA had actually brought an enforcement action against a company for strengthening its warning labels without CBE approval. Nor could it imagine that the FDA ever would. In *Stacel*, the court echoed a similar concern when it took issue with the defendant's inability to point to any instances where a generic manufacturer had been sanctioned for strengthening its label even though the NDA applicant had not. These judicial expressions of intent clearly suggest that the decisions are result driven. The *Stacel* line of cases quite possibly violates the separation of powers principle, the own divergent public policy interests, despite the legislature's clear expression of intent through the FDA.

Deference to Agency

Congress unmistakably delegated considerable power to the FDA to promulgate rules and to regulate the industry

when it passed the FDCA in 1938. Its grant of authority to the FDA, therefore, necessarily gives its rules and regulations the force of law. Thus, the judiciary is obligated to give deference to the Agency's interpretation on a rule of law so long as it is based on a permissible statutory construction. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). "If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 843-44. In such instances, courts cannot substitute their own interpretation of a statutory provision in place of an otherwise reasonable interpretation made by the administrative agency. *Id.* at 844. Anything more would suggest that the court is wiser than the legislature – a clear violation of the principle of separation of powers. See *Zhang v. United States*, 89 Fed.Cl. 263, 279 (Fed.Cl. 2009), quoting *Denkler v. United States*, 782 F.2d 1003, 1007-08 (Fed.Cir.1986).

On January 16, 2008, the FDA made clear its position that the CBE process is *not* generally available to generic manufacturers for the purpose of unilaterally requesting a labeling change. See 73 FR 2848 (01/16/08). At that time, the FDA published for notice-and-comment a proposed amendment to the CBE regulations that allowed a reference listed drug manufacturer to implement certain specified labeling changes upon receipt by the Agency of the supplemental NDA instead of having to wait for final approval. In the preamble to the notice-and-comment submission, the FDA was careful to note that, "CBE changes are not available for generic drugs approved under an abbreviated new drug application To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug." Thus, the very narrow use of the CBE process for generic manufacturers is limited to amending their labels to conform with changes made to the reference listed drug labels.

With regard to innovator manufacturers, the FDA declared that the purpose of the proposed 2008 amendment – which the FDA expressly limited to innovator manufacturers – is to "clarify that a CBE supplement may be used to add or strengthen a contraindication, warning, precaution, or adverse reaction" upon acquiring sufficient evidence of a causal association between the product and a particular adverse event. However, "allowing sponsors to unilaterally amend the labeling for approved products without limitation – even if done to add new warnings – would undermine the FDA approval process required by Congress. Indeed, permitting a sponsor to unilaterally rewrite the labeling for a product following FDA's approval of a product and its labeling would disrupt FDA's careful balancing of how the product's risks and benefits should be communicated." The pur-

pose of this cautionary language is to make clear the FDA's substantial interest in balancing the potential risks of a certain medication with its benefits. Exaggeration of the risks could discourage use of a life saving drug, and excessive warnings could cause more meaningful risk information to lose its significance. See Amicus Brief of the United States in *Levine*, supra, 2008 WL 2308908 at *17, citing 71 Fed.Reg. at 3935; *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 796 (8 Cir. 2001). This certainly suggests that speculation by certain courts over whether the FDA would ever actually bring an enforcement action against a company for strengthening its warning label may well miss the mark.

Those courts that have considered but rejected the FDA's comments in the preamble justify their position by pointing out that the preamble itself was never submitted for notice-and-comment. Prior rulings by the Supreme Court, however, support the notion that this position is a mere pretext for refusing to give the preamble constitutional deference in order to promote these courts' interests. Specifically, notice-and-comment rulemaking is not dispositive on the issue of deference, and courts are obligated to adhere to the FDA's clear expression of intent so long as "Congress has not previously spoken to the point at issue and the agency's interpretation is reasonable." See *United States v. Mead Corporation*, 533 U.S. 218, 230-31, 121 S.Ct. 2164, 150 L.Ed.2d 292 (2001); see also, *Chevron*, supra. In cases where Congress has granted such an expansive transfer of power, whether express or implied, "a reviewing court has no business rejecting an agency's exercise of its generally conferred authority to resolve a particular statutory ambiguity simply because the agency's chosen resolution seems unwise." *Mead*, 533 U.S. at 230. Nevertheless, while it would seem that the Congressional delegation of power to the FDA is clear by virtue of the FDCA and Hatch-Waxman Amendments, courts have been unwilling to afford the FDA's expression of intent the deference it deserves. The FDA's preamble leaves little room to debate its position on the issue of federal preemption for generic manufacturers; yet, adverse court decisions prove that courts are unwilling to cede this issue to the Legislature where it belongs, opting instead to usurp Congress' power and deny the FDA the deference to which it is constitutionally entitled in order to make policy contrary to the will of the Legislature. Courts addressing the issue of generic preemption certainly are aware of the FDA's position, but they have manufactured a loophole by virtue of the notice-and-comment provision to reach a contrary result. Nevertheless, the preamble remains a clear expression of the FDA's intent, and it should be given deference because it is consistent with the statutory language and does not exceed the grant of



power afforded by Congress. The fact that courts are unwilling to show deference to the FDA supports the conclusion that the judiciary has disregarded the constitutional principle of separation of powers in order to promote their own public policy interests over those of the FDA.

Nevertheless, the current prevailing view is to allow state court failure-to-warn actions against generic drug manufacturers. In the absence of a subsequent controlling Supreme Court decision or Congressional declaration to the contrary, the majority rule will likely continue to allow such claims to survive. Under the prevailing view, generic drug manufacturers will continue to face state court challenges on failure to warn cases where they have not taken affirmative steps to avail themselves of the CBE process and amend their warning labels independent of actions by the innovator manufacturer.

Predictions for the Future

On March 5, 2009, one day after the *Levine* decision was handed down, Representatives Henry Waxman and Frank Pallone, Jr. introduced the Medical Device Safety Act of 2009 (See H.R. 1346(2009)), and Senators Patrick Leahy and the late Ted Kennedy introduced companion legislation (See S.B. 540 (2009)). This legislation was introduced to undo the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008), which found that most state court claims against medical device manufacturers (whose products go through the more rigorous Pre-market Approval ("PMA") process) are preempted with few exceptions. (Interestingly, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), the Supreme Court held that state court claims against manufacturers of 510(k) devices are not preempted.) While medical device preemption and decisions such as *Riegel* and *Lohr* are beyond the scope of this article and certainly are distinguishable from pharmaceutical preemption cases because of a number of significant differences in the laws and regulations relating to each (see, e.g., 21 U.S.C. § 360k(a), in which Congress allows for express preemption for medical devices), if the proposed legislation passes, it would supersede *Riegel* and sound the death knell for federal preemption. Congress' reaction to the *Riegel* decision suggests that it no longer condones the FDA's pro-preemption stance of the past decade. Instead, it reflects the view of the Obama Administration, which currently has Congressional backing and intends to strip drug and medical device manufacturers of the safety blanket previously afforded by their compliance with the FDA regulatory process.



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Playing Doubles: Managing the Increased Coordination and Cooperation Between State Attorneys General and the Consumer Product Safety Commission and Federal Trade Commission

By Margaret Feinstein and Christopher J. Allen

During the last decade, State Attorneys General (AGs) have become highly influential consumer protection advocates who often act more quickly and on a broader variety of issues than their federal counterparts. Every State, as well as the District of Columbia, has a consumer protection statute that empowers its AG to protect consumers from unfair or deceptive trade practices. Many AGs have used their consumer protection authority to change how major industries conduct business.

Some of the increased AG activity is the result of the hesitation of federal agencies to enforce federal consumer protection regulations aggressively. New leadership and increased support from Congress, however, have reenergized the United States Consumer Product Safety Commission (CPSC) and Federal Trade Commission (FTC), which together are responsible for most federal regulation of consumer protection. These agencies regulate the business practices of a wide range of consumer industries.

The resurgence of the CPSC and FTC coincides with their increased coordination with AGs. Key leaders of the CPSC and FTC come from state agencies and view AGs as partners in consumer protection enforcement efforts. This synergy can be seen in the increase of joint enforcement actions by these federal agencies and the AGs. Such partnerships become consumer regulatory "force-multipliers," allowing those agencies and AGs to husband scarce resources while changing how more businesses conduct their consumer marketing. These joint efforts also provide AGs with na-

tional platforms for enforcement actions, which, in turn, helps further their political objectives. Understanding this trend is a critical first step in dealing with the enhanced regulatory environment.

The Reenergized CPSC and Its State Outreach Efforts

The CPSC is the primary federal agency responsible for ensuring the safety of consumer products. It can: (1) promulgate regulations regarding specific products, (2) investigate products that violate those standards or that otherwise pose an unreasonable risk of harm to consumers, (3) halt sales or distribution of consumer products, (4) order recalls, and (5) levy fines on companies that distribute noncompliant or hazardous products. 15 U.S.C. §§ 2051 *et seq.*

In response to the massive recall of millions of lead-contaminated toys imported from China in 2007, Congress drastically expanded the CPSC's resources and authority through the Consumer Product Safety Improvement Act of 2008 (CPSIA). Public Law 110-314 (2008), which amends, among other statutes, the federal Consumer Product Safety Act, 15 U.S.C. §§ 2051 *et seq.* As a result, the CPSC's 2010 resources have jumped by more than 71 percent since 2007, including a \$107 million budget and 530 total staff (up from \$63 million and 401 total staff), and its current number of commissioners has increased from three to five. The commissioners that President Obama appointed have strong ties to state government. The new chair, Inez Tenenbaum, spent much of her career in state govern-



ment, having most recently served as superintendent of education in South Carolina. Commissioner Robert Adler was a Deputy AG at the Pennsylvania AG's Bureau of Consumer Protection prior to serving as a counsel for both the CPSC and the U.S. House Subcommittee on Health and the Environment.

Not surprisingly, one of Chair Tenenbaum's first acts at the CPSC was to strengthen the relationship between her office and AGs. In recent congressional testimony, Chair Tenenbaum emphasized that AGs are an essential supplement to the CPSC's authority and that close cooperation with them is key. *See* Testimony of Inez Tenenbaum before the Senate Committee on Appropriations, Subcommittee on Financial Services and General Government (Apr. 14, 2010). Because the CPSIA empowers AGs to stop the sale of products that violate certain federal consumer product safety standards, including restrictions on lead content, 15 U.S.C. § 2073(b)(2), Chair Tenenbaum has directed the CPSC's Office of General Counsel to hold quarterly meetings with AGs to coordinate enforcement action. Almost every AG (either personally or through a consumer protection representative from his or her office) has attended these meetings. *See* Testimony of Inez Tenenbaum before the Senate Committee on Appropriations, Subcommittee on Financial Services and General Government (Apr. 14, 2010). This coordination is already having real consequences. The Kentucky AG recently launched a program called "KY Kids Alert," which coordinates activity between Kentucky state agencies and the CPSC to inform quickly thousands of child care centers and interested communities of any product recalled for posing a risk to children. Press Release, Ky. Att'y Gen., *AG and State Partners Team with U.S. Consumer Product Safety Commission to Launch New Child Product Recall Initiative* (Feb. 25, 2010). The Illinois and Kentucky AGs have investigated the safety of various consumer products with the CPSC, including their recent joint recall of drop-side cribs and their request to the Juvenile Products Manufacturers Association that it withdraw its approval from such products. Press Release, Ill. Att'y Gen., *Infants Still at Risk Amid New Crib Recalls* (Apr. 30, 2010); Press Release, Ky. Att'y Gen., *AG Issues Warning on Drop-Side Cribs* (May 12, 2010).

