Notes From the Editors

While most people think of sun, warm weather, beaches, and baseball during the summer, here at Products Liability Perspectives we think of medical device law. Well, not really. But it so happens this issue contains two excellent articles concerning medical devices. Also included is an informative, well-written article on The Political Question Doctrine. Of course, you will also find summaries of important developments in the products liability field, critical opinions published in the last six months, and the always anticipated "In the Trenches" section detailing significant victories by ALFA firms.

We hope to hear from you for articles and "In the Trenches" contributions for the next Perspectives issue. Finally, don't forget the 2008 Product Liability Practice Group Seminar, which will take place November 12-14, 2008, in Dana Point, California. For more information see page 15 of this issue. See you there!

-Steve Hamilton & Bryan Martin

Product Claims for Defective Class III Medical Devices; a Thing of the Past, or Stronger Than Ever?

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In a landmark decision, the U.S. Supreme Court in Riegel v. Medtronic, Inc., 552 U.S. __, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008), ruled that Section 360k of Title 21 of the United States Code, also known as the Medical Device Amendments to the Food, Drug & Cosmetic Act of 1938 ("FDC Act"), establishes "federal requirements" for purposes of preempting state defective design and labeling claims made against Class III medical devices that receive premarket approval ("PMA") by the U.S. Food and Drug Administration.

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may not pass a law inconsistent with the federal law. To determine whether a state law is preempted by federal law, courts first determine whether a specific requirement is imposed by the federal law, and, if so, whether the state law imposes different or additional requirements to the federal law. 128 S.Q. at 1006-1007. When it is clearly established that a federal law preempts a state law, the state law must be declared invalid. A state law may be struck down even when it does not explicitly conflict with federal law, if a court finds that Congress has legitimately occupied the field with federal legislation.

Prior to Riegel, while some federal and state courts recognized the preemptive effect the FDA's premarket approval process has on a Class III device, this was not a universal rule and some courts still permitted strict liability, negligent design/manufacture, failure to warn, and breach of implied warranty claims to be decided by juries with respect to these medical devices. The 8-to-1 decision in Riegel upholds the FDA's regulatory authority, and cleared the way with respect to challenges to its rigorous PMA process. Legislation currently pending in Congress, however, may take away what the U.S. Supreme Court recently recognized.

The History of Medical Device Regulation

Prior to the FDC Act, the only pertinent federal statute, the Food and Drugs Act of 1906, did not regulate medical devices. At that point, the FDA could only control medical devices through lawsuits against a manufacturer for marketing an unsafe product based on adulteration or misbranding. However, there was no requirement for premarket testing, review, or approval. Then in the early 1960's, Congress held extensive hearings in an effort to revise the FDC Act to impose requirements on the development and marketing of medical devices. However, it was not until several years later that any substantive legislation was created in the form of the Medical Device Amendments of 1976 ("MDA").

In the words of the MDA's preamble, the purpose of the amendments is "to provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539. The Act classifies medical devices in three categories based on the risk that they pose to the public. Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by "general controls." 21 U.S.C. §§ 360c(a)(1)(A). Devices that are potentially more harmful are designated Class II; although they may be marketed without advance approval, manufacturers of such devices must comply with federal performance regulations known as "special controls." § 360c(a)(1)(B). Finally, devices that either present a potential unreasonable risk of illness or injury, or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated Class III. § 360c(a)(1)(C). See Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S. Q. 2240 (1996). Of great significance to the medical device industry and to the Court in Riegel is the preemption clause contained in the MDA, which states as follows:

"Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -
(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."


Pre-and Post-Amendment Medical Devices

Following the passage of the MDA the FDA was faced with preamendment, post amendment and transitional devices. A preamendment device is one that was in commercial distribution before May 28, 1976, the date the MDA was signed into law. In order to continue marketing a preamendment Class III device, a PMA will be required to be submitted once the FDA publishes a regulation calling for the PMA submission. Eventually all Class III devices will require a PMA. Prior to the PMA effective date, these devices must have a cleared Premarket Notification, commonly referred to as a § 510(k) notice, prior to marketing. Examples of Preamendment devices include intra-aortic balloon and control systems (21 CFR § 870.3535), ventricular bypass (assist) devices (21 CFR § 870.3545), cardiovascular permanent pacemaker electrodes (21 CFR § 870.3680), and topical oxygen chambers for extremities (21 CFR § 870.5650).

A post amendment device is one that was first distributed commercially on or after May 28, 1976. Post amendment devices equivalent to preamendment Class III devices are subject to the same requirements as the preamendment devices.

Transitional devices are devices that were regulated by FDA as new drugs before May 28, 1976. Any Class III device that was approved by a New Drug Application ("NDA") is now governed by the PMA regulations. The Code of Federal Regulations requires these Class III devices to obtain §515 approval before they may be commercially distributed. See, e.g., 21 C.F.R. § 886.3600.

The Premarket Approval Process

Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance," is related to the relatively rigorous "premarket approval," or "PMA" process. The PMA process involves extensive scientific and regulatory review to evaluate the safety and effectiveness of medical devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. 128 S.Q. at 1004. Federal law requires that a PMA application and any supplements to the PMA contain the full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, properties and principles of operation of the device; a complete description of the manufacturing methods and processes; performance standards; and all proposed labeling for the device. 21 U.S.C. § 360e(c)(1); 21 C.F.R. §814.20; see also Riegel, 128 S.Q. at 1004 . The FDA spends on the average 1200 hours on each PMA application. Id. It is only these Class III medical devices marketed pursuant to the PMA process that are subject to the preemption provision of the MDA. Following its review, the FDA may grant or deny premarket approval. 21 U. S. C. § 360e(d). The agency is also free to impose device specific restrictions by regulation. 21 U. S. C. § 360(j)(e)(1).

It is important to note that the PMA process is a continuing process that does not end once the FDA approves the PMA. 128 S.Ct. at 1004-1005. Following approval, the manufacturer is required to comply with the standards in the PMA approval order. 21
C.F.R. §814.80. Moreover, most pre-market approvals are granted with “conditions of approval” that allow the FDA to continue its oversight of the medical device once the FDA approves the original PMA and any supplements. These conditions include submitting annual reports to the FDA. See 21 C.F.R. §814.84(b); see also www.devadvice.gov/pma. These annual reports identify, among other things, all changes made to the device, 21 C.F.R. §814.84(b)(1), and summarize all unpublished clinical and nonclinical test results, as well as published literature pertaining to the device during the reporting period. 21 C.F.R. §814.84(b)(2)(i) and (2)(iii). The FDA may also issue an order temporarily suspending or withdrawing approval of a PMA. See 21 C.F.R. §§814.46 and 814.47.

This continuing oversight applies to all changes that affect the safety or effectiveness of the device including changes to the labeling of the device. See 21 C.F.R. §814.39(a). Once a device receives premarket approval, “the [Medical Device Amendments of 1976] forbid a manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling or any other attribute, that would affect safety or effectiveness.” 21 U.S.C. §360e(d)(6)(A)(i) (emphasis added). “[I]t therefore naturally follows that any changes to a PMA-approved device that might affect the device’s safety and effectiveness will require further FDA approval.” Riegel v. Medtronic, Inc., 451 F.3d 104, 118 (2d Cir. 2006). If a manufacturer makes such a change, it must submit and the FDA must approve, an application for supplemental premarket approval. See 21 U.S.C. 360e (d)(6); 21 C.F.R. 814.39(a) (emphasis added); 128 S.Q. at 1005. “All procedures and actions that apply to an [original application] * * * also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change.” 21 C.F.R. 814.39(c). Thus, even the PMA supplement’s process imposes requirements specific to the device at issue. See 218 S.Q. at 1005; Riegel, 451 F.3d at 118 (PMA Supplement must be submitted for review and approval by the FDA before any change is made).

