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FEDERAL PREEMPTION DEFENSES IN PRODUCT LIABILITY CASES

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Introduction

Federal preemption in product liability cases has been an increasingly active area in recent years. Manufacturers, when required to comply with federal regulatory dictates, have asserted the defense when plaintiffs claim a defect exists which may conflict with the federal requirements. This article is intended to acquaint defense counsel with this potential defense which can be an effective tool to dispose of an entire case or certain specific allegations of a defect.

The recent tort reforms affecting Illinois product liability law apply similar concepts to preemption and can afford a defense where there has been prior government approval of a product.[1] A working knowledge of various federal statutes and regulations will be helpful whether asserting a preemption defense or taking advantage of the recent tort reforms concerning prior approval. In this article, the

Product Liability Committee offers an overview of significant developments in the preemption defense.

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Part I
Concepts of Preemption

The doctrine of preemption is based upon the Supremacy Clause of the United States Constitution, which provides:

> [t]his Constitution and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.[2]

The doctrine permits Congress to address problems of national scope by enacting comprehensive legislation that prevents state regulation in a given area. When a state law conflicts with or frustrates federal law, that state's law is without effect. *Maryland v. Louisiana*, 451 U.S. 725, 746, 1101 S.Ct. 2114, 68 L.Ed.2d 576 (1981); *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 111 S.Ct. 2476, 115 L.Ed.2d 532 (1991). The supremacy clause, when applicable, preempts all tort claims under a state's law, whether that state's law arises from statutory or case law. *CSX Trans., Inc. v. Easterwood*, 507 U.S. 658, 113 S.Ct. 1732, 123 L.Ed.2d 387, 402-03 (1993); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). A state law is preempted whenever Congress intends for it to be preempted by a federal law. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed.2d 1447 (1947).

Preemption issues generally fall into one of three categories. The first is "express preemption" which comes into effect when a particular federal statute explicitly provides that it preempts all state law. The second is "conflict in fact" preemption which arises when state and federal regulatory schemes conflict with one another, but there is no explicit preemption intent set forth in the federal statute. The third, and most frequently litigated in product liability cases, is "implied preemption." When the regulation by Congress of a particular field is so all-encompassing, implied preemption will be found and a state cannot regulate that activity contrary to federal provisions.

When dealing with implied preemption, the United States Supreme Court delineated the considerations to be analyzed:

> In the absence of explicit statutory language, however, Congress implicitly may indicate an intent to occupy a given field to the exclusion of state law. Such a purpose properly may be inferred where the pervasiveness of the federal regulation precludes supplementation by the States, where the federal interest in the field is sufficiently dominant, or where "the object sought to be obtained by the federal law and the character of obligations imposed by it ... reveal the same purpose." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447 (1947). Finally, even where Congress has not entirely displaced state regulation in a particular field, state law is preempted when it actually conflicts with federal law. Such a conflict will be found "'when it is impossible to comply with both state and federal law, *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43, 83 S.Ct. 1210, 1217-1218, 10 L.Ed.2d 248 (1963), or where the state law stands as an obstacle to the accomplishment of the

full purpose and objectives of Congress. *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 404, 85 L.Ed. 581 (1941).'"[3]

Congress may authorize federal administrative agencies to preempt state laws by the promulgation of administrative regulations. Once promulgated, those regulations have no less preemptive effect than federal statutes. *Louisiana Public Service Comm. v. Federal Communications Comm.*, 476 U.S. 355, 369, 106 S.Ct. 1890, 90 L.Ed.2d 369 (1986).

When applicable, a preemption defense can be useful regardless of the theory advanced by plaintiff. It has been held to apply not only to strict liability and negligence claims, but also to various warranty theories.[4]

It is important to remember that federal preemption is not jurisdictional, but rather is in the nature of an affirmative defense. Therefore, it must be raised at an appropriate time at the trial level. *Haudrich v. Howmedica, Inc.*, 169 Ill.2d 525, 662 N.E.2d 1248, 215 Ill.Dec. 108 (1996) refused to allow the manufacturer of an allegedly defective knee prosthesis to assert preemption by the medical device amendments to the Federal Food, Drug and Cosmetic Act because the doctrine had not been raised at the trial level. Therefore, an appropriate motion to dismiss or motion for summary judgment should be timely filed. The motion should be supported by evidence of compliance with the appropriate statute or regulation.