AGs also have helped the CPSC to facilitate the recall of other unsafe products. Indeed, before the CPSIA was enacted, AGs investigated companies for selling products with excessive levels of lead, including a coordinated action by 39 AGs in 2007 that resulted in Mattel's recall of two million toys made in China and a \$12 million settlement. Press Release, Pa. Att'y Gen., *AG Announces \$12 Million Multi-State Consumer Protection Agreement with Mattel & Fisher-Price*

Concerning Recalled Toys (Dec. 15, 2008). Since Congress enacted the CPSIA, AGs regularly notify the CPSC about unsafe products which, in turn, results in national recalls by the CPSC. *See, e.g.,* Press Release, CPSC, *Children's Toy Jewelry Sets Recalled by Playmates Toys; Charms Violate the Total Lead Standard* (Feb. 2, 2010) ("CPSC was alerted to this hazard by the State Attorney General of California.").

Further, AGs and the CPSC are jointly investigating other potential toxic chemicals in children's products, notably cadmium. After the CPSC and Connecticut AG announced their concern in May 2010 that overseas manufacturers are replacing lead in their products with other heavy metals, including cadmium, the Connecticut AG started to investigate cadmium levels in children's jewelry sold in his State. Justin Pritchard & Jeff Donn, *Walmart Pulling Jewelry Cited in AP Cadmium Report*, Associated Press, May 22, 2010. In June 2010, McDonald's agreed, in cooperation with the CPSC, to recall twelve million Shrek Forever After 3D collectable glasses because of high levels of cadmium. Press Release, CPSC, *McDonald's Recalls Movie Themed Drinking Glasses Due to Potential Cadmium Risk* (June 4, 2010).



Renewed Consumer Protection Focus of the FTC and Its State Outreach Effort

Although often better known for its oversight of antitrust and mergers, the FTC also is empowered to prevent unfair and deceptive trade practices in commerce. 15 U.S.C. § 45. Like the CPSC, the FTC has recently become more aggressive in such enforcement, and a cornerstone of its strategy is working with AGs. In recent Congressional testimony, the new FTC chair, Jon Leibowitz, emphasized that partnering with AGs has allowed the FTC to extend its regulatory reach and to notify consumers of potential danger more quickly and effectively. *See* Testimony of Jon Leibowitz before the Senate Committee on Appropriations, Subcommittee on Financial Services and General Government (May 20, 2010). Chair Leibowitz also recognized that the ability of AGs to collect civil fines, which the FTC lacks, provides significant additional leverage in the federal agency's enforcement efforts. *Id.*

The recent appointment of Julie Brill as the FTC's newest commissioner will only strengthen the coordination between the FTC and AGs. Before her appointment in April 2010, Commissioner Brill was Chief of Consumer Protection and Antitrust for the North Carolina Department of Justice and before that she was a Vermont Assistant Attorney General for Consumer Protection and Antitrust for more than twenty years. She also has lectured at the Columbia Law School's State Attorneys General Program, which educates

AGs and their staff on consumer issues.

The close coordination between the FTC and AGs already is evident in the enforcement actions against manufacturers and sellers of consumer products. In 2008, an FTC and 32 AG investigation of Airborne Health and its claims that its cold remedy product effectively prevented and treated the common cold resulted in a \$37 million payment to the AGs and consumers. Tracy Turner, *Maker of Airborne Settles False-Claim Suit*, Columbus Dispatch, Dec. 17, 2008, at 8C. More recently, in March 2010, the FTC and 35 AGs jointly obtained a \$12 million settlement and injunctive relief from LifeLock for misrepresenting the identity theft protection it offered consumers. Press Release, FTC, *LifeLock Will Pay \$12 Million to Settle Charges by the FTC and 35 States That Identity Theft Prevention and Data Security Claims Were False* (Mar. 9, 2010).

In addition to enforcement actions, AGs are assisting the FTC's efforts to develop new regulations addressing specific consumer protection issues. In 2008, the AGs of Arkansas, California, Connecticut, Delaware, Illinois, Maine, Mississippi, New Hampshire, New Mexico, Oklahoma, and Vermont filed a letter with the FTC urging its adoption of rigorous standards for "green claims," which tout a product as being environmentally friendly. *Letter from Vermont Office of the Attorney General*, FTC Filing No. 533254-00051, Project No. P074207 (Jan. 25, 2008), available at <http://www.ftc.gov/os/comments/carbonworkshop/533254-00051.pdf>. The FTC has held a workshop to consider the AGs' proposals, and it is anticipated that the AGs will likely have a significant impact in this and other rulemaking. FTC Announcement of Public Workshop; Request for Public Comment, 73 Fed. Reg. 11,371-75 (Mar. 3, 2008).

Preparing for a Game of Doubles by Understanding the Role of AGs and the CPSC and FTC

The coordination and cooperation between AGs and their federal counterparts in the CPSC and FTC will grow as it further enhances their efficacy as regulators. This means that companies making, distributing, or selling consumer products face a greater likelihood of confronting coordinated challenges from AGs and the federal government. Companies that do not routinely deal with AGs may not anticipate the impact of these kinds of joint investigations.

Responding to an AG investigation or litigation initiated by an AG is different from dealing with a private litigant. Many AG and consumer protection statutes empower AGs to issue subpoenas and demand sworn testimony. *See, e.g.*, Fla. Stat. §§ 501.206-207 (AG may request information under oath, subpoena witnesses or documents, collect evidence,

and obtain court orders commanding compliance with his or her investigation of suspected violations of the consumer protection law); N.Y. Gen. Bus. Law § 349 (New York AG may issue subpoenas to investigate any practice believed to be harmful). Yet, tools to limit discovery, such as those available under the Federal Rules of Civil Procedure, are generally unavailable in AG investigations. These factors substantially increase the complexity for companies attempting to respond to AG investigations, especially when conducted in coordination with their federal counterparts. Dealing with these issues becomes even more challenging when trying to resolve an investigation in a manner that avoids litigation and the accompanying negative publicity.

In-house counsel, as well as those in government relations, should therefore make efforts to understand AGs and their consumer protection staff, who often have been in their AG's office before the AG was elected (and may therefore exert significant influence over an AG's decision to pursue a matter). Having an existing relationship with AGs or counsel who regularly specialize in this area on a national basis may help companies to quickly, efficiently, and effectively address the consumer protection concerns that AGs and their staff have before those concerns escalate. Companies should also work at understanding the priorities of key personnel at the CPSC and FTC. Again, retaining counsel who regularly deal with the CPSC and FTC as well as AGs will enable a company to develop a comprehensive strategic plan to resolve issues as favorably as possible. Ultimately, adapting to the reality of increased coordination between federal regulators and AGs is a necessity for any company hoping to comply successfully with the regulatory climate of the 21st Century.



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Effective Use of a Regulatory Expert in Product Liability Litigation

by Beth S. Rose

Regulatory issues are often front and center in complex pharmaceutical and medical device product liability litigation. Plaintiffs' complaints routinely focus on product labels, and claim that they do not adequately reflect risks which were known or learned during pre-clinical testing, clinical trials or through post-marketing adverse event reporting. For prescription drug or medical device manufacturers to combat these charges, they must have a strategy to educate the jury about the role the Food and Drug Administration ("FDA") plays in evaluating new drugs and medical devices, and how the agency regulates these products through their entire life cycle. While company witnesses from regulatory and safety are useful in this regard, they are no substitute for the testimony of an FDA/regulatory expert – typically, a former FDA employee with the experience to explain the context in which the manufacturer's conduct should be evaluated.

Like all witnesses, expert testimony is governed by and subject to the applicable rules of evidence. The challenge for the trial lawyer is to craft a direct examination that withstands evidentiary objections that the expert's testimony is invading the province of the jury or is nothing more than a legal conclusion. This is no easy feat inasmuch as the regulatory expert's opinion is often based on the relationship between a complex set of facts and applicable law. This article describes the principal areas in which testimony by a regulatory expert has been offered, allowed or disallowed and offers best practices to maximize the admissibility of such testimony at trial.

Explaining the General Framework of the FDA and its Regulations

Testimony explaining how the FDA and its regulations operate is the most traditional and least controversial area for a regulatory expert. An expert may testify about the structure of the FDA, the education and experience of agency reviewers, and how the FDA goes about evaluating a New Drug Application ("NDA") or Pre-Market Application ("PMA") to determine the safety and efficacy of a pharmaceutical or medical device not yet on the market. The expert may explain to the jury the circumstances under which a drug or device manufacturer must provide post-market adverse event data to the FDA. This type of testimony is almost always permitted, because it fulfills the traditional role of an expert - aiding the jury in understanding specialized

evidence and helping it determine a fact in issue. *See, e.g., Fed. R. Evid. 702; In re Fosomax Prods. Liab. Litig.*, 2009 U.S. Dist. LEXIS 64661, *68 (S.D.N.Y. 2009).

Providing a Factual Summary of the Regulatory History of a Product or the Defendant's Actions

A party may utilize an FDA expert to provide a summary or narrative of the regulatory history of a product. In the prescription drug context, the testimony may include an explanation of the animal testing conducted before human testing was initiated. Likewise, in a medical device case, the expert may explain why the manufacturer submitted a supplemental pre-market application to initiate a label change. This type of expert testimony is traditionally admissible provided that the expert is "adding" something to the evidence he or she is summarizing. Courts are more likely to allow an expert to summarize a product's regulatory history where the expert is explaining the regulatory significance of the evidence, defining complex or specialized terms or drawing inferences from the documents that are only apparent because of the expert's specialized knowledge or experience. *See In re Fosomax*, 2009 U.S. Dist. LEXIS 64661 at *72-73. Parties tend to face admissibility problems where the expert is quoting, summarizing or regurgitating



documents without providing an additional commentary or analysis beyond the text of the documents themselves. *See generally, In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871 (E.D. Ark. 2008) (striking an FDA expert's testimony where it consisted solely of summarizing and quoting documents without any expert commentary or analysis).

Evaluating and Opining on the Defendant's Compliance with FDA Regulations

Having an expert discuss the FDA framework and comment on the significance of the regulatory evidence can be very helpful. Most parties, however, want the expert to take the next logical step, and evaluate whether the manufacturer "complied" with or "violated" FDA regulations. The admissibility of such testimony can be dicey especially where the expert uses certain buzzwords such as "complied," "violated" or "adequate." Many courts have balked at allowing FDA experts to express these opinions because they view them as legal conclusions or an invasion of the province of

the jury. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) (“Such testimony usurps the role of the trial judge in instructing the jury as to the applicable law and the role of the jury in applying that law to the facts before it.”). Some courts, however, have allowed FDA experts to opine as to the “reasonableness” of the defendant’s conduct in the context of the applicable FDA regulations. *See, e.g., In re Guidant*, 2007 WL 1964337, *7 (D. Minn. June 29, 2007) (holding that plaintiff’s FDA expert could testify as to whether the defendant’s actions were “reasonable and appropriate”). Attorneys planning to use an FDA expert to give this type of opinion testimony, should try to use phrases such as “reasonable,” “appropriate” and “properly” during their direct examination to increase the likelihood that the testimony will be admitted.