A less stringent FDA review process for marketing new Class III medical devices is known as the §510(k) process. Pursuant to §510(k), a medical device may be deemed to be "substantially equivalent" to another medical device already authorized to be marketed pursuant to 21 U.S.C. §510(k). Riegel, 128 S.Q. at 1004. The §510(k) process is by far the most widely used method to get a new Class III medical device to market. Based on information published by the FDA, the PMA process only accounts for approximately one percent of all Class III medical devices approved by the FDA. Riegel, 128 S.Q. at 1004 citing P. Hutt, R. Merrill & L. Grossman, Food and Drug Law 992 (3d Ed. 2007). In fiscal year 2005, out of the 3,148 new Class III devices that received approval to enter the market through the PMA process, only 32 went through the PMA process. Id. Hence, merely because a Class III medical device is authorized to be marketed does not mean it completed the rigorous PMA process. Significantly, Riegel affects only medical devices that receive premarket approval.

The Facts of Riegel and Application of the MDA

Riegel involved a Class III medical device, a balloon catheter, used during surgeries to open clogged arteries. Riegel, 128 S.Q. at 1005. Prior to the marketing and sale of the catheter, Medtronic received approval, through the PMA process, to market the device. Id. Specifically, on August 30, 1994, the FDA approved Medtronic’s PMA application for the Evergreen Balloon Catheter, and on April 27, 1995 and April 8, 1996, the FDA approved Medtronic’s PMA supplements, which requested approval for revised design and labeling for the device. Riegel, 451 F.3d at 107, Riegel was injured after one of these catheters ruptured while he was undergoing coronary angioplasty. Riegel, 128 S.Ct. at 1005.

Following FDA approval of the catheter, his physician used the device during Riegel’s surgery. 128 S.Q. at 1005. The device burst during the procedure causing complications. Id. Riegel and his wife subsequently filed suit against Medtronic in the Northern District of New York, alleging five state common law causes of action: (1) negligence in the design, testing, inspection, manufacture, distribution, labeling, marketing, and sale of the balloon catheter; (2) strict liability; (3) breach of express warranty; (4) breach of implied warranty; and (5) loss of consortium. Id. In its amended answer, Medtronic raised the affirmative defense of federal preemption; and (5) loss of consortium. Riegel, 451 F.3d at 107, Riegel, 128 S.Q. at 1005.

Prior to Riegel, the issue of preemption of state law claims for premarket approved medical devices was not universal. Much debate still existed over the interpretation of the U.S. Supreme Court’s 1996 decision in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), which addressed the MDA and preemptions of state law claims for a medical device that was marketed pursuant to §510(k), and not the PMA process. In Lohr the Court rejected the contention that §510(k) approval imposes federal requirements specific to a given medical device. 218 S.Q. at 1007. However, the door to preemption as it applied to premarket approved devices was left open following Lohr. In order to reach the decision it did, the Court distinguished the Lohr holding that §510(k)-approved devices are not subject to specific federal requirements by noting that a §510(k) device must merely remain substantially equivalent to its relevant pre-1976 device “as a qualification for an exemption rather than a requirement.” 518 U.S. at 493-494. As the Court noted in Lohr, the FDA regulations governing the §510(k) process, were...
not requirements specific to the device in question - - they reflected 'entirely generic concerns about device regulation generally.’” 518 U.S. at 501 cited in 128 S.Q. at 1006. On the other hand, the Court found that premarket approval does impose requirements specific to individual devices, “[a]nd it is in no sense an exemption from federal safety review - - it is federal safety review.” 128 S.Q. at 1007 (emphasis in original). The distinction, as noted by the Court, is that §510(k), and not premarket approval, is “focused on equivalence, not safety.” 128 S.Ct. at 1007.

With respect to whether state tort claims establish different or additional requirements, the Court adhered to the view reached in Lohr that state “common-law causes of action for negligence and strict liability do impose ‘requirements’ and would be preempted by federal requirements specific to a medical device.” Riegel, 128 S.Q. at 1007.

Understandably, Petitioners in Riegel seized on the reasoning in Lohr that state law damages suits were not preempted, notwithstanding the MDA. Although Riegel asserted that federal and state appellate courts are divided regarding the proper application of Lohr to the question of preemption under the PMA process, in reality, the majority of the federal courts of appeal that have considered the issue agreed with the Second Circuit. Only the Eleventh Circuit Court of Appeals and at least one state supreme court have held that the PMA approval process does not preempt state-law damages claims. See Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999); Weiland v. Telelectronics Pacing System, Inc., 721 N.E.2d 1149 (III. 1999). The Supreme Court resolved this Circuit dispute in favor of preemption.

Rammifications of Riegel

The impact of Riegel is seen in the two significant issues it decided. First, the Court held that the PMA process for Class III medical devices establishes specific federal "requirements" within the meaning of § 360k for each device. 128 S.Q. at 1006. Second, state law claims similar to those alleged in Riegel establish "requirements" that are "different from, or in addition to" and "relate to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.” 128 S.Q. at 1006, citing § 360k(a). Thus, the preemption clause contained in the MDA bars state statutory and common law tort claims challenging the safety and effectiveness of medical devices marketed through the PMA process.

The type of claims that potentially remain are "parallel" state law claims "premised on the theory that [the manufacturer] violated federal law”, i.e., the FDA regulations governing the PMA application. Riegel makes clear that such claims are not preempted. However, some members of Congress are taking steps to ensure plaintiffs are no longer hampered by the preemption clause of the MDA. U.S. Congressman Frank Pallone of New Jersey, and Henry Waxman of California, the chairman of the House Committee on Oversight and Government Reform, are co-sponsoring a bill to amend the FDC Act. HR 6381, called The Medical Device Safety Act of 2008, was introduced on June 26, 2008 and would amend § 360k to state that the MDA is not intended to “modify or otherwise affect” lawsuits brought in state courts. As the bill is currently written, it would apply to any civil action pending or filed on or after the date of enactment. A companion bill is expected to be introduced in the Senate.4 Until the Medical Device Safety Act of 2008, or some similar bill becomes law, manufacturers of Class III medical devices marketed through the PMA process can remain confident that state tort law claims are all but a thing of the past.

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1 Investigational devices marketed under an investigational device exemption (IDE) for purposes of a clinical trial constitute another category. See 21 C.F.R. §§ 812-813.

2 See, e.g. Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004); Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001); Brooks v. Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001); Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000); Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997).

3 Moreover, it is unclear whether a fraudulent concealment claim would be preempted. See, e.g., In Re: Medtronic, Inc. Implantable Defibrillators Litigation, 05-MDL-1726, D.Minn., Nov. 28, 2006). Such claims assert that the manufacturer withheld “key information” from the FDA. Public policy seems to dictate that the PMA is not complete if information affecting safety and effectiveness is concealed, thus, there would not be any conflicting state requirements at issue to invoke the preemption doctrine.

4 The status of the proposed legislation is current as of June 30, 2008.
THE POLITICAL QUESTION DOCTRINE

The Political Question Doctrine Should Provide a Complete Defense to Product Liability Design Defect Claims in Cases Where the Plaintiff’s Alleged Illness Arose Exclusively From the Plaintiff’s Exposure To An Allegedly Defective Product During Military Service.¹

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The question of the applicability of the Political Question Doctrine to a product liability action arose for us and our national counsel in the context of a plaintiff who alleged that his only exposure to our client’s product (and asbestos packing associated with it) occurred while he was in the service of the U.S. Navy during the Korean War. Regarding the presence of asbestos on board naval vessels, the facts established that for a period of more than fifty years, the Navy had designed, constructed and overhauled its entire fleet of war ships utilizing literally tons of asbestos insulation and hundreds of pieces of asbestos-containing equipment on each vessel. The decision to use asbestos was made for strategic purposes relating to the survivability and efficiency of naval vessels at times of war, providing for the safety of the crew from fire and smoke during battle, and in providing for the overall defense of our nation. The decisions were made at the highest levels of the Navy, as the Navy considered asbestos to be an essential strategic mineral to the defense of our country and, through its Military Specifications, it required its extensive use on board all naval vessels, despite the Navy’s demonstrated knowledge that exposure to asbestos could cause serious and permanent lung disease. While there are no appellate decisions in or outside of California which have addressed the Political Question Doctrine in product liability cases involving asbestos, the doctrine is well suited for application to claims of this nature.