If the preemption motion is denied, the court should be encouraged to deny the motion without prejudice. In that way, the defense can raise the argument at trial, and in the process, obtain favorable testimony on national policy considerations and the defendant's compliance. Defense counsel may want to seek a special interrogatory for the jury to determine if the defendant complied with relative federal requirements.

Preemption may afford a basis for removal to federal court. *Richardson v. Advanced Cardiovascular Systems, Inc.*, 865 F.Supp. 1210 (E.D. La. 1994) was a product liability action against an angioplasty balloon manufacturer and two in-state health care providers in Louisiana state court. With the consent of the in-state defendants, the manufacturer timely removed the case to federal court on the grounds that preemption gave rise to federal question jurisdiction. When plaintiffs moved to remand the case more than 30 days thereafter on the basis that complete diversity did not exist, the court held it was untimely and refused. The court also stated that in cases "in which Congress has so completely preempted a particular area, any civil complaint raising the select group of claims is necessarily federal in character ...".

Part II
Federal Cigarette Labeling and Advertising Act

The Federal Cigarette Labeling and Advertising Act (the "Act") requires that specific warnings be included on cigarette packages. Specifically, it requires all cigarettes manufactured, imported, or packaged for sale or distribution within the United States to bear the statement: "Warning: The Surgeon General has Determined That Cigarette Smoking Is Dangerous to Your Health."[5] With respect to preemption, the Act provides that no statement relating to smoking and health other than this statement shall be required on any cigarette packaging.[6] Moreover, no requirement or prohibition based on smoking and health shall be imposed under state law with respect to advertising or promotion of any cigarette the packages of which is in conformity to the requirements of the Act.[7]

Since its enactment, the courts have been divided as to the exact scope of the Act's preemption provision, especially with respect to what constitutes a "requirement or prohibition" of Section 1334(b) preempted by the Act. This question was finally addressed and clarified by the Supreme

Court in its decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992).

A. *Cipollone*

I n *Cipollone*, a smoker and his spouse sued a cigarette manufacturer after the smoker contracted lung cancer. The Court held the Act preempted state claims based on a failure to warn theory to the extent that those claims relied on alleged omissions or inclusions in the manufacturer's advertising or promotions. However, the Act did not preempt claims based on express warranty, intentional fraud or misrepresentation, or conspiracy.

In reaching this decision, the Court recognized that the preemptive scope of the Act is determined by the express language in its preemption provision. It reasoned that Congress' enactment of a provision expressly defining the preemptive scope of a statute implies that matters beyond its reach are not preempted. As such, the Act did not preempt state law claims against cigarette manufacturers and sellers in general. Rather, each claim must be considered separately.

Thus, the Court concluded that the central inquiry in determining the Act's preemptive scope with respect to state actions is whether the underlying legal duty upon which the state law claim arises satisfies the express terms in Section 1334(b). In applying this analysis, the court emphasized giving consideration to each phrase in Section 1334(b), as each phrase clarifies and limits its preemptive reach.

Section 1334(b) provides, "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to advertising or promotion of any cigarette the packages of which are labeled in conformity with the provisions of this chapter."[8] Thus, giving consideration to each phrase, the inquiry comes down to whether the state claim is predicated on a requirement, prohibition or duty (1) imposed by state law; (2) relating to advertising and promotion and (3) based on concerns for smoking and health.