Interpreting and Opining on Regulations

While regulatory experts are generally precluded from offering opinions that amount to legal conclusions, the difficulty often lies in determining what type of testimony actually constitutes a legal conclusion. The context of the expert’s testimony is critical to this determination. In *Steele v. DePuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439 (D.N.J. 2003), the court was asked to determine whether the FDA’s approval of the product at issue pre-empted plaintiff’s claims. Plaintiffs submitted an affidavit of a regulatory expert who concluded that the “Real Time Review” procedure that the FDA used to evaluate and approve the product was more akin to the 510(k) process (which the Supreme Court found does not pre-empt state tort claims) than the PMA process. The court struck the expert’s affidavit because his opinion addressed a purely legal issue – pre-emption – and was not designed to aid the jury in understanding the evidence or determine an issue in dispute. *Id.* at 445-46. Courts have also precluded FDA experts from opining on an FDA regulation where the expert’s interpretation is inconsistent with the court’s view of the FDA’s guidance on an issue. *McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 262-65 (N.J. App. Div. 2008).

Opining on How the FDA Would Have Reacted To Regulatory Submissions

To rebut a claim that the manufacturer should have warned about an alleged side effect, it is helpful to show that the FDA would have rejected the additional language plaintiffs propose. An argument can be made that an FDA expert who has considered label changes during his or her tenure at the agency has the requisite training and experience to offer such an opinion. Most courts, however, have rejected such an argument, finding that the opinion lacked a proper evidentiary foundation and was speculative. *See McDarby*, 949 A.2d at 263 (precluding an FDA expert from testifying that

had Merck submitted a label change for Vioxx pursuant to the CBE process, the FDA would have rejected it). FDA experts are prohibited from giving an opinion on the intent, motives and state of mind of FDA reviewers and officials, or their anticipated reactions to regulatory submissions because despite their specialized knowledge and training, FDA experts cannot read the minds of FDA employees. *See In re Fosomax Prods. Liab. Litig.*, 2009 U.S. Dist. LEXIS 64661 at *72-73.

Nevertheless, depending on the subject matter and assuming that the regulatory expert is a former FDA employee, it may be possible to lay a sufficient foundation and elicit the desired testimony. For example, in a trial last year in federal court, the judge initially sustained an objection to questions regarding whether a document prepared for a foreign regulatory agency should have been submitted to FDA. After the expert testified that she was familiar with foreign regulatory submissions and had reviewed them while at the FDA, the court allowed her to opine that the company acted reasonably by not submitting the document to the agency.

Conclusion

Retention and development of a well qualified, credible regulatory expert in complex product liability litigation is essential to a successful defense. A carefully constructed direct examination will help maximize the expert’s utility at trial. While the evidentiary issues are challenging, anticipating and addressing potential objections prior to trial is well worth the effort.



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Canada's Consumer Product Safety Legislation

By Peter Pliszka and Richard Butler

As many U.S. manufacturing corporations and their attorneys are aware, Canada has previously taken a distinctly *laissez faire* approach toward the regulation of most consumer products. However, proposed regulatory changes for consumer products in Canada will re-constitute Health Canada as a powerful regulator over manufacturers, importers, sellers and advertisers of consumer products in Canada. The proposed changes are included in federal Bill C-36, "An Act respecting the safety of consumer products," also known as the Canada Consumer Product Safety Act ("CCPSA").

The impetus for Bill C-36 was a number of high profile recalls in 2007 and 2008 (including, among others, leaded paint in children's toys, and melamine in infant formula), and a perceived need to modernize Canada's health and food product safety regime to deal with "new economic realities," including new products, new technologies and increased global trade. The stated purpose of the CCPSA, is to create a stronger and more standardized consumer product safety regime in Canada. The CCPSA's most significant features are (i) imposition of increased and onerous reporting responsibilities upon the consumer products industry; (ii) creation of a new power for Health Canada to order recalls of consumer products, and; (iii) implementation of a new prosecution and penalty regime to compel regulatory compliance by the industry. This article will briefly summarize the regulatory context, and some of the highlights, of the CCPSA.

Current Regulatory Landscape

Consumer products in Canada fall under the jurisdiction of Health Canada, the government's public health department responsible for researching and assessing health risks and safety hazards associated with the various consumer products. The current primary legislation governing consumer product safety generally is the Hazardous Products Act ("HPA") (R.S., 1985, c. H-3), which was first enacted in 1969.

However, the HPA does not apply to all consumer products generally. Under the HPA, Health Canada's mandate includes the regulation of:

"...any product, material or substance that is or contains a poisonous, toxic, flammable, explosive, corrosive, infectious, oxidizing or reactive product... [which] is or is likely to be a danger to the health and

safety of the public;

or any product designed for household, garden or personal use, for use in sports or recreational activities, as lifesaving equipment or as a toy, plaything or equipment for use by children... [which] is or is likely to be a danger to the health or safety of the public because of its design, construction or contents." [emphasis added]

Section 6(1) subs. (a) and (b), describing the authority of the federal Government to include items that meet the above noted description to part I (banned items) or II (restricted items) of Schedule I.

The manufacture, import and sale of a limited number of consumer products is regulated under a few product-specific statutes including the Canadian Food Inspection Agency Act (relating to food), the Food and Drugs Act (relating to food, drugs, medical devices and cosmetics), or the Motor Vehicle Safety Act (relating to motor vehicles).



The HPA is divided into a number of sections based on the type of restrictions or prohibitions attached to the product/material. *As it relates to consumer products*, the HPA consists of two parts. Part I

of the HPA identifies approximately 55 consumer products that are either restricted through regulation, or outright prohibited. In brief, under the HPA, no person shall advertise, sell or import a prohibited product. Secondly, no person shall advertise, sell or import a restricted product except as authorized by the regulations.

Part I of Schedule I identifies the "prohibited" consumer products that are banned from import, sale and advertisement in Canada. Part I focuses on inherently dangerous products, or products containing inherently dangerous materials, including some of the more obvious hazards ranging from asbestos to lawn darts. Also included, with particular reference to children, are toys that infringe a number of prescribed hazards, including flammability, presence of heavy metals, physical hazards (could break apart and become choking hazard) and toxicity.

Part II of Schedule I lists the restricted products that may be imported, sold or advertised in Canada provided certain specified regulations are met. This list covers a range of products and substances, the regulation of which is guided by

more detailed product-specific regulations. These products may be dangerous, depending on their design, packaging or toxicology (including children's cribs and cradles, consumer chemicals and containers).

Under the HPA, Health Canada's enforcement powers are *reactionary* in nature and limited to products that are *already prohibited or restricted*. At present, the HPA does not confer upon Health Canada any legislative authority to compel parties in the supply chain to initiate product recalls. Further, at present, Health Canada lacks legislative authority to regulate the manufacture and sale of consumer products, generally, which are not within the scope of the HPA.

The Proposed CCPSA and Health Canada's Potential New Powers

The CCPSA is the Canadian Government's proposed legislation to overhaul consumer product regulation in Canada. The CCPSA will repeal and replace Part I of the HPA. It will apply to all "consumer products" that are, or are likely to be, a danger to the health or safety of the public regardless of whether they are already listed in the HPA's Schedules, or subject to product-specific regulations. As a result, a large number of consumer products not currently subject to detailed regulation will be caught by the proposed legislative regime. Thus, the CCPSA will shift Canadian consumer products safety to a *proactive* or anticipatory position that is more consistent with the consumer product regulatory regime in the U.S.

The CCPSA contains several broad prohibitions which build upon the prescribed products restricted by the HPA, and it prescribes a broad general prohibition against manufacturing, importing, advertising or selling a consumer product that:

- Is a danger to human health or safety;
- Is the subject of a recall order made under section 31 or reviewed under section 35 [reviewed by the federal Minister of Health], or is the subject of a voluntary recall in Canada because the product is a danger to human health or safety; or
- Is the subject of a measure that the manufacturer or importer has not carried out but is required to carry out under an order made under section 32 [order for recalls and taking measures] or such an order if it is reviewed under section 35.

Increased Reporting Responsibilities

CCPSA also imposes upon suppliers of consumer products a duty to notify Health Canada, and the person from whom they received the consumer product, of any "incident." "Incident" is broadly defined and includes:

- An occurrence involving a consumer product, whether in Canada or elsewhere (clause 14(1)(a)) that resulted, or may reasonably have been expected to result, in an individual's death, or to have had serious adverse effects on his or her health, including a serious injury;
- A defect or characteristic that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury (clause 14(1)(b));
- Incorrect or insufficient labelling information or instructions that may reasonably be expected to result in a death or serious adverse health effects; or
- A recall or measure that is initiated for human health or safety reasons by a foreign entity or a provincial government (clause 14(1)(c)).

S. 14(1) "Duties in The Event of an Incident."

The CCPSA will impose very onerous, and arguably impractical, timing obligations for these reports. It will require the manufacturer, importer or seller to provide Health Canada with "all the information in their control regarding any incident" within just two days after they become aware of the incident. The manufacturer or importer will be further required to provide Health Canada with a subsequent written report containing information about the incident, the product, any other products that they manufacture or import that could be involved in a similar incident, and corrective measures they plan to take, within ten days after they become aware of the incident.

Enhanced Powers of Compliance and Enforcement, Including Recalls

The CCPSA stipulates that the administration and enforcement functions will be performed by new officials called "inspectors." Pursuant to sections 21 and 22, inspectors will be empowered to enter any place in which they have reasonable grounds to believe that a consumer product is manufactured, imported, packaged, stored, advertised, sold, labelled, tested or transported, or a document relating to the administration of this Act or the regulations is located. Inspectors will be able to seize materials or documents, or make an order that materials be tested.

More significantly, if Health Canada believes on reasonable grounds that a consumer product is a danger to human health or safety, the Minister will be empowered to order the person who manufactures, imports, or sells the product to recall it. Further, the Minister of Health will be empowered to order the time and manner in which the recall is to be conducted. If a person does not comply with such an order, Health Canada will be able to carry out the recall itself, at the expense of that person. S. 31.

Contraventions of obligations imposed by CCPSA will fall into one of two categories – “violations” or “offences.” Failure to adhere to an inspector’s order is a violation (S. 49. states that every person who contravenes an order that is made under section 31 or 32 or reviewed under section 35 commits a violation and is liable to the penalty established in accordance with the regulations). Violations will be addressed by the new Administrative Monetary Penalties Scheme (“AMPS”). AMPS is a flexible process for sanctioning non-compliance, with penalty ranges set by regulation, and the possibility of a reduced penalty if the party enters into a Compliance Agreement with Health Canada. A Compliance Agreement is an agreement between the Minister of Health and the person in violation of the CCPSA, including any terms and conditions that are satisfactory to the Minister, but which may include a provision for a reasonable security and/or the reduction of the penalty for the violation per S. 54.

A person who contravenes a provision of the CCPSA, or an order made under it, may be found guilty of an “offence” (S. 41. (1) A person who contravenes a provision of this Act, other than section 8, 10, 11 or 20, a provision of the regulations or an order made under this Act is guilty of an offence and is liable...). On conviction, the person could potentially be fined up to \$5,000,000, or imprisoned up to two years, or both (S. 41. (1)(a), for indictable offences). Beyond that, section 41(3) will authorize the court to impose even more severe penalties for persons who wilfully or recklessly contravene a provision of the CCPSA or an order made under it. A person in that circumstance can be fined up to “the amount of which is at the discretion of the court,” or to imprisonment for a term of up to five years, or both. Further, the CCPSA will provide for recourse against officers and directors. Section 42 states that officers and directors who direct, authorize, assent to, acquiesce in, or participate in the commission of an offence, are a party to that offence and are liable to the same punishment as described above.