The Political Question Doctrine is a reflection of the limit on the power granted the judiciary under Article III.² The presence of a political question, therefore “suffices to prevent the power of the federal judiciary from being invoked by the complaining party.”³ A judicial determination of the presence of a political question is not an adjudication on the merits, but merely expresses a court’s inability to bring its “powers to bear on a matter.”⁴ Thus, while prudential consideration may “assist in identifying cases the Constitution forbids courts from hearing,” the political question is “at bottom a jurisdictional limitation imposed by the Constitution itself.”⁵ Courts “must adhere” to the jurisdictional limitations imposed on the judiciary in the context of the Political Question Doctrine.⁶

Thus, the presence of a political question renders the claims pending against a defendant nonjusticiable.⁷ Because jurisdiction is a fundamental limit on the judiciary’s power, jurisdiction may be challenged at anytime in the litigation and may be raised sua sponte.⁸

The United States Supreme Court in Baker v. Carr, 363 U.S. 186, 217 (1962), listed six factors indicative of a political question which is outside the scope of judicial review:

1. A textually demonstrable constitutional commitment of the issue to a coordinate political department; or,
2. A lack of judicially discoverable and manageable standards for resolving it;
3. The impossibility of deciding without an initial policy determination of a kind clearly exclusively for nonjudicial discretion; or
4. The impossibility of a court’s undertaking independent resolution without expressing lack of the respect to coordinate branches of government; or
5. An unusual need for unquestioning adherence to a political question already made; or
6. The potentiality of embarrassment to multifarious pronounce-ments by various departments on one question.

Although the Baker Supreme Court listed six possible tests to determine if a claim presents a nonjusticiable political question, a finding that a claim presents a political question under even any one of the tests is sufficient to bar adjudication of the question.⁹

Since reaching the merits of the plaintiff’s claim that the manufacturer supplier of asbestos-containing equipment should be liable for design defect for including asbestos within the valves necessarily requires impermissible adjudication of facts and circumstances (1) which are textually committed to the Executive and Legislative Branches under the Constitution; (2) the court (and the jury) lack judicially discoverable and manageable standards for resolving it; and (3) the question cannot be resolved without an initial policy determination of a kind clearly exclusively for nonjudicial discretion, and therefore design defect claims are nonjusticiable under the Political Question Doctrine and should be dismissed.

Based Upon the Textually Demonstrable Commitment of the Military to the Political Branches of Government, the United States Supreme Court has Repeatedly Held that Military Decision-Making is Beyond the Purview of Judicial Standards and Requires Policy Determinations Unsuitable for Judicial Discretion

The text of the United States Constitution expressly provides that military matters are within the discretion of the Executive and the Legislative Branches. In addition to the power to declare war, Article I vests in Congress the power to “provide and maintain a Navy” and to “make Rules for the Regulation of the land and Naval Forces.” Section 8, Clauses 11-14. Among the President’s duties, Article II states that the “President shall be Commander in Chief of the Army and Navy of the United States, and
the Militia of the several States." Section 2, Clause 1. Inherent in this grant is the power and obligation of the Legislative and Executive Branches to organize, arm and discipline the Military. In contrast, Article III is silent about the role of the judiciary in relation to the Navy, war, and the military generally. As Alexander Hamilton concluded, the judiciary has "no influence over . . . the sword." The Federalist No. 46, at 402 (Gideon ed., 2001).

Based upon the textually demonstrable commitment of the military to the political branches, the Supreme Court has repeatedly held military issues are largely beyond the purview of judicial standards and policy determination. In Gilligan v. Morgan, 413 U.S. 1, 8 (1973), the United States Supreme Court discussed the theory behind the constitutional allocation of military powers to Congress and the President and held that it "would be difficult to think of a clearer example of the type of governmental action that was intended by the Constitution to be left to the political branches directly responsible -- as the Judicial Branch is not -- to the electoral process." The "ultimate responsibility" for military training, equipping and controlling the military force is vested in the branches of government which are periodically subject to electoral accountability. The Gilligan Court's analysis echoes the earliest analyses of constitutional theory, in which Alexander Hamilton observed that the Constitution rightfully places control of the military in the hands of "the representatives of the people." The Federalist No. 26 & 28, at 127, 137-38 (Gideon ed., 2001).

Although the Gilligan case involved the National Guard rather than the Army or Navy, identical rules and considerations apply. The Supreme Court further stated, "I believe that the Congressional and Executive authority to prescribe and regulate the training and weaponry of the National Guard, . . . clearly precludes any form of judicial regulation of the same matter. I can envision no form of judicial relief which, if directed at the training and weaponry of the National Guard, would not involve a serious conflict with 'coordinate political departments; . . . a lack of judicially discoverable and manageable standards for resolving [the question]; . . . the impossibility of deciding without an initial policy determination of a kind clearly for nonjudicial discretion; . . . the impossibility of a court's undertaking independent resolution without expressing lack of respect to coordinate branches of governments; . . . an unusual need for unquestioning adherence to a political decision already made; the potentiality of embarrassment from multifarious pronounce-

ments by various departments on a question." 413 U.S. at 8-9. [Emphasis in original.]

The Gilligan court summarized its view that the courts are not an appropriate body to review decisions made by the Military, by stating, "[I]t is difficult to conceive of an area of governmental activity in which the courts have less competence. The complex, subtle, and professional decisions as to the composition, training, equipping and control of a military force are essentially professional military judgments, subject always to civilian control of the Legislative and Executive Branches. The ultimate responsibility for these decisions is appropriately vested in the branches of the government which are periodically subject to electoral accountability. It is the power of oversight and control of military force by elected representatives and officials which underlies our entire constitutional system." 413 U.S. at p.10.

Many other courts have echoed the Supreme Court's view that matters of Military decision-making, policies and actions should not be the subject of second-guessing by the Judicial Branch. See e.g., Chappelle v. Wallace, 425 U.S. 296, 301 (1987) among others. In Tiffany v. United States, 931 F.2d 271, 277 (2nd Cir.1991), the Second Circuit Court of Appeals, citing Postiker v. Goldberg, 45 U.S. 57, 64-67 (1981), stated, "the present controversy implicates a discretionary decision of the most serious sort. It involves a civilian inquiry that followed from actions taken in actual military defense of our country. Of the legion of governmental endeavors, perhaps the most clearly marked for judicial deference are those for national security and defense."

In Fisher v. Halliburton, 454 F. Supp. 637, 641 (S.D. Tex. 2006), the court stated, "[T]he Constitution mandates that war and foreign policy are the provenance of the Executive. In recognition of this, courts have consistently held that issues involving war and actions taken during war, are beyond judicial competence."

A Claim Against Civilian Manufacturers and Suppliers of Equipment Required by the Military To Include Asbestos Is Barred by the Political Question Doctrine Since the Resolution of the Claim Requires Examination of the Correctness or Appropriateness of Military Decision-Making

The Political Question Doctrine should likewise render nonjusticiable those claims against military contractors which cannot be determined without adjudicating a military issue beyond the scope of the judiciary's Article III powers. In Fisher v. Halliburton, supra, at p. 641, the Political Question Doctrine rendered nonjusticiable claims for injuries sustained during combat by military contractors providing transportation services in Iraq. The court held that "the private character of the actions do not preclude the application of the political question doctrine." Id. at 641. Rather, it looked at whether "the court could extricate the defendants' acts from the Army's acts." Id. at 642.

Similarly, in Whittaker v. Kellogg Brown & Root, Inc., 444 F. Supp. 2d 1277 (M.D. Ga. 2006), the Political Question Doctrine prevented a ruling on the merits of claims by the surviving parents of soldiers killed in Iraq. The plaintiffs directed their claims against the contractors responsible for a military supply convoy in which their son was killed. Id. at 1278. The court found that "a soldier injured at the hands of a contractor which is performing military functions subject to the military's orders and regulations also raises the same political questions . . . the use of those civilian contractors to accomplish the military objective does not lessen the deference due to the political branches in this area." Id. at 1281; Smith v. Halliburton Co., 2006 U.S. Dist. LEXIS 61980, 21 (S.D. Tex. 2006) (applying the same reasoning and reaching the same result on a failure-to-warn claim against a military contractor operating a soldier's dining facility bombed in Iraq).