B. Following *Cipollone* - Implications

1. Strict Liability and Negligence - Defective Design

The Supreme Court in *Cipollone* did not directly address whether claims of strict liability and negligence based on defective designs were preempted. However, the district court handling *Cipollone* held that such claims were not preempted. *Cipollone v. Liggett Group, Inc.*, 649 F.Supp. 664 (D.N.J. 1986); *See also Pennington v. Vistron Corp.*, 876 F.2d 414 (5th Cir. 1989). In reaching that conclusion, the district court reasoned that the duty underlying such claims was to prevent manufacturers and sellers from marketing cigarettes with manufacturing defects or to encourage them to use a safer alternative design for cigarettes. As such, this duty is connected with defendant's testing and research and unrelated to advertising and promotion.

As the Supreme Court in *Cipollone* did not overrule nor address the district court's ruling with respect to this issue and having repeatedly emphasized that the Act's preemptive scope reaches only those claims arising from requirements related to advertising and promotion, it appears that claims based on defective design which are unrelated to advertising would not be preempted. Subsequent to *Cipollone*, courts have followed this rationale and held that claims based on strict liability and negligence for defective design are not preempted. *Castano v. American Tobacco Co.*, 870 F.Supp. 1425 (E.D. La. 1994); *See also Grinnell v. American Tobacco Co.*, 883 S.W.2d 791 (Ct.App.Tex. 1994).

2. Failure to Warn

To establish liability for an alleged failure to warn, a claimant must show that a warning was necessary to make a product reasonably safe for its intended use and that such a warning was not

provided. In *Cipollone*, the Court held that to the extent claims based on the failure to warn rely on state law requirements or prohibitions related to advertising and promotion, they are preempted. Thus, where the claims are based on allegations that advertising or promotion of the product should contain additional, more clearly stated warnings, such claims are preempted. Following this rationale, the court in *Burton v. R.J. Reynolds Tobacco Co.*, 884 F.Supp. 1515 (D.Kan. 1995), similarly dismissed claims based on a failure to warn as being preempted.

However, the Court in *Cipollone* also held that to the extent that such claims rely solely on the manufacturer's testing or research practice or practices unrelated to
advertising or promotion, they are not preempted. In *Grinnell v. American Tobacco Co.*, 883 S.W.2d 791 (Ct.App.Tex. 1994), the court following the rationale in *Cipollone*, held that strict liability claims based on a failure to warn were not preempted, but rather preemption applied only to very limited classes of claims based on the failure to warn.

3. Breach of Express Warranty

To establish a claim for breach of express warranty, the claimant must establish that an affirmation of fact was made by the seller to the buyer which relates to the good and such representation became part of the basis of the bargain. In *Cipollone*, the Court held that claims based on breach of express warranty were not preempted. In reaching this decision, the Court reasoned that the requirement underlying an express warranty claim is not state imposed, but rather is imposed by the warrantor. As such, it is irrelevant that the warranty may be set forth in advertisements as opposed to a separate sheet of paper, as the duty underlying the express warranty claim is not imposed by state law. Subsequent to *Cipollone*, various courts have adopted this stance and held that breach of express warranty claims are not preempted. *Castano v American Tobacco Co.*, 870 F.Supp. 1425 (E.D. La. 1994); *See also Grinnell v. American Tobacco Co.*, 883 S.W.2d 791 (Ct.App.Tex. 1994).

4. Breach of Implied Warranty

Although *Cipollone* did not address claims based on breach of implied warranty, courts following *Cipollone* have held that such claims were not preempted. *Castano v. American Tobacco Co.*, 870 F.Supp. 1425 (E.D. La. 1994) held such claims were not preempted, the court reasoned that although such claims were predicated on a duty imposed by state law, it was not one based on advertising or promotion, but rather based on the defendant's manufacture and sale of cigarettes, regardless of whether the defendant advertise or promote its product. *See also Grinnell v. American Tobacco Co.*, 883 S.W.2d 791 (Ct.App.Tex. 1994).

5. Fraudulent Misrepresentation

With respect to claims of fraudulent misrepresentation, *Cipollone* held that claims based on allegations that the manufacturer, through their advertising, neutralized the effect of a federally-mandated warning requirement were preempted. In reaching such a conclusion, it reasoned that such claims are based on state law prohibitions against statements in promotional material and advertising which tend to minimize the risk of health hazards related to smoking.