Byzantine History of CCPSA

Bill C-36 is the third incarnation of the CCPSA. The CCPSA was originally introduced in Canada’s House of Commons in 2008 as Bill C-52. That Bill died when that session of Parliament was dissolved in September, 2008 for a federal election. Upon the start of a new Parliament shortly after that election, the bill was re-introduced in January, 2009, as Bill C-6. Bill C-6 was eventually passed by Canada’s House of Commons, and by the Senate (Canada’s “upper house”), with some amendments, by mid-December, 2009, but not yet proclaimed into law. However, just before Christmas, the current Conservative minority government unexpectedly prorogued Parliament, thereby unilaterally closing Parliament and ending all bills which had not yet been enacted.

Parliament reconvened in early March, 2010. Bill C-36 has very recently (June 9, 2010) been reintroduced. The current Government continues to champion the CCPSA. Bill C-36 is expected to become law in Canada since it has generally enjoyed all-party support in the House of Commons. However, there are now rumors of a fall election in Canada. As such, once again, the potential of an abbreviated Parliamentary session is placing the life expectancy of the CCPSA in limbo.

Conclusion

If and when it becomes law, the CCPSA will affect all companies, both Canadian and non-Canadian, that manufacture or sell consumer products in the Canadian marketplace. Any such companies, which do not currently have comprehensive recall or information tracking systems in place, should seriously consider developing and implementing such programs before the CCPSA becomes law in Canada. The potential breadth of Health Canada’s new investigative and recall powers under the CCPSA, the increased severity of the offence provisions under the CCPSA, and the Canadian Government’s recent focus on product safety generally, will mean a far greater risk for any company that does not have these systems in place whenever any product safety incident may occur in the future. Forewarned is forearmed.



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The Québec Consumer Protection Act is Changing— Are You Ready?

By Enrico Forlini, Fasken Martineau DuMoulin LLP, Montréal, Québec



On June 30, 2010, Bill 60, *An Act to amend the Consumer Protection Act* came into force. Bill 60 (S.Q. 2009, ch. 51) *An Act to amend the Consumer Protection Act*. This Bill intro-

duced important amendments to the Quebec Consumer Protection Act ("CPA"). R.S.Q., ch. P-40.1. These changes will have a significant impact on manufacturers, distributors and retailers of consumer products who operate in the province of Quebec. Many will have to review and update their consumer contracts to ensure compliance with the amendments or face the risk of potentially expensive litigation if they do not adapt. This paper will review and highlight some of these changes to the Act.

When Does the CPA Apply?

The CPA applies to every contract for goods or services entered into between a consumer and a merchant in the course of his business, with a few limited exceptions (section 2 CPA). The notion of "consumer" refers to a natural person, except a merchant who obtains goods or services for the purpose of his business. The term "merchant" is not defined in the CPA but has been interpreted by the courts as including sole proprietorships and companies.

Prohibited Stipulations in Consumer Contracts

The CPA already contained numerous prohibitions against certain stipulations. For example, the Act already prohibited a stipulation whereby a merchant purported to limit its liability or a clause which obliged the consumer to refer a dispute to arbitration. Sections 10 and 11.1 CPA.

As of June 30, 2010, the CPA will also prohibit the following stipulations in a consumer contract:

- a) Any provision which gives a merchant the right to unilaterally amend a contract. These stipulations will only be tolerated if they comply with strict conditions adopted under the new legislation. For example, if the amendment entails an increase in the consumers' obligations or a reduction in the merchants' obligations, the consumer may refuse the amendment and cancel the contract. Section 11.2 CPA;
- b) Any stipulation under which a merchant may unilaterally cancel a fixed term service contract will be prohibited, under reserve of the merchant's right to cancel the contract when the consumer has defaulted in a serious manner or, in the case of an obligation of successive performance, the default occurs repeatedly. Section 11.3 CPA;
- c) Any stipulation having the effect of obliging a consumer to submit a dispute to a court other than a court of the province of Québec. Section 25.8 of the *Regulation Respecting the Application of the Consumer Protection Act*, R.R.Q., 1981, c. P-40.1, r.1 as amended by the *Regulation to Amend the Regulation Respecting the Application of the Consumer Protection Act*, O.C. 495-2010, 9 June 2010, G.O.Q. 2010.II.1389A ("Regulation");
- d) Any stipulation intended to exclude or limit the right of the consumer to assert a claim based on the fitness for purpose warranty or the warranty of durability. Section 25.4 Regulation;
- e) Any stipulation which restricts a consumer's right to exercise certain rights provided by the Act against either a merchant or the product's manufacturer. Section 25.6 Regulation; and
- f) Any stipulation whereby a merchant or manufacturer contractually excludes or limits its obligation

to be bound by a written or verbal statement made by its representative concerning a good or service. Section 25.5 Regulation.

The amendments to the CPA with respect to prohibited stipulations also will require proactive disclosure by merchants, retailers and manufacturers. Indeed, a new provision introduced into the Act provides that any stipulation that is inapplicable in Quebec under a provision of the Act or its Regulation must be immediately preceded by an implicit and prominently presented statement to that effect. Section 19.1 CPA. Thus, retailers or manufacturers who have adopted a standard contract for their goods sold throughout Canada may be forced to redraft their contracts to add the mandatory language required by the amendments to the CPA. The common practice of inserting a provision in a contract whereby the retailer states that some states or provinces may confer greater rights than those provided in the contract will no longer be sufficient to comply with the CPA.

Prepaid Cards

Until the CPA was amended through Bill 60, prepaid cards were not regulated in the province of Quebec. As of June 30, 2010, prepaid cards will be significantly regulated as a result of the amendments introduced in the Act.

The Act defines prepaid cards as a certificate, card or other medium of exchange that is paid in advance and allows the consumer to acquire goods and services from one or more merchants. Section 187.1 CPA.

The Act will prohibit any stipulation providing for an expiry date on a prepaid card. Section 187.3 CPA. A contract for the sale of a prepaid card for mobile telephone services will be exempt from this rule. Section 79.1 Regulation.

In addition, the Act also prohibits imposing a charge to a consumer for the issuance or use of a prepaid card. Section 187.4 CPA. The Regulation has carved out certain exceptions to this rule notably for open loop prepaid cards issued by financial institutions for the procurement of goods or services from all merchants using the international payment network identified on the card. Section 79.6 Regulation.

Finally, the Act also requires a merchant to refund to the consumer at the latter's request the balance on a prepaid card when the balance is \$5.00 or less. Section 187.5 CPA. Open loop prepaid cards issued by financial institutions will be exempt from this requirement. Section 79.6 Regulation.

Prohibited Business Practices

The CPA regulates different business practices aimed at consumers. Bill 60 will simply add to these. A provision

introduced through Bill 60 will require all merchants, manufacturers or advertisers to resort to all-inclusive pricing in advertisements. Section 224, paragraph 2. The price advertised must include the total amount the consumer must pay for the goods or services, but need not include provincial and federal sales taxes. This will force advertisers and manufacturers in some industries such as the airline industry and the automobile industry to alter their pricing strategies. It also raises practical difficulties for national TV, internet or radio advertising campaigns, since this rule does not exist in all Canadian provinces.

The new legislation will also address extended warranty contracts, a popular form of contract in the consumer retail market. Such contracts are defined as including a contract under which a merchant binds himself toward a consumer to assume directly or indirectly all or part of the costs of repairing or replacing goods in the event they are defective or malfunction, otherwise than under a basic warranty given freely to every consumer who purchases goods or has them repaired. Section 1 (e.1) CPA. Under the new legislation, before a merchant concludes a contract that includes an extended warranty, the merchant must inform the consumer of the existing legal warranties associated with the product as well as provide the consumer with a compulsory notice in paper form. The notice must contain, among other things, references to the legal warranties already provided by the CPA and refer the consumer to the website of the Quebec Consumer Protection Office for more information on legal warranties. Section 228.1 CPA and sections 91.9 and 91.10 Regulation.

Section 228.1 CPA will also require any merchant who proposes such a contract to inform orally the consumer of the existence and duration of the basic contractual warranty offered with the product.

Conclusion

The CPA has undergone significant change. Retailers and manufacturers who sell consumer goods in the province of Québec cannot sit idly by and ignore these changes, lest they expose themselves to considerable liability, notably in the form of class action lawsuits. This risk is expanded given a recent decision of the Québec Court of Appeal which has held that punitive damages may be awarded under the CPA even in the absence of compensatory damages. In *Brault & Martineau inc. v. Riendeau* [2010] QCCA 366, the Québec Court of Appeal affirmed a lower court judgment that awarded class action plaintiffs \$2 million in punitive damages against a furniture retailer who violated the provisions of the Act concerning misleading advertising. Prior to this decision, it was not clear whether punitive damages could be awarded under the CPA where there was no proof of compensatory damages.



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A Cautionary Tale: The Duty To Preserve And Collect Documents Revisited

by Beth S. Rose

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The Honorable Shira Scheindlin of the Southern District of New York — author of the seminal *Zubulake* opinions — recently issued another landmark e-discovery decision that practitioners will be analyzing for years to come. In *The Pension Committee of the University of Montreal Pension Plan, et al. v. Banc of America Securities LLC, et al.*, No. 05 Civ. 9016 (SAS), 2010 WL 184312, S.D.N.Y. (Jan. 15, 2010), Judge Scheindlin revisits the issue of spoliation of evidence and the duty to preserve documents. As most practitioners now know, the duty to preserve documents may arise well before the filing of the complaint or even the retention of counsel. The test is whether the party reasonably anticipates litigation.

The duty to preserve documents, however, is intertwined with the duty to collect them. Not only must a party institute a written litigation hold in a timely way, it also must collect documents from key players, and depending on the facts and circumstances of the case, collect documents from peripheral and former employees and preserve backup tapes.

The Pension Committee decision involved spoliation sanctions against 13 plaintiffs based on their alleged failure to timely issue written litigation holds and to preserve certain evidence before the filing of the complaint. While acknowledging that litigants were not required to produce documents with “absolute perfection,” the court cautioned that “at a minimum they must act diligently and search thoroughly at

the time they reasonably anticipate litigation” or face potential spoliation of evidence consequences and sanctions, including but not limited to dismissal of their pleading, an adverse inference and monetary sanctions as may be appropriate. Certain plaintiffs found to have been “grossly negligent” were ultimately subject to an adverse inference instruction and monetary sanctions even though the court found no “egregious examples of litigants purposefully destroying evidence.”

In February 2004, plaintiffs, a group of investors holding shares in two British Virgin Island-based hedge funds seeking to recover alleged losses of \$550 million arising from the liquidation of the funds, commenced an action in the United States District Court for the Southern District of Florida. In October 2005, the matter was transferred to the Southern District of New York. Between 2004 and February 2007, all discovery was stayed

as was required by the Private Securities Litigation Reform Act.