In cases against military contractors, courts have concluded that in most circumstances the contractor's liability cannot be determined without implicitly adjudicating a political question. Thus, in Corrie v. Caterpillar, 503 F.3d 974, 982 (9th Cir. 2007), the Ninth Circuit Court of Appeals found that it could not adjudicate the liability of Caterpillar for selling bulldozers used by Israeli Defense Forces to level homes in the Palestinian Territories without "implicitly" determining the propriety of the United States Government's decision to sell the bulldozers to the Israel in the first place. ("Plaintiffs' claims can succeed only if a court ultimately decides that Caterpillar should not have sold its bulldozers to the IDF"). Likewise, in Zuckerbraun v. General Dynamics Corp., the court found itself without jurisdiction, because "it seems unavoidable that this case would touch on military decisions which are committed to the Executive Branch and for which the court lacks judicially manageable standards." 755 F. Supp. 1134, 1142 (D. Conn. 1990) (dismissing claims against manufacturers, designers, testers, and mar-
keters of an anti-missile system); Nejad v. United States, 724 F. Supp. 753, 755 (C.D. Cal. 1989) (dismissing design defect among others claims against military contractor under the political question doctrine because "it seems indubitably clear that plaintiffs' claim calls into question the Navy's decisions and actions in execution of those decisions"); Bentzlin v. Hughes Aircraft Co., 833 F. Supp. 1486, 1497 (C.D. Cal. 1993) (dismissing claims against military contractor because "no trier of fact can reach the issue of manufacturing defect without eliminating other variables which necessarily involve political questions").

The Political Question Doctrine Should Apply to Bar Products Liability Design Defect Claims Against an Equipment Manufacturer, Whose Equipment Contained Asbestos As Required By the Navy, Pursuant to the Navy’s Decision to Utilize Tons of Asbestos On Every Warship in the Entire United States Navy Fleet Beginning During World War II Through At Least the Late 1960’s

As previously noted, the Political Question Doctrine should bar courts from reaching the merits of such a plaintiff's claims under at least three of the tests set forth by Baker v. Carr.

The "first and arguably the most important formulation of the Baker tests is a textually demonstrable commitment of the issue to a coordinate political department." Fisher v. Halliburton, Inc., supra, 454 F. Supp. 2d at 640. As discussed at length by the Supreme Court in Gilligan v. Morgan, supra, issues such as the training, equipping, and controlling of soldiers are committed in the text of the Constitution to Congress and the President. 413 U.S. at 9. Determinations about how the Navy should have constructed and outfitted its fleet, fall directly within the scope of control of the military. At the heart of this question is the relationship between soldiers and the military, a relationship which is "indubitably within the province of the Executive." Bentzlin v. Hughes Aircraft Co., supra, 833 F. Supp. at 1498.

The second Baker test looks to whether courts have judicially manageable and discoverable standards for resolving the claims before it. In Smith v. Halliburton Co., supra, the court found the second Baker test barred adjudication because the court lacked the "facts, expertise, and standards with which to evaluate" the military situation at issue. Here, courts and certainly juries lack the facts, expertise, and standards to analyze the effect the relationship between the Navy and its contractors, suppliers and vendors to which the Navy specified the design of equipment it determined, with its vast experience and expertise, should be used on board its vessels, including technical and engineering specifications regarding the precise composition of materials to be used.

The only way to determine that such an equipment manufacturer is liable for defectively designing the equipment it supplied to the Navy is to second-guess the Navy, which is impossible for a jury to do, unless it could be privy to everything known to the Navy's teams of expert Admirals, Commanders, engineers, etc. Essentially, facts considered by the Navy in deciding to require and utilize tons of asbestos on its warships, required knowledge about the technological capacities, capabilities and availability of alternative materials discovered and known to be available in the 1930s through 1960s which could have served to protect servicemen, ships and equipment from fire, smoke and heat beginning during World War II, expert knowledge of fuel availability and each warship's requirements for the rate of usage given the typical weight of or amounts of protective insulation required to effectively fight naval battles, information regarding the designs, materials and capabilities of the ships designed and maintained by enemy countries, as well as policy determinations arising from weighing the saving of lives, equipment, and ships and prevailing in or preventing war in the short-term versus the potential health hazards which might befall some small percentage of navy personnel many decades later. A mere jury, even provided with ad hoc expert witness testimony, could not be in any legitimate position to second-guess the judgment of the U.S. Navy and Government in its choices in how to successfully fight World War II and the Korean War and protect our nation during the Cold War. Even farther removed from any sense of reasonableness is to allow a jury, based upon merely its consumer expectations about asbestos, to make such a determination. Simply, the judiciary and juries lack appropriate standards on which to base a determination.

The third Baker test reveals a political question when a claim requires an initial policy determination of a kind unfit for judicial determination. In Bentzlin v. Hughes Aircraft Co., 833 F. Supp. 1486, 1497 (C.D. Cal. 1993) the court found a political question because the claims against the contractor required the court to inquire into "military strategy." As Bentzlin illustrates, the Court may not inquire into issues so intimately related to the workings of the chain of command without making policy determinations unfit for judicial determination.

Conclusion

The Political Question Doctrine should operate to bar design defect causes of action against manufacturer/suppliers of the military, where it can be shown that the military controlled the design of the product, and the product and its components were essential to its war-making and defense efforts. If the facts also establish that the military was well aware of the potential health hazards of its product choice and made a policy decision to require its use Nonetheless, the case for successful application of the doctrine should be substantial.

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* Significant credit must be given to our national counsel (in Chicago) whose input in developing the application of this defense to asbestos Navy cases was invaluable.

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** References **

1. The scope of this article is limited to design defect causes of action. However, the Political Question Doctrine should also operate to bar failure to warn claims in a product liability context, where it can be shown that the military was knowledgeable about the health hazards of the subject product and controlled warnings, if any, through its chain of command and training.

2. The Political Question Doctrine is different than the government contractor defense, and is in no way dependent upon the foundation or principles upon which application of the government contractor defense rests. Among the differences, the Political Question Doctrine is based upon separation of powers principles set forth in the U.S. Constitution, while the government contractor defense is based upon principles of sovereign immunity. The government contractor’s defense is an affirmative defense which focuses on the actions of the defendant in complying with the contractual specifica-
Dismissal for Raw Material and Component Part Manufacturers Under the Biomaterials/Access Assurance Act

Devi C. Yorty
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On March 31, 2008 the United States District Court for the District of Colorado handed down an important, and first impression, decision under the Biomaterials Access Assurance Act (“BAAA”). In spite of being on the books since 1998, United States courts were virtually silent upon application of the BAAA until 2008. The Colorado District Court's decision indicates that the BAAA can and will be a powerful tool for parties that supply raw materials and component parts for use in medical implants and wish to avoid the costs of litigation.

History and Content of the Biomaterials Access Assurance Act

The Biomaterials Access Assurance Act is a legislative attempt to ensure access to medical implants and devices for American patients by sparing component part and raw material suppliers (“biomaterial suppliers”) the burdens of costly products liability actions aimed at finished implants. The BAAA responded to events in the early 1990’s when E.I. Du Pont De Nemours & Company (DuPont), and other biomaterial suppliers, faced extensive litigation for their roles in supplying Teflon for defective temporomandibular joint (TMJ) implants. Although the Teflon suppliers did nothing more than provide Teflon for use in jaw implants designed, marketed, and sold by an unrelated third party, in the span of ten years, DuPont faced 651 lawsuits in 41 states and spent several million dollars in defending product liability suits related to failure of the jaw implants. DuPont was successful in the litigation and obtained rulings that their warnings to manufacturers of medical devices were sufficient as a matter of law. In spite of this success, DuPont lost: it spent millions of dollars defending lawsuits over the sale of miniscule amounts of Teflon.