However, the Court in *Cipollone* also held that claims of intentional fraud and misrepresentation are not preempted even if they arise from a state imposed requirement with respect to advertising or promotion, where the underlying duty upon which such claims are predicated is a duty not to deceive and not a duty based on smoking and health. The Court recognized that a state law prohibition of false statements does not create the diverse non-uniform sets of laws, a concern when Congress enacted the Act.

In accordance with *Cipollone*, *Castano v. American Tobacco Co.*, 870 F.Supp. 1425 (E.D. La. 1994) held that claims based on allegations of fraud and deceit were not preempted, as the duty upon which such claims were predicated was a duty not to deceive. There, the plaintiffs claimed that the defendant intentionally concealed information that nicotine was addictive. *See also Burton v. R.J. Reynolds Tobacco Co.*, 884 F.Supp. 1515 (D.Kan. 1995), and *Grinnell v. American Tobacco Co.*, 883 S.W.2d 791 (Ct.App.Tex. 1994), which held that claims based on misrepresentation and concealment were not preempted. Following this rationale, courts have found that claims of negligent misrepresentation are similarly not preempted as the duty underlying such a claim is also the duty not to deceive. *Castano v. American Tobacco Co.*, 870 F.Supp. 1425 (E.D.La. 1994).

6. Conspiracy to Misrepresent or Conceal Material Fact

With respect to claims based on a conspiracy to misrepresent or conceal, the Court held that the Act did not preempt such claims. It reasoned that the predicate duty underlying such claims was a duty not to conspire to commit fraud and as such was not a prohibition based on smoking and health. Adopting this rationale, *Burton v. R.J. Reynolds Tobacco Co.* held that claims of conspiracy to commit fraud were not preempted. *See also Grinnell v. American Tobacco Co.*, 883 S.W.2d 791 (Ct.App.Tex. 1994), where the court held that claims of civil conspiracy was not preempted.

7. Intentional Infliction of Emotional Distress

Following the reasoning in *Cipollone*, the court in *Castano v. American Tobacco Co.*, 870 F.Supp. 1425 (E.D.La. 1994), held that claims of intentional infliction of emotional distress were not preempted as such claims are predicated on a duty not to deceive, or not to act in an extreme or outrageous manner through continual deceitful conduct.

8. Violation of Consumer Protection Statute

Although *Cipollone* did not address claims based on violation of a state's consumer protection statute, courts following the inquiry adopted in *Cipollone* have held that such claims are not preempted. *Mangini v. R.J. Reynolds Tobacco Co.*, 875 P.2d 73 (Ca. 1994), held such claims were not preempted. It reasoned that the predicate duty underlying plaintiff's claim for violation of the California Consumer Protection Statute was a duty not to engage in unfair competition by advertising illegal conduct or encouraging others to violate the law and found the phrase "based on smoking and health" did not encompass the general duty not to assist or advertise illegal conduct. *See also Castano v. American Tobacco Co.*, 870 F.Supp. 1425 (E.D.La. 1994). *Burton v. R.J. Reynolds Tobacco Co.*, 884 F.Supp. 1515 (D.Kan. 1995), following the reasoning of *Cipollone*, held that claims based on violations of the Kansas Consumer Protection Act for deceptive advertising were not preempted as they were based on a duty not to deceive.

C. Summary

It appears that the preemptive scope of the Federal Cigarette Labeling and Advertising Act is limited to those claims whose underlying duty stems from a state-imposed requirement or prohibition regarding advertisement and promotion related to smoking and health. Thus, a federally-preempted claim must stem from requirements or prohibitions with respect to advertising or promotion, as opposed to requirements or prohibitions regarding research and development of safer products. Moreover, the claims sought to be preempted must relate to smoking and health. As such, claims predicated on a duty or requirements with other concerns in mind, such as that of preventing deceptive conduct or illegal activities, would fall outside the Act's preemptive reach. It appears that the Act's preemptive scope reaches primarily two types of claims: (1) claims of failure to warn predicated on

state-imposed requirements relating to advertisement and promotion and (2) claims of misrepresentation in the manufacturer or seller's advertising where the underlying concern is that for advertising and promotion which tends to minimize the health hazards associated with smoking and leaves intact a wide range of state civil claims and remedies. *See Allgood v. R.J. Reynolds Tobacco Co.*, 80 F.3d 168 (5th Cir. 1996).