Duty to Preserve

In April 2003, the funds' manager had filed for bankruptcy and, in July 2003, the funds were placed into receivership in the Southern District of Florida. After being retained in October 2003, counsel contacted plaintiffs and instructed them to begin document preservation and collection. Counsel instructed plaintiffs by phone, e-mail and memoranda to be “over, rather than under, inclusive” and to include electronic documents in the production. In what may come as a surprise to some, the court determined that this protocol did



not meet the litigation hold standard because it did not: (1) direct the preservation of all relevant paper and electronic records; (2) create a mechanism to collect the preserved records; or (3) provide for someone other than the employee to determine whether the preserved records were responsive under counsel's supervision. Although the court noted that "not every employee will require hands-on supervision from an attorney," it cautioned that "attorney oversight of the process, including the ability to review, sample, or spot-check the collection efforts, is important" and that the "adequacy of each search must be evaluated on a case-by-case basis." Despite filing the complaint in 2004, counsel did not issue a written litigation hold until 2007 — after the stay was lifted — which was determined by the court to be "grossly negligent."

The court also determined that plaintiffs' duty to preserve attached in April 2003 — even before retaining counsel — based on the facts presented. There were several events, including the bankruptcy filing by the funds' manager, certain plaintiffs retaining counsel and the filing of a prior complaint that caused the duty to preserve to attach. The court reiterated that the "duty to preserve evidence arises when a party reasonably anticipates litigation" and that once it attaches, the party "must suspend its routine document retention/destruction policy and put in place a 'litigation hold' to ensure the preservation of relevant documents."

Spoliation of Evidence

During discovery in October 2007, a group of defendants, the Citco defendants, alleged that plaintiffs' document production contained "substantial gaps." At the close of discovery, the Citco defendants moved for sanctions and to dismiss the complaint based on plaintiffs' alleged failure to preserve and produce both paper and electronic documents. The court ordered plaintiffs to provide declarations describing their document preservation and production efforts. The Citco defendants deposed several of the custodians regarding their declarations and identified at least 311 additional documents that were not produced. They also alleged that nearly all of the declarations were "false and misleading and/or executed by a declarant without personal knowledge of its contents."

As a general matter, the court explained that the "[f]ailure to preserve evidence resulting in the loss or destruction of relevant information is surely negligent, and, depending on the circumstances, may be grossly negligent or willful. For example, the intentional destruction of relevant records, either paper or electronic, after the duty to preserve has attached, is willful." In addition, "[t]he failure to issue a written litigation hold constitutes gross negligence because the failure is likely to result in the destruction of relevant information."

The court further determined that the "failure to collect records — either paper or electronic — from key players constitutes gross negligence or willfulness as does the destruction of email or certain backup tapes after the duty to preserve has attached." In contrast, the court noted that the "failure to obtain records from all employees (some of whom may have had only a passing encounter with the issues in the litigation), as opposed to key players, likely constitutes negligence as opposed to a higher degree of culpability." The court further reviewed other recent decisions finding that the "failure to collect information from the files of former employees that remain in a party's possession, custody, or control after the duty to preserve has attached" constituted gross negligence and the "failure to assess the accuracy and validity of selected search terms" constituted negligence.

The court also provided a "cautionary note" regarding backup tapes. Although it did not require the preservation of all backup tapes, the court advised that "if such tapes are the sole source of relevant information (e.g., the active files of key players are no longer available), then such backup tapes should be segregated and preserved." However, if "accessible data satisfies the requirement to search for and produce relevant information, there is no need to save or search backup tapes."

After reviewing the conduct of each of the 13 plaintiffs, the court determined that some plaintiffs were "grossly negligent" while others were only "negligent" in failing to timely implement a written litigation hold and failing to preserve relevant documents. With respect to the "grossly negligent" plaintiffs, the court imposed the sanction of permitting the jury, if they so chose, to determine that the lost evidence was both relevant and favorable to the Citco defendants, and to draw an adverse inference against those plaintiffs. In addition, the court ordered all 13 plaintiffs to pay the Citco defendants monetary sanctions, including reasonable costs and attorneys' fees related to reviewing the plaintiffs' declarations, the depositions of these declarants, and in filing their spoliation motion.

While the Pension Committee decision is not binding on New Jersey courts, it surely will be viewed as persuasive authority and parties seeking sanctions are likely to rely on this opinion. Although spoliation of evidence is fact specific and will be analyzed on a case by case basis, the Pension Committee decision makes clear that anything less than a timely written litigation hold put in place as soon as litigation is reasonably anticipated can constitute "gross negligence" and could result in dismissal, an adverse inference jury charge, and monetary sanctions. Moreover, once litigation is reasonably anticipated, a party must direct the preservation of all relevant paper and electronic records by identifying key players involved in the litigation, including current and former employees, implement a procedure to collect the pre-

served records that includes attorney oversight and supervision of the process, does not simply rely on the employee to determine whether materials are responsive, and provides for evaluation of the adequacy of each search conducted.



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ISO 9001 and the Legal Implications of Document Control

©Timothy J. Budacki and James W. Kolka, 2010

Introduction

The following five statements capture various aspects of the legal implications of document control:

- If you can't prove it, it doesn't exist!
- Everything you write or say can and will be used against you in a court of law!
- Once legal action has begun, the destruction of documents is a criminal offense (e.g. Arthur Andersen/Enron)!
- All documents can be obtained in discovery by Plaintiff's Request for Production of Documents! Attorney-client privilege cannot be used to withhold documents from Plaintiff's Request for Production of Documents!

This article will explore each of these statements in the context of document control and, more specifically, ISO 9001. Because companies are now adopting the ISO 9001:2008 standard, the article will focus on that standard.

While the issue of "document control" is far broader than control within ISO 9001:2008, many people now, unfortunately, identify document control so closely with ISO 9001 that they often give the ISO standard greater credence than it deserves. An example would be corporate counsel and executive management who believe internal and third party auditors examine legal and liability issues when they examine ISO 9001 documents. Consequently, they see no reason to examine document control separately from a legal perspective, which can be a costly mistake. ISO 9001:2008 provides an excellent platform to address legal issues and liability exposure, but it requires a different skill set and professional expertise to put it in place.

What is the Purpose of Document Control in an ISO 9001:2000 Quality Management System?

The significance of documentation in an ISO 9001 Quality Management System is described in *ISO 9000:2000*

American National Standard, Quality management systems – Fundamentals and vocabulary, 2.7 Documentation:

2.7.1 Value of documentation

Documentation enables communication of intent and consistency of action. It contributes to:

- a) achievement of conformity to customer requirements and quality improvement,
- b) provision of appropriate training,
- c) repeatability and traceability,
- d) provision of objective evidence, and
- e) evaluation of the effectiveness and continuing suitability of the quality management system.

Generation of documentation should not be an end in itself but should be a value-adding activity.

2.7.2 Types of document used in quality management systems

- a) documents that provide consistent information, both internally and externally, about the organization's quality management system; such documents are referred to as quality manuals;
- b) documents that describe how the quality management system is applied to a specific product, project or contract; such documents are referred to as quality plans;
- c) documents stating requirements; such documents are referred to as specifications;
- d) documents stating requirements or suggestions; such documents are referred to as guidelines;

- e) documents that provide information about how to perform activities and processes consistently; such documents can include document procedures, working instructions and drawings;
- f) documents that provide objective evidence of activities performed or results achieved; such documents are referred to as records.

Each organization determines the extent of documentation required and media to be used. This depends upon factors such as the type and size of the organization, the complexity and interaction of processes, the complexity of products, customer requirements, the applicable regulatory requirements, the demonstrated ability of personnel, and the extent to which it is necessary to demonstrate fulfillment of quality management system requirements.

An ISO 9001 Quality Management System allows companies to systematically monitor their processes and to achieve consistency in process operations. In other words, the focus is on process management. Internal audits and external audits of an ISO 9001 QMS do not examine liability issues related to products. These issues are outside of the purview and competence of the auditors. We will now turn to the issue of legal liability and document control.

If you can't prove it, it doesn't exist!

Central to product liability litigation is the ability of a company to prove that it makes a safe product. Proof of product safety begins with design. Design documents must demonstrate that safety was a key issue when the product was designed. Since lawsuits most often occur years after the product was designed, the quality of design files is critical. They need to stand on their own merits, particularly since the documents' authors will likely have moved on to other positions, other companies or retired when the files are requisitioned in a lawsuit.

When a Legal Summons arrives, the cause of action against a manufacturer typically alleges one of the following:

- **Manufacturing Defect** where the product departs from its intended design, is physically flawed, damaged or incorrectly assembled.
- **Design Defect where** foreseeable risks could have been reduced by the adoption of a reasonable alternative design, thereby creating an unsafe product.
- **Defective Design** due to non-conformance with

state-of-the-art design development or the allegation that alternative, technologically feasible and practical designs were not used, resulting in an unsafe product.

- **Warning Defect** because foreseeable risks in the use of the product could have been reduced by providing reasonable warnings and instructions and the omission of these warnings and instructions render the product unsafe.

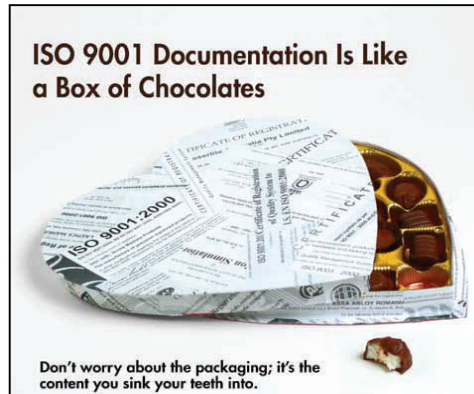
For products heading toward Europe or marked for global sales, the EU's new approach directives, essential safety requirements, EN safety standards and technical files could be added to the list of design safety requirements affecting product liability litigation.

A company may believe that it designs the very best and safest products on the market, but, "If you can't prove it, it doesn't exist"! Plaintiff counsel will use the absence of well drafted design documents to imply that the manufacturer was indifferent to safety during the design phase or had something to hide. Whatever the reason for the absence of design documents, plaintiff counsel will argue this fact to make their case that the product design was defective. In response, the manufacturer will have to spend time and resources to find people who were present when the product was designed and have them attest that safety was of the utmost concern. The jury is then left to decide which version of the "facts" it believes. Documentation created at the time of product design is obviously more credible than documentation created after a lawsuit is filed. Having to reconstruct a design file by testimony from long gone designers in response to a design defect claim is a terribly expensive lesson to learn about poor design documentation.

ISO 9001 internal and external auditors will not look at design documentation from a legal perspective. In many instances, they simply cannot; for numerous third party auditors this would constitute consulting as well as practicing law without a license.

Everything you write or say can or will be used against you.

Companies must have good documentation to manage an ISO 9001 Quality Management System and defend themselves in liability lawsuits. Examples of poor documentation that can lead to grief in the courtroom include the following:



- Quality System Audit Reports including non conformities
- Corrective and Preventive Action Reports and minutes
- Management Review Minutes
- System Safety Reports: FMEA, HAZOP, hazard analysis/risk analysis, human factors studies, EU essential requirements checklists, EN safety standards and technical files
- Validation Master Plans, Validation (IQ, OQ, PQ) Protocols and SOP's
- Discrepancy Tracking Reports
- Traditional memos
- Field notes
- E-mail
- Voicemail
- Electronic and paper records
- Palm Pilot notes
- CYA memos
- Day Planners
- Meeting minutes and discussions
- Meeting minutes "marginalia"
- Project documents
- Patent applications
- Reports
- Customer complaints

Each of these types of documentation has been introduced in various lawsuits and each has contributed to adverse decisions against manufacturers. Words such as "defective", "negligent", "unsafe", "unreasonably dangerous", "hazardous", "reckless", "callous", "malicious", "completely safe", "shatterproof", "harmless", "indestructible" and "failsafe" have called into question the safety of a product.