Due to this and other cases, many biomaterials suppliers ceased supplying raw materials for use in medical devices because the cost of litigation far outweighed the benefits of sales in the medical market. One report, cited in the BAAA legislative history, noted that, “75 percent of the suppliers of biomaterials required for implantable medical devices have banned sales to U.S. device manufacturer. One hundred percent of these suppliers have cited liability exposure as a key factor in discontinuing sales of their products.” The House of Representatives noted in its report that “leaving biomaterials suppliers susceptible to high litigation costs in any state would harm all of the United States and their citizens because medical devices and implants would be more scarce and expensive.”

According to the BAAA’s “Findings” section, the biomaterial suppliers are rarely found to be at fault for the failure of a finished implant and are not responsible for the rigorous testing and design that ensure an implant’s safety under existing laws. In spite of this, Congress determined that several biomaterial suppliers already had or would soon stop selling products to and developing products for the medical implant industry in order to avoid the costs of defending themselves, even successfully, in products liability actions. In response, the BAAA allows biomaterial suppliers to move for immediate dismissal from actions regarding the failure of the larger implant so long as the biomaterial supplier was not the “manufacturer” of the implant, the “seller” of the implant, or failed to meet contractual specifications in its supply of its component part or raw material. This dismissal takes the form of a motion to dismiss unless the parties contest whether the biomaterial supplier failed to meet contractual specifications in the sale of its component parts or raw materials. In such a case, proceedings take the form of a motion for summary judgment. After dismissal, if proceedings against the implant’s manufacturer reveal that a component part or raw material supplier was actually at fault, the raw material supplier or component part manufacturer is subject to impleader after the suit resolves. The BAAA spares component part and raw material suppliers the burdens of litigation even while it allows plaintiffs to recover from those few raw material and component part suppliers that are actually at fault for an implant’s failure.

Victory for the Defense in Whaley v. Morgan Advanced Ceramics Ltd.

On August 15, 2007, Morgan Advanced Ceramics moved to dismiss Ms. Whaley’s claims against it pursuant to the BAAA, 21 U.S.C. § 1605(a). Without the benefit of any past interpretations or applications, Morgan Advanced Ceramics argued through counsel Morgan Advanced Ceramics deserved dismissal from Ms. Whaley’s action. In spite of stiff opposition from Ms. Whaley, the court agreed that Morgan Advanced Ceramics was not the manufacturer of an implant, the seller of an implant, or a component part supplier that failed to meet contractual expectations. Accordingly, the court dismissed the action against Morgan Advanced Ceramics.

Conclusion

Although virtually ignored in published case law until ten years after its passage, the BAAA is a powerful tool for biomaterial suppliers joined in lawsuits regarding the failure of medical implants. A biomaterial supplier dismissed pursuant to the BAAA cannot escape liability if found to be at fault after its dismissal but, in the long run, escape from lengthy discovery and other litigation costs makes filing a motion to dismiss under the BAAA worthwhile for the majority of biomaterial supplier defendants. The United States District Court for the District of Colorado’s recent decision in Whaley v. Morgan Advanced Ceramics Ltd., No. 07 cv-00912-REB-CBS, 2008 U.S. Dist. LEXIS 29918 (D. Colo. March 31, 2008), provides the first real guidance available for practice under the BAAA.

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Case and Statute Analysis

CONGRESS OVERWHELMINGLY PASSES CPSC OVERHAUL BILL

The U.S. Senate passed legislation last week that reforms the Consumer Product Safety Commission (CPSC) by providing the commission significant new funding and strengthening several safety rules. The legislation, officially known as the Consumer Product Safety Improvement Act of 2008, is considered the most comprehensive overhaul of consumer product safety laws since the creation of the CPSC in 1972.

The bill was introduced in November 2007 following several well-publicized recalls of imported toys with lead paint and other hazards. Versions of the bill cleared the House in December and the Senate in March. The final version of the legislation passed by a vote of 89-3 in the Senate and 424-1 in the House of Representatives. The bill is expected to be signed by President Bush shortly.

The legislation is expected to be far reaching in its scope and likely will impact all manufacturers, importers, distributors and retailers of consumer products. Some of the most significant provisions of the legislation include:

- Removal of lead from toys and other children’s products.
- Widespread ban on the plastic additive phthalates from toys and other children’s products in light of recent studies linking the chemical to serious health risks. (The European Union already has prohibited the chemical from use in children’s products.)
- Mandatory third party testing and certification for imported children’s products.
- New warnings in advertising and websites for toys and games.
- Substantially increased civil penalties for violations of the legislation to $100,000 for each violation, with a maximum cap of $15 million for a related series of violations.
- Authorizing state attorneys general to enforce federal product safety laws through court injunctions.
- Significant whistleblower protections for private employees who report violations, testify or otherwise provide assistance in consumer product safety enforcement proceedings and the ability of employees to file retaliation claims against employers who take adverse action against employees who refuse to violate CPSC laws or regulations.
- The elimination of the requirement that directors, officers or agents of companies be aware of violations of the CPSC laws or regulations in order to face criminal prosecution.

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**Reference Notes**


6. Id.


15. The BAAA Motion to Dismiss was prepared and argued by Darin J. Lang and Devi C. Yorty of ALFA International Denver, Colorado member firm Hall & Evans, LLC, in Denver, Colorado.
Banning of 3-wheeled all-terrain vehicles and the strengthening of regulations of other ATVs, especially those intended for use by youth.

Mandating that the CPSC establish a searchable online database for consumers to report and learn about deaths and injuries reportedly caused by consumer products, and which includes manufacturers’ names, product names and other information.

Requiring that the CPSC share information collected by it with federal, state, local, and foreign governmental agencies for law enforcement or consumer protection purposes.

This new legislation is likely to have a broad impact on the consumer product industry as a whole. The CPSCs increased budget and resources likely will translate into stricter product regulation, stronger enforcement of those regulations by CPSC staff, and generally more governmental oversight of product manufacturers. Similarly, the enhanced availability of product safety information and expected increase in enforcement actions will likely result in an increase in liability claims as the plaintiffs’ bar can be expected to monitor the new CPSC databases and product lists for litigation opportunities.

SUPREME COURT RESTRICTS MARITIME PUNITIVE DAMAGES RATIO TO 1:1


On March 24, 1989, the supertanker Exxon Valdez ran aground on the Bligh Reef off the Alaskan coast, spilling 11 million gallons of crude oil into Prince William Sound. The accident happened after the tanker’s captain, Joseph Hazelwood, left the bridge and a difficult course correction, in the hands of unlicensed subordinates. Hazelwood had a history of alcoholism and the evidence suggested Hazelwood was heavily intoxicated at the time of the spill.

At the close of the trial, the jury awarded $287 million in compensatory damages to commercial fisherman, $5,000 in punitive damages against Hazelwood, and $5 billion in punitive damages against Exxon.

On appeal, the Ninth Circuit Court of Appeals twice remanded the case for adjustments to the punitive award and ultimately the court remitted the award to $2.5 billion because of constitutional due process concerns. The Supreme Court granted certiorari to consider whether the punitive damages awarded against Exxon were excessive as a matter of maritime law.

In coming to its decision to restrict punitive damages to a 1:1 ratio with compensatory damages, the Court noted the need to protect against the possibility of unpredictable and unnecessary awards while seeking the goals of deterrence or retribution. The Court noted that although studies indicated the median ratio of punitive damages was 0.62:1, there was a great spread with regard to individual cases and outlier cases subjecting defendants to punitive damages much larger than corresponding compensatory damages.

The Court analogized punitive damages to the criminal sentencing system, noting that both strive to promote punishment and deterrence. The Court noted that in the last quarter-century, federal sentencing has moved from an “indeterminate” system to a system of detailed guidelines, and that as long “as there are no punitive-damages guidelines...it is inevitable that the specific amount of punitive damages awarded whether by judge or by a jury will be arbitrary.” (quoting Mathias v. Accor Economy Lodging, Inc., 347 F.3d 672, 678 (7th Cir. 2003)).

The judgment of the Ninth Circuit Court of Appeals was vacated and the case was remanded to remit the punitive damages to the District Court’s calculation of total compensatory damages in the amount of $507.5 million.