The following example underscores this point: A mid-level engineer writing a "stream of consciousness" memo to his boss recommended a small design change resulting in a California jury awarding compensation and punitive damages of \$100 million dollars. The memo stated that the manufacturer could dramatically improve the safety of a product by incorporating a \$.30 design modification. The manufacturer opted to disregard the modification on a cost/benefit analysis. A decade later, the plaintiff's attorneys located the memo during discovery and used it as the centerpiece of their catastrophic burn case. There are other examples.

Nearly all communication is fair game in a lawsuit and can be discovered. Most recently, plaintiff's attorneys have turned to electronic communications. E-mails, thought by employees to have been erased or trashed, have been retrieved or resurrected through electronic sleuthing and have come back to haunt companies at trial. Only a small portion of the communications identified above would fall under ISO 9001 document control, but all of them give rise to legal and liability concerns about document control.

Once legal action has been initiated, the destruction of documents is a criminal offense (e.g. Arthur Anderson/Enron)

Given the attention in the news about the collapse of Enron and the shredding of documents by employees at Arthur Andersen and Enron, this statement probably is the easiest to understand. Criminal indictments for obstruction of justice can be brought against those doing the shredding. Those indicted may negotiate with prosecutors and provide evidence in exchange for reduced sentences. External observers (both lawyers and journalists) have noted that shredding documents has allowed the government to move much faster in its pursuit of the facts than originally anticipated. Intentionally destroying documents after litigation has been initiated is clear criminal action, and can violate state and/or federal law.

"Unintentional" destruction of documents in the litigation context may not result in criminal conviction, but can likewise cause grief. Companies often have established Records Management Programs that identify certain documents that are to be disposed of on a timely basis following a formal time schedule. Document retention plans are both legal and useful, formal document retention programs must be suspended when litigation is anticipated. If they are not, spoliation and other unpleasant claims are likely to follow.

All documents can be obtained in Discovery by Plaintiff's Request for Production of Documents

In product liability litigation, it is the manufacturer's behavior in relation to the design and development of the "product", and all of its components, that often go on trial. The "product" includes the assembled, finished product and all of its components, including, catalog data, service manuals, advertising, labels, packaging, maintenance, field assembly, installation, service, warranty, owners manuals and sales brochures. A defect in the design, development and manufacture of any of these items can be the proximate cause of a mishap and personal injury, whether the product is a medical device, pharmaceutical, automobile or appliance. Product designers need to understand the full definition of a product so that their loss prevention activities include controls for all product components.

A plaintiff attorney who otherwise may have no case against a manufacturer will look for records that show a pattern of irresponsible behavior in order to question the safety of a product. Federal Rules of Civil Procedure 401 and 402 state that, "all relevant evidence is admissible," and evidence is "relevant" if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more or less probable than it would be without the evidence." Consequently, Plaintiff's Request for Production of Documents will cast a wide net in an effort to obtain every conceivable record and document that could suggest a product is unsafe. Naturally, this will include the documents relevant to an ISO 9001 Quality Management System, but it will extend well beyond them as well.

It is obvious that if company representatives destroy documents, they can face criminal charges, but such allegations may also apply if company representatives simply withhold discoverable documents from plaintiff attorneys. On September 7, 1999, Atlanta Fulton County State Judge G. Brogdan issued a ruling that two prominent law firms may have committed fraud in a product liability lawsuit by withholding damaging documents concerning the safety of two General Motors fuel tanks. The ruling suggests that the GM's in-house counsel may have aided in committing the fraud as well.

"In certain instances GM, by and through its counsel, toyed and ignored court orders, ethical constraints and legal barriers. Plaintiffs have exposed a shameful scheme by GM to defraud and mislead several courts, to thwart and obstruct justice and enjoy the ill-gotten gains of likely perjury." (*The Atlanta Constitution*, Thursday, September 9, 1999, pp. 1 and 12)

The Judge's ruling stemmed from a collection of lawyers' notes and memos about a crash-safety report written by a GM engineer that was withheld from plaintiffs for years, based upon the attorney-client privilege. In his order, Judge Brogdan said, "the evidence of GM's conduct in fuel-tank product liability litigation 'soars beyond' the legal threshold that must be cleared before finding that the automaker committed fraud on the court and obstructed justice." The judge ordered GM to produce the documents within five days. On September 29, 1999, *The Wall Street Journal* reported that the case was settled in "the mid eight figures" range.

If a company withholds documents in litigation it does so at its peril.

Attorney-client privilege cannot be used to withhold documents from Plaintiff's Request for Production of Documents!

As Judge Brogdan made clear, companies cannot blindly rely on the attorney-client privilege to preclude production. It has its limits. The Eastern District of Arkansas emphasized that point in *Case IH Fire Products Liability Litigation*, where Judge Eisle ordered defendant Case Company to turn over ISO manual materials to plaintiffs' attorneys.

There, plaintiffs observed that 140 fires involving cotton pickers valued in the range of \$90,000 to \$200,000 occurred between 1994 and 1997. Demanding production of defendant's ISO documentation, plaintiffs argued "[t]he number of fires alone causes alarm and concern. However, the significance of the problem is magnified by the fact that these losses were preventable and that Defendant is doing nothing to correct and prevent the losses as required by its own ISO 9001 program."

Why were the materials subject to production? Plaintiffs asserted that "The ISO 9000 standards and its own quality assurance procedures require that [defendant] conduct an analysis of these fires and that it take corrective and preventive action."

In addition to the ISO manual materials, plaintiffs' counsel sought documentation concerning internal audits, customer complaints, corrective and preventive action and management review. Defendant Case Company objected to their production because an attorney was present during the corrective action review; thus, these documents should be protected by the attorney-client privilege. When the District Court rejected defendant's argument and ordered production of the documents, defendant appealed to the Eighth Circuit.

On January 24, 2000, the Eighth Circuit Court of Appeals denied Defendant's petition for protection based upon the attorney client privilege, upholding the lower court's order to produce the ISO documents, which included minutes of the company's corrective actions and management reviews. In April 2000, Case Company filed a petition for writ of certiorari with the United States Supreme Court to overturn the Circuit Court's decision, which the Supreme Court denied, on June 5, 2000. The ruling effectively prevents (or, at the very least, makes it much more difficult to apply) the attorney-client privilege to ISO 9001 records and documentation despite the presence of an attorney during corrective action reviews.



Conclusion

While the legal implications of document control extend far beyond the control contained in ISO 9001, these ISO 9001 documents, records and minutes are fair game for discovery and trial. There is no special legal exemption for them just because they are part of a quality management system.

Finally, it is worth noting that most product liability cases are based on four questions.

- Did the manufacturer provide a product that was free of design (formula) defects?
- What the product manufactured according to the design?
- Was the product suitable for the purpose for which it was sold?
- Did the company establish an effective system to monitor and analyze post-sale problems and hazards?
- Did the company follow-up on its knowledge of hazards with appropriate and adequate action.

These questions give new meaning to Yogi Berra's saying, "It ain't over till it's over!" Product design is never over, because complaints and customer feedback are continual triggers to revisit design when necessary. This is a legal obligation with or without an ISO 9001 Quality Management System. The fact that ISO documents and records capture so many aspects of the design-production-feedback dynamic is of legal consequence.

Can an ISO 9001 QMS be used to respond to legal questions and liability exposure? The answer is yes, an ISO 9001 Quality Management System provides an excellent platform for systematically using preventive law to address legal issues and liability exposure, but it will require competent professional attention and legal expertise for that to happen. Just as risk management without preventive law is not risk management, ISO 9001 without preventive law becomes unmanaged risk.



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For the past 18 years, Jim has been working with companies preparing to meet the European Union CE marking requirements for Machinery Safety, Medical Devices, Toy Safety and related EU Directives and FDA's QSR. He has developed a comprehensive loss prevention program incorporating elements of both the ISO 9001 Quality Management System and ISO 14001 Environmental Management System as well as sector specific quality management systems for automobiles, aircraft, maritime, telecommunications, and finance to reduce company liability exposure in the US and EU markets. He uses forensic legal analysis to review product liability history and liability exposure for manufacturers, service companies and insurance companies.

Jim specializes in guiding companies through the CE marking process for their products (e.g., Machinery, Pressure Equipment, Explosive Atmospheres, PPE, EMC, Low Voltage, Medical Devices, Toys, Product Liability, and Product Safety) for companies preparing to enter the EU market and for companies in the US who stipulate CE marking for market flexibility and/or liability protection. He conducts litigation evaluations (including product risk analyses/risk assessments) for manufacturers who want to identify key areas of

product liability exposure and reduce their losses in the US and EU. Jim conducts forensic legal evaluations of company Quality Management Systems (e.g., ISO 9001), FDA's Quality System Regulation, and Environmental Management Systems (e.g., ISO 14001) and serves as a legal expert for insurance companies and law firms involved in litigation. Presently, he also is working with SAI Global & US/EU Insurance Companies.

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Economic Loss Doctrine Refresher

By Nora Loftus of Frantz Ward LLP

Most litigators practicing in the product liability arena are familiar with the Economic Loss Doctrine. Depending on the state law that governs, the Economic Loss Doctrine can serve as a complete bar to claims for economic damages where the plaintiff lacks contractual privity with the defendant. The Doctrine provides that, under tort law, one party cannot recover damages from another party for economic loss only; instead, it must seek a recovery under a contract theory. In essence, it sets the boundary between contract and tort law. This boundary is particularly important in product liability law, where the line between the two theories become blurred. Product liability law developed under public policy auspices that people need more protection from dangerous products than contract law provided. In the product liability arena, the Economic Loss Doctrine serves as a restraint on that policy-made law, limiting recovery and providing some protection to manufacturers. The Economic Loss Doctrine applies to other areas of law, particularly in construction law relating to professional design services by architects and engineers. However, this article is limited to the Doctrine's application to claims for defectively manufactured products.

Whether by statute or common law, the majority of jurisdictions in the United States prohibit product liability claims sounding in tort when there is economic loss alone, and will grant a dispositive motion in these instances. The general distinction between states in their application of the Doctrine is the focus on the "harm" component. Some, focus on the nature of the defect and the potential harm that defect can cause, while others focus on the actual harm caused in the particular case before it. However, many states have also created exceptions to their general rule for certain circumstances. For this reason, even though the Doctrine is recognized in some form in nearly every state, it is not a rule that can be applied consistently across states.

Did the Plaintiff Incur Economic Loss Only?

The first question in determining if the Doctrine will bar a claim is whether the alleged damages are for economic loss only. The answer depends on the controlling law. Economic

loss (also known as commercial loss in some jurisdictions) is generally considered any monetary loss that does not arise from personal injury or property damage. Economic loss in most jurisdictions includes both direct and indirect (or consequential) losses. Direct economic loss is the difference in the product's value as promised and as it currently exists with its defect; this value being most commonly measured by repair or replacement costs. Indirect economic loss includes other economic damages such as lost profits.

The precedent in many states is that damage to the product itself falls under "economic loss" and, as such, those damages can only be recovered under a contract theory. However, in certain states, economic loss excludes loss to the actual defective product at issue. (Compare California law, defining economic loss as "damages for inadequate value, costs of repair and replacement of the defective product or consequent loss of profits—without any claim of personal injury or damages to other property..." *Robinson Helicopter Co., Inc. v. Dana Corp.*, 34 Cal. 4th 979, 989 (Cal. 2004) with Connecticut's product liability statute, which excludes the defective product from its definition of "commercial" loss. Conn. Gen. Stat. § 52-572n(a)). Consequently, in some states a party is able to bring a tort claim against a remote manufacturer, but is limited by the damages that can be recovered from the manufacturer to repair or replacement of the product itself. Lost profits and other indirect economic loss can only be recovered from a contracting party.

"Other Property Damage"

As part of the "economic loss" determination, the practitioner will need to determine whether there was damage to "other property" or simply to the defective product itself when the part is just one component of a larger product. States vary on what is considered "the product" and what is "other property" in this instance. In Alabama, if a defective replacement part or manufactured component causes damage to the entire product, that constitutes property damage other than to the product itself and tort claims are not barred by the

Economic Loss Doctrine in that scenario. *Everett v. Brad Ragan, Inc.*, 2000 U.S. Dist. LEXIS 4124 (S.D. Ala. Mar. 28, 2000).

In contrast, other states follow the “integrated products rule,” which bars recovery in tort for a defective part or component when it causes damage to the product as a whole.

A New Jersey court addressed this issue in a case involving defective residential exterior siding that caused damage to other parts of the home. In *Dean v. Barrett Homes, Inc.*, 406 N.J. Super. 453, 467 (App.Div. 2009), the court looked to other jurisdictions for guidance in determining whether the damage to other parts of the home was damage to “other property” sufficient to preclude the Economic Loss Doctrine and allow the plaintiffs to bring tort claims. The court in an opinion extensively analyzing both sides of the issue, ultimately found that the damage was not to “other property,” and that plaintiffs’ tort claims were barred. In reaching this decision, the court adopted the integrated products rule, explaining that “plaintiffs purchased a house, not exterior siding, and the exterior siding was an integrated component of the finished product of that house.” See also *Trans States Airlines v. Pratt & Whitney Can.*, 177 Ill. 2d 21, 49 (Ill. 1997) (damage to the airframe of an airplane caused by the defective engine constitutes damage to a single product when plaintiff bargained for and received a “fully integrated aircraft”).

At least one court, however, has held that this is an issue to be determined by the trier of fact, and not appropriate for a dispositive motion. See *KB Home v. Superior Court*, 112 Cal. App. 4th 1076, 1087 (Cal. App. 2d Dist. 2003) (“distinguishing between “other property” and the defective product itself in a case involving component-to-component damage requires a determination whether the defective part is a sufficiently discrete element of the larger product that it is not reasonable to expect its failure invariably to damage other portions of the finished product”).

What General Rule Applies and Are There Exceptions?

The next step in the analysis involves determining the controlling law of the governing state. Most states follow one of three general rules, with the majority applying the most liberal application of the Economic Loss Doctrine. Nonetheless, even in those states, exceptions to the rule may exist.

The “Seely” or Majority Rule

The majority of states have established law following the rationale first set forth by the California Supreme Court in *Seely v. White Motor Co.*, 63 Cal. 2d 9, 15, 403 P.2d 145, 149 (1965). There, plaintiff purchased a defective truck from a dealer. For many months, the dealer, with help from the manufacturer’s representative, unsuccessfully attempted to fix the defects. The brakes ultimately failed, causing the truck to overturn. Although the plaintiff was not personally injured, the plaintiff incurred costs to repair the truck. He then stopped making payments on the truck, resulting in its repossession. The plaintiff sued both the dealer and the manufacturer for the costs incurred in repairing the vehicle, as well as for the purchase price actually paid and lost profits. The court rejected any tort theory of recovery and limited the plaintiff’s recovery to damages under a contractual warranty claim finding the damages were solely economic losses. While the court acknowledged that consumers should not bear the risk of incurring personal injury from use of a product, a consumer properly bears the risk that a product will not meet “economic expectations.”



Many states did not adopt the *Seely* rule until after the U.S. Supreme Court addressed the issue nearly 20 years later in *East River S.S. Corp. v. Transamerica Delaval, Inc.*, 476 U.S. 858 (1986); a case based on admiralty law. In *East River*, the plaintiffs chartered ships under an agreement that required the plaintiffs to assume the costs of all repairs. When the turbine engines failed, the plaintiffs bore the cost of repairing them. The plaintiffs then sued the manufacturer of the engines under a subcontract with the ships’ builder. When the case reached the Supreme Court it was forced to “decide whether a cause of action in tort is stated when a defective product purchased in a commercial transaction malfunctions, injuring only the product itself and causing purely economic loss” and “whether injury to a product itself is the kind of harm that should be protected by products liability or left entirely to the law of contracts.” *East River*, 476 U.S. at 859. The Supreme Court analyzed both the majority rule established in *Seely*, the minority rule set forth in *Santor*, and those jurisdictions that carved out exceptions to establish an “intermediate” rule (both the minority and intermediate rules are addressed below). The Court sided with *Seely* and held that there is no viable tort action for pure economic loss, including loss of the product itself. An injured party is forced to recover in contract alone.

The states that now follow law similar to that set forth in *Seely* and *East River* include Alabama, Delaware, Florida, Indiana (by statute), Maine, New York, New Jersey, North Carolina, Minnesota (by statute), Ohio (by statute), Nebraska, Nevada, Pennsylvania, Texas, Virginia, and Wisconsin. It is important to note that many of these states make exceptions for certain circumstances, most notably for asbestos cases. Other exceptions include cases of fraud, non-commercial transactions, or instances where a special relationship exists. For example, Delaware enacted the Home Owner's Protection Act, which rejects the Economic Loss Doctrine for claims relating to residential construction. 6 Del. C. §§ 3652. Florida, likewise, provides an exception where a plaintiff has no other avenue of recovery and a special relationship exists. See *Airport Rent-A-Car v. Prevost Car*, 660 So. 2d 628 (Fla. 1995).

The Intermediate Rule

The key determining factor of the intermediate rule is the risk created by the nature and manifestation of the defect, rather than the type of damage incurred. States that have adopted the intermediate rule try to create a balance between "the disappointed users . . . and the endangered ones." *Russell v. Ford Motor Co.*, 281 Ore. 587, 595 (1978). These courts carve out exceptions for products that are inherently dangerous or situations where the defect manifests itself in a particularly dangerous way. States that generally follow the intermediate rule include Alaska, Massachusetts, Maryland, Georgia (by statute), Washington (by statute), West Virginia, Arkansas, Arizona, Oregon, Kansas, and Michigan (commercial parties only).

Maryland's highest court in *Lloyd v. GMC*, 397 Md. 108 (Md. 2007), articulated the rationale for the intermediate rule in a class action relating to defective car seatbacks. The plaintiffs in *Lloyd* sued several car companies to recover the costs to repair or replace the defective seats. Although the same defect had caused personal injury to other classes, none of the plaintiffs in the class before the court had suffered personal injury or property damage. The trial court granted the defendants' motion to dismiss holding that the Economic Loss Doctrine barred the plaintiffs' claims. The plaintiffs appealed on the grounds that Maryland law allows them to recover for economic loss alone "when the product defect factor creates an unreasonable risk of death or serious injury." The highest court agreed holding that, although a manufacturer generally is not liable for meeting particular consumer expectations, it is always liable for ensuring that its product does not create a risk of unreasonable harm. Therefore, when a "product defect presents a substantial, clear and unreasonable risk of death or personal injury, it is inappropriate to draw a distinction" between economic loss and personal injury. See also *Valley Forge Ins. Co. v. Sam's Plumbing, LLC*, 220 Ariz. 512 (Ariz. Ct. App. 2009) (trial

court overruled when finding negligence claim was barred by the economic loss rule because explosion created extreme risk of danger); *Capitol Fuels v. Clark Equip. Co.*, 181 W. Va. 258 (W. Va. 1989) (trial court affirmed when allowing plaintiffs to recover economic loss only when defect in front-end loader caused "sudden calamitous" fire creating potentially dangerous risk).

The "Santor" or Minority Rule

New Jersey established what has now become the minority rule with its decision in *Santor v. A & M Karagheusian, Inc.*, 44 N.J. 52, 207 A.2d 305 (1965). In *Santor*, the plaintiff purchased defective carpeting for his home from a retailer. After the retailer went out of business, the plaintiff sued the manufacturer alleging breach of an implied warranty, despite the lack of any direct contractual relationship. Because the plaintiff could not recover from the manufacturer in contract due to the lack of privity, the court allowed the plaintiff to recover under a tort theory, holding that the manufacturer is "the father of the transaction" and the retailer "simply a way station." The court acknowledged that many other jurisdictions that allow a plaintiff to recover under a tort theory involved personal injury, but rejected that as a limiting factor. The court determined that a consumer should be entitled to recover from the immediate seller in contract or, when the immediate seller was no longer available, from a remote manufacturer under tort law. However, New Jersey overruled this law in *Spring Motors Distributors, Inc. v. Ford Motor Co.*, 98 N.J. 555, 489 A.2d 660 (N.J. 1985) and *Alloway v. Gen. Marine Industries*, 695 A.2d 264 (1997), adopting the majority rule in its place.

Louisiana remains one of the few jurisdictions that continue to follow the minority rule and permits recovery in tort for economic damages alone without exceptions. See *De Atley v. Victoria's Secret Catalogue, LLC*, 876 So. 2d 112 (La.App. 4 Cir. 2004) for the interplay between claims under Louisiana's product liability statute and common law redhibition claims. Other states that generally follow the minority rule, like Connecticut and Colorado, will recognize the Doctrine, but only in commercial transactions.

Conclusion

The Economic Loss Doctrine is an important consideration in defending product liability claims. Whether it can be effectively invoked depends on a variety of factors that vary throughout the states. These factors include the type of damages claimed, whether those damages are for pure economic loss, and whether economic loss includes the product itself. Other factors include the nature and manifestation of the defect, and the status of the parties consumer versus commercial bringing the claim.

Although the basic premise of the Economic Loss Doctrine is simple, it has created a complex set of rules and exceptions that vary from state to state. Nearly every state recognizes the Doctrine in at least some circumstances. Consequently, careful consideration as to its application should always be given since it is a viable defense in many jurisdictions.



Nora Loftus is an associate at Frantz Ward LLP and focuses her practice on general litigation, with a special interest in construction law. Nora both prosecutes and defends a variety of contract and tort claims, generally between commercial entities. She has defended many personal injury and property damage claims and litigated insurance coverage disputes. Nora has significant trial experience and has served as lead counsel in several cases tried to the bench.

CASE NOTES

NEVADA

Food and Drug Administration's Pre-market Approval Preempts Product Liability Claim

Miller v. DePuy Spine, Inc.,
638 F. Supp 2d 1226 (2009 D. Nev.)

Plaintiff Roger Miller received a Charite Artificial Disc implant as part of a surgery for a bulging disc in November of 2005. The Charite Disc previously received Pre-Market Approval following rigorous review by the Food and Drug Administration. The Charite Disc implant remained in Mr. Miller, but he alleged continued back pain and required subsequent surgeries to remedy his pain.

Mr. Miller filed suit against DePuy Spine, the seller of the Charite Disc, in November of 2007. The case began in the Clark County District Court, but soon removed to the United States District Court for the District of Nevada. Mr. Miller alleged the Charite Disc implanted in his spine was defective and sought to impose liability under theories of strict product liability, negligence, and breach of implied and express warranties. DePuy Spine filed a motion for summary judgment, arguing that Mr. Miller's product liability claims were preempted under the Medical Device Amendments of the Food, Drug, and Cosmetic Act (FDCA), as interpreted by *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008), because the Charite Disc received Pre-Market Approval from the U.S. Food and Drug Administration (FDA).