Although the Court’s decision was specific to maritime cases, the Court’s reasoning will have a significant impact on future analysis of punitive damages. The unpredictability of punitive awards was the main reasoning that the Court cited in its move towards a more “quantitative” approach. Indeed, the Court noted that most states already use some statutory ratio or maximum multiple. The Court’s adoption of a 1:1 ratio may signal a trend of reduction of statutory ratios for non-maritime cases in response to the Court’s reasoning that such a ratio encompasses even outlier cases. The Court stated a 1:1 ratio is appropriate for all but the “most exceptional” of cases, and where compensatory damages are substantial a lesser ratio reaches the outer limits of the due process guarantee.

This decision also represents the Court using its power to control the common law. The Court noted that although Congress retains superior authority over such matters, the Court also has a responsibility to control common law remedies. In their dissent, Justice Stevens and Ginsburg noted that although the Court possesses the power to make such a ruling, it is a decision better left to Congress. The majority reasoned that the absence of federal legislation restricting punitive damages does not imply a congressional decision that there should be no such rule.

CALIFORNIA

SUPREME COURTadopts "Sophisticated User" DOCTRINE

Johnson v. American Standard, Inc.,
43 Cal.4th 56; 179 P.3d 905 (April 13, 2008)

Plaintiff William Johnson sued American Standard, Inc., the manufacturer of air conditioning equipment, for damages as a result of being exposed to phosgene gas while working in the normal course of duties as an HVAC technician. According to Plaintiff, he was exposed to phosgene gas while he brazed refrigerant lines that contained R-22 refrigerant on an evaporator Defendant manufactured. The exposure, Plaintiff argued, caused him to develop pulmonary fibrosis.

Plaintiff’s causes of action against Defendant included negligence, strict liability failure to warn, strict liability design defect, and breach of implied warranties. Under each cause of action, Plaintiff alleged that Defendant knew that servicing the evaporator would create harmful phosgene gas and that Defendant failed to provide Plaintiff with an adequate warning. The defendant moved for summary judgment of the claim, arguing that California’s “Sophisticated User” doctrine applied. The doctrine provides a defense in cases where the plaintiff’s negligence is based on the product’s inherent characteristics or design, if the plaintiff was “sophisticated” and should have known about the dangers of the product.

The trial court denied the motion, and the case was tried to a jury. The jury awarded $15.5 million, $2 million in compensatory damages and $13.5 million in punitive damages. Plaintiff’s appeal of the judgment was granted, and the Ninth Circuit Court of Appeals remanded the case for reconsideration. On remand, the trial court lowered the punitive damages award to $507.5 million.

The Supreme Court granted certiorari to determine whether the “Sophisticated User” doctrine applies to Plaintiff’s claims. The Court agreed with the Ninth Circuit that the doctrine does not apply, reasoning that the doctrine is intended to limit liability in cases where the plaintiff’s negligence is based on the product’s inherent characteristics or design, and that Plaintiff’s negligence was based on his failure to use the product as intended, not on the product’s inherent characteristics or design.
mary judgment arguing that it had no duty to warn about hazards because it did not manufacture the R-22 compound. Alternatively, Defendant argued it had no duty to argue about the risks of exposure to R-22 because it could assume the trained professionals exposed to the compound were aware of the associated risks of R-22. The trial court granted Defendant's Motion for Summary Judgment on both grounds.

The Court of Appeals upheld the trial court's ruling solely on the ground that Plaintiff's action was defeated by the "sophisticated user" defense. Thus, the issue on appeal was whether California should adopt the "sophisticated user" doctrine as an affirmative defense to negate a manufacturer's duty to warn of potential danger when the Plaintiff knew or should have known, as a result of his or her knowledge and/or experience, of the inherent risks associated with the product.

The California Supreme Court held the defense is applicable to defeat a failure to warn theory of liability as to both negligence and strict liability causes of action. In reaching this holding, the Supreme Court analyzed the underlying policy of a failure to warn defense to negate a manufacturer's duty to warn of potential danger when the Plaintiff knew or should have known, as a result of his or her knowledge and/or experience, of the inherent risks associated with the product.

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**KENTUCKY**

**PLAINTIFFS’ EXPERT IN CARBON MONOXIDE WRONGFUL DEATH ACTION EXCLUDED UNDER DAUBERT**

_Early, et al. v. Toyota Motor Corp._


Plaintiffs filed a wrongful death action against Toyota Motor Sales, U.S.A., Inc. and Toyota Motor Corp., ("Toyota") alleging that defects with a 1994 Toyota pickup truck resulted in the carbon monoxide poisoning of decedents Joshua Early and Timothy Mullins. According to Plaintiffs, Joshua and Timothy stopped at a rest stop while in route to their home in Shelbyville, Kentucky. The decedents were later found dead by a rest stop worker after she noticed that the truck had remained in the parking lot for a significant period of time. It was determined that the carbon monoxide level inside the truck was 400 parts per million which is 20 times the level permitted by Toyota engineering standards. Based on the investigation performed by the Kentucky State Police, the carbon monoxide entered the cab of the truck as a result of a significant exhaust leak at the joint between the manifold and exhaust downpipe.

Plaintiff sued Toyota alleging the truck had a faulty dust seal, and that Toyota had not used reasonable care in selecting the proper materials from which to manufacture the dust seal or in determining its useful life. In support of this claim, Plaintiffs retained expert consultant Jay Nogan who opined during his deposition that the dust seal's failure was due to Toyota's selection of poor materials and that there were probably many Toyota vehicles with dust seals in similar condition. However, Mr. Nogan had not performed any testing on the dust seal at issue despite Plaintiff's counsel's request to do so early on in the litigation.

The Court of Appeal noted that the trial had been continued on numerous occasions. Further, the court noted that just prior to the close of discovery, Plaintiffs' counsel sent letters to Kentucky residents with Toyota pickup trucks similar to the decedent's vehicle. Subsequently, Toyota filed a Motion for Protective Order and a Motion to exclude evidence of the condition of other dust seals of other Toyota vehicles. The basis of the Toyota's Motion was that Plaintiffs had not responded to Toyota's prior discovery requests on that very issue and that evidence acquired in response to Plaintiff's letter would lead to a significant amount of discovery that would not be able to be completed prior to trial.

In advance of Toyota's Motion for Protective Order, Plaintiffs responded to Toyota's outstanding discovery requests, including a summary of responses received from other Toyota pickup truck owners. At the hearing, Toyota argued that it would have to conduct an extensive investigation into the service, repair and accident history of each Toyota vehicle with alleged similar dust seal problems that Plaintiff sought to introduce into evidence. The trial court inquired as to why Plaintiff's counsel did not seek such supporting evidence prior to Mr. Nogan's opinions on causation at deposition. Plaintiff responded that Mr. Nogan considered the rubber used for the dust seal and concluded that it would last longer and withstand higher temperatures and that his opinions were in response to Toyota's expert's opinions.

Defendant, while the Motion was pending, filed a Motion to exclude Mr. Nogan's testimony and opinions. Plaintiff simultaneously filed a motion for trial continuance in order to allow Mr. Nogan to conduct testing of the seal and to allow Plaintiffs to contact Toyota pickup truck owners in Shelby County. The Court continued the trial pending its decision on Toyota's Daubert motion. In its subsequent ruling on the defendant's motion to exclude, the Court determined that Mr. Nogan was not qualified to render such opinions in that he did not have an engineering license, nor did he have any experience in automotive design or manufacturing or experience in "designing, installing or researching any kind of automobile seal." With respect to warnings, the Court highlighted that Mr. Nogan had not reviewed or written any owner's or repair manuals for any product, had never created a maintenance schedule for a sealed system and made no assertion that he was an expert on warnings.

With regard to reliability, the Court observed that Mr. Nogan only examined the seal after it was removed, had not determined the reason it failed and did not consider the vehicle's prior front end collision. Further, he had not examined the service records or any exemplar vehicle, nor was he familiar with the material that was used to manufacture the dust seal. He also had not conducted any tests to support his opinion that an alternative material would
have been better for the dust seal. In reviewing these facts in conjunction with the standards for the admission of expert opinion testimony as set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 113 (1993) and Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), the court excluded the testimony of Mr. Nogan. Defendants thereafter moved for summary judgment, which was unopposed by Plaintiff as a result of the court’s prior ruling. As a result, the trial court dismissed Plaintiff’s action. The Sixth Circuit Court of Appeal upheld the district court’s ruling holding that the trial court did not abuse its discretion in excluding Mr. Nogan’s testimony based on the grounds that his opinions did not “pass muster under a single Daubert criterion.”