The Supreme Court in *Riegel* held that the grant of Pre-Market Approval indicated that the FDA conducted extensive review and determined the device to be safe and effective. The Supreme Court further held that state tort law standards which would require a device to be made or labeled

differently from the Pre-Market Approval requirements were preempted under the federal law. Based on this reasoning, the Supreme Court affirmed that the FDCA expressly preempts state law "claims of strict liability; breach of implied warranty; and negligence in design, testing, inspection, distribution, labeling, market and sale of the [device]."

The court held that the *Riegel* decision was direct precedent for summary judgment in favor of DePuy Spine on Mr. Miller's strict product liability claims. The court reasoned that Plaintiff's strict product liability claims alleged that the design, manufacturing of, or warnings given with the Charite Disc should have been different from what the FDA approved when granting the Pre-Market Approval. These claims were preempted because such claims could only prevail by imposing state law which was "different from, or in addition to," the federal requirements imposed by the Pre-Market Approval.

The court considered Mr. Miller's claims based on express and implied warranty separately, but similarly found this claim to be preempted. Mr. Miller's allegations as to express and implied warranty dealt with the safety and effectiveness of the Charite Disc, subjects that the FDA previously considered when issuing the Pre-Market Approval. Preemption applied to these claims, as with the strict liability claims, because a finding to the contrary would require the device to be made in a fashion other than as approved by the FDA.

Mr. Miller argued that his claims merely sought a state law remedy for a violation of federal requirements, and were not claims based on state law "different from or in addition to" any federal requirements. For Mr. Miller's claim to survive, the court explained, he would have to offer evidence that the Charite Disc implanted during his surgery was manufactured out of conformity with the specifications approved by the FDA in the Pre-Market Approval. Absent any such evidence, however, preemption applied and summary judgment was appropriate.

The Plaintiff also contended that DePuy Spine misrepresented or omitted material information in its submission to the FDA for a Pre-Market Approval. Mr. Miller presented no admissible evidence to support this claim. Furthermore, the court noted that Congress stated its intent that the FDCA be enforced only by the Federal Government. The court concluded that Nevada law could not provide a remedy for any violation of FDA regulation, given the clear legislative in-

tent. After concluding that Plaintiff's claims were preempted or otherwise unsupported, the court granted DePuy Spine's motion for summary judgment.

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SOUTH CAROLINA

New Case Addressing Limits on Expert Testimony in State Court

Watson v. Ford Motor Company, Op.
 No. 26786 (Filed March 15, 2010)

In a brand new opinion, South Carolina's Supreme Court proclaimed an end to the seemingly limitless breath of the admissibility of expert testimony. In *Watson v. Ford Motor Company, Op. No. 26786* (Filed March 15, 2010) the court gave additional analytical heft to its 2009 decision in *State v. White*, 382 S.C. 265, 676 S.E.2d 684 (2009), which has been read as the court's direct instruction to the trial courts that they more stringently enforce Rule 702 of the South Carolina Rules of Evidence, which sets forth the admissibility criteria for expert testimony. In *Watson*, the court articulated analytical instructions so clear that they suggest the court had been eager for the right case to declare its preference for more selective admissibility of expert testimony.

The case involved a single car motor vehicle accident which was caused by the Ford Explorer in which the plaintiffs were travelling, and which was under the apparent control of the vehicle's cruise control feature, unexpectedly and without human stimulus accelerating, causing the vehicle to roll over and the plaintiffs to be ejected. The injuries were severe, and the jury awarded eighteen million dollars actual damages to the two plaintiffs. Ford appealed on several bases, most notably that the trial court erred in admitting the testimony of plaintiffs' experts Bill Williams and Dr. Antony Anderson.

According to the court's recitation of the facts, "[the plaintiffs'] theory of the case was that the Explorer's cruise control system was defective because it allowed electromagnetic interference (EMI) to affect the system." Williams, testifying in the field of "cruise control diagnosis," was presented in order to offer evidence from third parties of similar cruise control failures in other Ford products. Anderson, an expert in EMI, offered his theory as to how EMI can cause the very malfunction which allegedly caused the subject accident. After reviewing the record, the Supreme Court ruled

that both experts should have been excluded.

With respect to Williams, the court noted that in the course of the motion *in limine* concerning Williams' testimony, Williams had described his experience as involving training, consulting, and developing and writing software for the automotive industry, with particular current emphasis on issues involving brake failures. He acknowledged that prior to being retained in the lawsuit, he had no professional experience of any kind in cruise control systems, never had compared the cruise control system in the Explorer in question to any other system, and never had published a paper on cruise control systems. Despite these limitations, the trial court qualified Williams as an expert in "the training and operation of the cruise control and brakes" and permitted him to testify on "cruise control diagnosis." While the casual reader might believe this was obvious error on the trial court's part—and while, indeed, that conclusion is clear from a reading of Rule 702—in practice qualification of experts on so specious a basis has been utterly routine.

So the Supreme Court's determination that Williams was not qualified and should have been excluded was no small surprise. Specifically, the court ruled that Williams' lack of pre-litigation experience with the subject matter of the litigation—during the motion *in limine* he described "how he taught [himself] the Explorer's cruise control, or speed control system"—was fatal. Because it appeared he "merely studied the Explorer's system just before trial," he was not qualified to discuss the cruise control system, despite his vast qualifications in other aspects of automotive engineering. South Carolina's trial judges undoubtedly will hear this principle argued frequently in the years to come.

While Williams should have been excluded due to inadequate qualification, the court's finding concerning Anderson concerned the other cornerstone of expert testimony's admissibility: methodological reliability. Anderson's testimony was damning to the defense: it established not only that EMI could cause a malfunction in the cruise control system, but that Ford had a technically and economically feasible alternative at hand: the use of a "twisted pair" wiring schematic. Examining Anderson's qualifications, the Supreme Court noted that while an eminently qualified electrical engineer, Anderson had no particular experience with cruise control

mechanisms, or even with the automotive industry as a whole. Coupling this experiential inadequacy with Dr Anderson's inability to support with meaningful explanation his theory that "twisted pair" wiring would have prevented the particular malfunction that he theorized, the court found that testimony concerning the twisted pair wiring theory—*i.e.*, the feasible alternative—should have been excluded as unreliable.

The court went a step further, ruling that Anderson's testimony concerning the specific mechanism by which the EMI caused the cruise control malfunction should have been excluded as well. While acknowledging that Anderson was qualified to testify to EMI and to its effects generally, the court concluded that his testimony was the product of unreliable methods. He had not published any peer reviewed paper on EMI's effect on cruise control systems, and could not identify the source of the EMI he claimed had caused the malfunction. Further, he had not tested his theory and, indeed, testified that his theorized EMI reaction could not be replicated in a laboratory or other testing environment. In light of this, the court found that Anderson's EMI theory was the product of unreliable methods and should have been excluded.

Encapsulating the trial court's error, the Supreme Court rendered what to litigants and practitioners in South Carolina

must be considered the opinion's critical statement: "In our view, the trial court's error in admitting Dr. Anderson's testimony is largely based on solely focusing on whether he was qualified as an expert in the field of electrical engineering and failing to analyze the reliability of the proposed testimony." This statement must be taken as an exceedingly clear signal to trial courts in South Carolina: the days of admitting any testimony solely because its subject matter falls within the expert's general area of expertise—the standard practice in this state—are over. That an expert's methodology makes no sense and cannot be confirmed by scientific methods affects the opinion's admissibility and not merely its weight, as so often had been proclaimed. Should the trial courts heed the Supreme Court's obvious intent, this opinion has the potential to effectuate a fundamental shift in personal injury litigation from motor vehicle accidents to product liability to premises liability.

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"In the Trenches"

Notable Accomplishments of ALFA Attorneys

Defense Verdict After Long, Difficult Trial

Renaud Cook Drury Mesaros, PA attorneys William W. Drury and William S. Sowders, successfully defended a product liability and premises liability claim arising out of an incident at an L.A. Fitness gym in a May 2010 trial. Plaintiff, a 60 year old computer hardware technician, alleged that the lower back exercise machine he was using collapsed, causing him to fall off the back and land on his head. He was temporarily rendered a quadriplegic and at the time of trial had healed to the point that he was tetraparetic (marked lack of control and weakness in all four extremities).

Plaintiffs asserted premises and product liability claims against L.A. Fitness and product liability claims against the co-defendant manufacturer, Brunswick. Plaintiff alleged that L.A. Fitness failed to properly repair and maintain the subject back extension machine. The evidence proved the manufacturer did not provide any instructions with the subject machine and that L.A. Fitness assembled it backwards.

L.A. Fitness argued, with the assistance of biomechanical and mechanical engineers, that the only cause of plaintiff's injuries, was user error.

Following an unsuccessful mediation where plaintiffs demanded a total of \$12,000,000.00, L.A. Fitness made an offer of judgment for \$100,000.00, which was rejected. At trial, plaintiff husband sought special damages, including lost wages and a life care plan, in excess of \$1.5 million. His wife sought an unspecified amount in excess of the \$1.5 million for her loss of consortium. The jury repeatedly asked when they were going to get the case for deliberation. At the close of the 16 day trial, the jury deliberated for less than 30 minutes, ultimately reaching a unanimous defense verdict for both defendants. As a result of the defense verdict, sanctions pursuant to Rule 68 of Arizona Rules of Civil Procedure (offer of judgment) were ordered, making plaintiff liable to L.A. Fitness for \$137,000.00 (double taxable costs and reasonable expert fees).

Favorable Verdict Awarded to the Defense

Lorance & Thompson, PC attorneys Robert Smith and David Escobar received a favorable verdict in May 2010 in Hardin County, TX. East Texas venues are notoriously pro-plaintiff. Plaintiff alleged product defect related to a 5 ton overhead hoist manufactured by defendant, arguing a rope guide would have prevented the accident. Plaintiff was trained to lift only straight up and down, but he and his co-workers had a practice of lifting a 1400 pound pack of oxygen bottles at an angle which caused the wire rope to snap and the bottles fell on plaintiff's leg, causing multiple femur fractures. Defense counsel added plaintiff's employer as a responsible third party (not a third party defendant) so the

jury could consider the employer's responsibility but without plaintiff having a direct action against the employer. After more than 10 hours of deliberation, the jury assigned 60% of responsibility to the employer, 30% to the plaintiff, and only 10% to defendant manufacturer. After the percentages are applied, defendant will pay about \$31,000 after offering \$100,000 the Friday before trial.

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Upcoming ALFA International Events

August 11, 2010

The A, B, Cs of Medicare Recovery – Always Be Cognizant of Medicare's Right of Recovery

An ALFA International Tele-Seminar
12:00 Noon to 1:30 p.m., Central Standard Time
ALFA Contact:
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September 23-25, 2010

2010 International Law Practice Group Seminar

The Westin Paris
3 Rue de Castiglione
75001 Paris, France
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October 21-23, 2010

2010 ALFA International Annual Business Meeting

The Ritz-Carlton, Buckhead
3434 Peachtree Road, N.E.
Atlanta, Georgia
ALFA Contact:
Katie Garcia at kgarcia@alfainternational.com

November 10-12, 2010

2010 ALFA International Labor & Employment Seminar

The Ritz-Carlton Laguna Niguel
One Ritz-Carlton Drive
Dana Point, California
ALFA Contact:
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March 3-6, 2011

2011 ALFA International - International Client Seminar

Westin Diplomat Resort & Spa
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