**MAINE**

**UNFAIR TRADE PRACTICES ACT CLAIMS NOT PREEMPTED BY THE FEDERAL CIGARETTE LABELING AND ADVERTISING ACT**

*Good v. Altria Group, Inc.*

501 F.3d 29 (2007)

This action arises out of cigarette smokers’ claims that Phillip Morris employed unfair and deceptive practices in the design, manufacturing, promoting, marketing and selling of Marlboro Lights and Cambridge Lights cigarettes purporting to be “light” and having “lowered tar and nicotine” all while it knew those cigarettes would not deliver less tar or nicotine to consumers. The smokers claimed that these misrepresentations amounted to unfair or deceptive acts or practices in violation of the Maine Unfair Trade Practices Act.

Phillip Morris moved for summary judgment on the following grounds: (1) plaintiffs’ claims were expressly pre-empted by the Federal Cigarette Labeling and Advertising Act (FCLAA), (2) plaintiffs’ claims were implicitly pre-empted by the FCLAA or Federal Trade Commission’s oversight of tar and nicotine claims in advertising through consent orders, and (3) plaintiff’s claims were barred by the exemption for “transactions or actions otherwise permitted” under Me. Rev. Stat. Ann. tit. 5, § 208(1). The United States District Court for the District of Maine granted Phillip Morris’ summary judgment motion and ruled that the smokers’ Maine Unfair Trade Practices Act (MUTPA) claims based on the marketing of “light” cigarettes were preempted by the FCLAA. Plaintiff smokers appealed the judgment.

The Appellate Court held that the District Court erred in treating the smokers’ claims as based on implied representations on health, which were preempted as failure to warn or warning neutralization claims. The Appellate Court held that the claims sought to enforce state-law prohibitions on fraud, not on cigarette advertising based on smoking and health and therefore concluded that the MUTPA claims were not expressly or impliedly preempted by the FCLAA. The Appellate Court also concluded that the MUTPA claims were not barred by the exemption for “transactions or actions otherwise permitted” under Me. Rev. Stat. Ann. tit. 5, § 208(1). The Appellate Court vacated the judgment and remanded the case for further proceedings.

Phillip Morris filed a petition for writ of certiorari to the United States Court of Appeals for the First Circuit, which has been granted. The Supreme Court is expected to issue a ruling whether the smokers’ claims are pre-empted by federal law shortly.

**MINNESOTA**

**PLAINTIFF CLASS MUST ALLEGED ACTUAL INJURY IN ORDER TO MAINTAIN CLASS ACTION FOR PRODUCT DEFECT AND RELATED CLAIMS**

*O’Neil v. Simplicity, Inc.*

553 F. Supp. 2d 1110 (2008)

This action arose out of a recall of children’s cribs by Defendant Simplicity, Inc. A class action was brought by purchasers of the crib. The crib had been recalled due to an alleged defect that had caused child injuries and deaths. Specifically, the crib included a “drop side,” which allowed one side of the crib to be raised and lowered to more easily place a child into the crib. There were several instances where the drop side of the crib separated from the crib frame, creating a gap between the frame and the drop side. As a part of the recall, Simplicity was not accepting returns of the cribs, but was offering to send new hardware which could be used to immobilize the drop sides of the crib.

The named plaintiffs, the O’Niel’s, used the crib without problems until learning of the recall, then subsequently stopped using the crib and did not order the new hardware because the crib was useless to them without a functional drop side. They asserted claims under the Magnuson-Moss Warranty Act, the Minnesota Deceptive Trade Practices Act, the Minnesota Consumer Fraud Act, and the Minnesota False Statement in Advertising Act, and for breach of warranty and unjust enrichment. The O’Neil’s purported to represent a class of all persons in Minnesota who purchased a Simplicity crib. The class expressly excluded any individual who suffered a personal injury while using a defective crib.

The defendants filed a Motion to Dismiss under Rule 12(b)(6) based on the argument that the O’Neil’s failed to assert a legally cognizable injury. The crux of defendants’ argument was that the O’Neil’s crib never actually malfunctioned and as such, this case fell within the line of “no injury” product liability cases where the plaintiff alleges a defect that could cause injury or might cause a safety hazard, but fails to allege actual harm.

The court held that the action could not proceed because the purchasers had not asserted a legally cognizable injury. Damages were an element of each of the purchasers’ claims, with the exception of the Deceptive Trade Practices Act (DTPA) claim and a declaratory judgment claim. The declaratory judgment claim was duplicative of the warranty claim, and the sole DTPA remedy was injunctive relief.

It was not enough for the purchasers simply to allege that the crib was unsafe; they had to allege an actual manifestation of the alleged defect that resulted in some injury. Alleged “benefit-of-the-bargain” damages were insufficient to support the claims in light of the fact that the purchasers’ crib had not malfunctioned. The purchasers could not seek injunctive relief, having failed to plead that the allegedly defective cribs were still being sold. As the plaintiffs already had three bites at the apple, the district court dismissed the case, with prejudice.
“In the Trenches”
Notable Accomplishments of ALFA Attorneys

CALIFORNIA/ILLINOIS

ALFA INTERNATIONAL FIRMS TEAM UP FOR APPELLATE VICTORY

In October 2005, Skip Martin of Haight Brown & Bonesteel, Los Angeles, CA and Kevin Owens of Johnson & Bell, Ltd., Chicago, Illinois successfully defended a lawsuit brought against APV Crepaco. The product involved in the lawsuit was a distillation column that stripped acetone from edible oils. During a maintenance procedure, the contents of the column erupted, severely burning one individual and killing another.

Conopco, a division of Unilever, settled the two lawsuits with the plaintiffs for a sum in excess of $13 million. Conopco then filed a third-party action against APV Crepaco and OIS, who was cleaning the column at the time of the eruption. Conopco sought $7 to $9 million in settlement from APV. The jury found APV to be 5% at fault, rendering a verdict in the approximate amount of $700,000.

APV, however, had faith that Skip and Kevin could prevail in the Appellate Court. Appellate Briefs were prepared by Skip, Kevin and Johnson & Bell’s Appellate Department with Skip and Kevin arguing the appeal in March of 2008.

The Appellate Court entered Judgment N.O.V. reversing the jury verdict in favor of Conopco, ruling that APV had no liability. The Appellate Court also reversed the 2% finding of liability against OIS on the basis of improper jury instructions and remanded the case back to the trial court for a new trial between Conopco and OIS.

KANSAS/WASHINGTON

HINKLE ELKOURI LAW FIRM OBTAINS DEFENSE JURY VERDICT FOR DEFENDANT THE COLEMAN COMPANY


In September of 2006, three men were on a hunting trip near Packwood, Washington. After a day of hunting, the owner a Coleman Powermate Model 5045 heater operated it inside of a camper, contrary to the warnings provided on and with the product. Two of the three men ultimately died from carbon monoxide poisoning.

The plaintiff -- a 38-year-old woman who lost her father and husband in the incident -- asserted product liability claims based on allegations that the product was defective in both design and warnings. Specifically, the plaintiff claimed that the heater should have included a safety device to shut it off before lethal levels of carbon monoxide could be generated if the heater was taken into an enclosure contrary to its warnings. The plaintiff further alleged that the heater’s warnings and instructions were defective and failed to adequately warn users of the risk of operating the heater inside of enclosures.

The subject heater was a 45,000 BTU heater specifically designed for outdoor and well-ventilated use only, as its warnings clearly indicated. Due to the high heat output of the heater, the plaintiff theorized that the owner and operator of the heater -- and lone survivor of the incident -- operated it under a condition that the plaintiff’s experts referred to as “tank valve control.” This theory rested on the speculation that the survivor turned down the valve on the propane tank to reduce the heater’s output, which would have allowed the heater to run longer without rapidly overheating the enclosure. Otherwise, as admitted by the plaintiff’s experts, the camper’s occupants would have extinguished the heater because of the high temperatures it generates long before they would have experienced high levels of CO or decreased oxygen.

Prior to trial, the plaintiff had demanded $3.8 million in settlement. Coleman rejected the offer and proceeded to trial in the USDC-WDWA before the Hon. Karen Strombom, Tacoma, Wash. Division. After a two-week trial, the nine-person jury rendered an unanimous verdict in favor of Coleman on all counts, finding that the subject heater was not defective in design or warnings, and ultimately absolving Coleman of any fault or liability in the case.

MICHIGAN

DEFENDANT GRANTED RULE 56 SUMMARY JUDGMENT AGAINST PLAINTIFF WHO CONCEALED PERSONAL INJURY CLAIM IN BANKRUPTCY

In Rodriguez v. Mustang Manufacturing Company, Case No. 07-CV-13828, 2008 WL 2605471 (E.D. Mich. June 2008), Rodriguez lost his leg in a skid steer loader incident. Between the time of the incident and filing a product liability suit against Mustang, Rodriguez filed for and was granted a discharge in bankruptcy. In the bankruptcy, he filed a “Summary of Schedules” which declared he had no “contingent and unliquidated claims” of any nature. Additionally, he did not list the loader in question as personal property. Six months before his bankruptcy the loader was examined by his tort counsel and then less than two weeks after his discharge Rodriguez and the same attorney examined the loader with an expert. Mustang moved for summary judgment and the federal district court granted it for two reasons: (1) Rodriguez was not the real party in interest and (2) judicial estoppel barred Rodriguez’s claim.

First, the Court held under FRCP 17(a) Rodriguez could not bring the claim because upon filing bankruptcy all of the debtor’s legal and equitable interests in property became part of his estate. The bankruptcy trustee was the real party in interest. Rodriguez was not allowed an opportunity under FRCP 17(a) to substitute the trustee as the real party in interest. The Court rea-
sioned Rodriguez had almost two years to ascertain and add the
trustee as the real party in interest. Further, in the 30 days since
the objection was raised, Rodriguez had not taken action to substi-
tute the trustee. “...Rodriguez has been given sufficient opportunity
to ensure his claim is brought by the real party in interest.”

Second, the Court, independent of the lack of standing under
FRCP 17, found the doctrine of judicial estoppel barred the Rodri-
guez claim. The Court found Rodriguez concealed his personal
injury claim in the bankruptcy because Rodriguez failed to list the
personal injury claim, Rodriguez failed to disclose the loader, and
due to the timing of Rodriguez's attorney and expert inspections.
Having determined that Rodriguez concealed his claim, the Court
noted “Judicial estoppel is an equitable doctrine that preserves the
integrity of the courts by preventing a party from abusing the judi-
cial process through cynical gamesmanship, achieving success on
one position, then arguing the opposite to suit an exigency of the
moment.” “Rodriguez's omission of his personal injury claim
against Mustang is a ‘contrary position [taken] under oath in a prior
proceeding and...accepted by the court’ such that he should be
estopped from pursing the present claim.”

Dennis Day, Ernest Bazzana, and Kristen Netschke of the ALFA
firm, Plunkett Cooney in Detroit, Michigan represented Mustang.
Plaintiff has not appealed as of July 16, 2008.

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**Upcoming ALFA International Events**

**October 23-25, 2008**  
Annual Business Meeting  
The Capital Hilton  
Washington, District of Columbia

Contact Info  
ALFA Contact: Amy Sammon

**November 12-13, 2008**  
International Law Practice Group Seminar  
Mumbai, India

Contact Info  
Chair: Rajarshi Chakrabarti  
Co-Chair: Harvey Cohen  
Co-Chair: Ignacio Lopez-Balcells  
ALFA Contact: Joely Nicholson

**November 12-14, 2008**  
Product Liability Practice Group Seminar  
The Ritz-Carlton Laguna Niguel  
Dana Point, California

Contact Info  
Chair: Charles A. (Chuck) Stewart III  
Bradley Arant Rose & White LLP, Montgomery, Alabama  
(334) 956-7700, cstewart@bradleyarant.com  
ALFA Contact: Katie Garcia

**March 5-8, 2009**  
2009 ALFA International - International Client Seminar  
Westin Kierland Resort & Spa  
Scottsdale, Arizona

Contact Info  
Chair: George Fagan  
Leake & Andersson, L.L.P., New Orleans, Louisiana  
(504) 585-7500, gfgan@leakeandersson.com  
ALFA Contact: Joely Nicholson

**May 6-8, 2009**  
Transportation Practice Group Seminar  
Hotel del Coronado  
Coronado (San Diego), California

Contact Info  
Chair: Paul T. Yarbrough  
Butt Thornton & Baehr PC, Albuquerque, New Mexico  
(505) 884-0777, ptyarbrough@btblaw.com  
ALFA Contact: Katie Garcia

**June 17-19, 2009**  
Insurance Law Roundtable  
New York Marriott Downtown - New York, New York

Contact Info  
Practice Group Chair: Kevin O'Brien  
Life, Health & Disability Program Chair: Angela Logan Edwards  
Property & Casualty Program Chair: Stephen Carter
The California Coast at Dana Point forms the backdrop for Beyond the Horizon...A New Dawn for Product Liability Claims, a cutting edge seminar presented by ALFA International's Product Liability Practice Group. Starting with an evening reception on Wednesday, November 12, 2008, ALFA members and invited clients will gather to explore developments in the law in the beautiful setting of the Ritz-Carlton Laguna Niguel.

With exciting topics ranging from warnings and instructions to multi-district medical device litigation to effective and appropriate investigation techniques, the Seminar will arm attendees with effective strategies for dealing with today's increasingly complex product liability claims and litigation. There will also be ample opportunity for one-on-one discussions on presentation topics with ALFA attorneys and experienced industry professionals.

The program will include a Thursday general session on common product liability claims mistakes and how to avoid them with input from experienced trial counsel, clients and insurance industry claims personnel. Breakout sessions tackle such important issues as preparing the company witness for deposition and the impact of the new ANSI Z535 warnings and instruction standard.

How to effectively deal with the increasing incidence of fire claims will get an in-depth panel presentation, as will current developments and trends in medical device multi-district litigation. The legal ramifications of manufacturing in China will be reviewed with a presentation by in-house counsel for manufacturers and national retailers. Moreover, you'll receive a “nuts and bolts” discussion on how to effectively utilize insuring and indemnity agreements to protect today's global manufacturers and retailers.

The Seminar concludes on Friday morning with two timely General Sessions. First, attendees will embark on “2008: A Discovery Odyssey”, a journey through the canyons of E-Discovery under the new federal rules. Then, attendees will be presented with a panel on the investigation process that answers such important questions as who should be involved in an investigation, when the attorney/client privilege or attorney work product doctrine applies...and when it does not, and the discoverability of any pre-litigation investigation, among other issues.

The setting for this important legal conference is the spectacular Ritz-Carlton Laguna Niguel Resort in Dana Point, California. This beautiful Pacific Coast venue offers unparalleled ocean vistas and a host of amenities. Attendees will be treated to a welcoming reception and buffet at the resort’s Monarch Bay Courtyard & Pool upon arrival on Wednesday, November 12, 2008. Following Thursday's presentations, guests will enjoy a cocktail reception on the Pacific Promenade Lawn, followed by a dinner buffet. After adjournment and a luncheon buffet on Friday afternoon, attendees may choose from a number of afternoon activities, including golf, a walking tour of the Mission San Juan Capistrano, or a bike tour, followed by a casual Friday evening cocktail reception and buffet. Dana Point is a great place to relax ... consider extending your stay over the weekend!

Don't miss this great opportunity. Mark your calendars now for November 12-14, 2008 and watch for registration materials coming soon. Plan now to join us in Laguna Niguel...Beyond the Horizon!
Disclaimer

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This edition of the Products Liability Perspectives was compiled by Mary M. Oldendorph, Marketing Manager, Haight Brown & Bonesteel LLP, Los Angeles, CA.