Part III
Federal Food, Drug and Cosmetic Act

A. Prescription Drugs

The Federal Food, Drug and Cosmetic Act of 1938[9] regulates all aspects of pharmaceuticals. Under the Act, all drug manufacturers must obtain approval of the Food and Drug Administration (FDA) before distributing new prescription drugs based on a showing that the product is safe and effective.[10] The FDA must also approve the content and format of all package labeling and warnings accompanying prescription drugs. Finally, manufacturers are required to submit to the FDA results of testing and any reports of adverse drug reactions.

A failure to comply with the requirements of the Act may be deemed evidence of negligence in a product liability suit. For example, labeling of a drug contrary to the Act's requirements is misbranding and may constitute evidence of the inadequacy of a warning.[11]

The Federal Food, Drug and Cosmetic Act does not have an express preemption provision. Therefore, although drug manufacturers must obtain the FDA's approval to market prescription drugs, the vast majority of courts have found that product liability claims for prescription drugs are not preempted by the Act.[12] The courts have rejected preemption claims for design defect cases, as well as failure to warn claims, involving pharmaceuticals.[13]

The most recent Illinois case addressing preemption and prescription drugs is *Martin by Martin v. Ortho Pharmaceutical Corp.*, 169 Ill.2d 234, 661 N.E.2d 352 (1996). In that case, plaintiffs attempted to twist the preemption doctrine in their favor. They argued that the common law learned intermediary doctrine should be preempted by the FDA regulations concerning oral contraceptives since those regulations require that patients be fully informed of the benefits and risks of these drugs.[14] Under the Illinois learned intermediary doctrine, a manufacturer is merely required to provide warnings to the prescribing physician in order to fulfill its common law duty. The Illinois Supreme Court rejected plaintiff's preemption argument and followed the majority rule adopted by other states in the interpretation of this federal regulation. The Supreme Court concluded that no exception should be derived from the FDA regulation since prescribing physicians, and not drug manufacturers, are in the best position to provide direct warnings to patients.

B. Medical Devices

In its most recent opinion on a preemption issue, the United States Supreme Court on June 26, 1996 held that state court suits for defective products are not necessarily preempted by the Medical Device Amendments of 1976[15] to the Food and Drug Act.[16] *See Lohr v. Medtronic, Inc.*, Nos. 95-754 and 95-886, 116 S.Ct. 2240 (1996). In *Lohr*, the plaintiff sued a pacemaker manufacturer under theories of negligence, strict liability, and breach of warranty after her pacemaker failed resulting in her undergoing emergency surgery. The defendant had obtained summary judgment on the negligence and strict liability claims arguing that the claims were preempted by the Medical Device Amendments (MDA).[17] On review, the Supreme Court held, in a plurality opinion, that the MDA and its underlying regulations did not preempt any of plaintiff's claims under common law.

Prior to *Lohr*, federal circuit courts routinely granted preemption defenses to medical device manufacturers when sued under theories such as failure to warn, failure to test, manufacturing defect, design defect, and express and implied warranties.[18] Whether preemption was available depended upon the class of the medical device involved. The Medical Device Amendments categorize medical devices into three classes: Class I devices are those which present no unreasonable risk of illness or injury, such as tongue depressors or medical gowns, and are subject only to minimal regulation by general controls.[19] Devices that are potentially more harmful are Class II. These devices, such as tampons, may be marketed without advance approval although manufacturers are required to comply with federal performance regulations known as special controls.[20] Class III devices are those which 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 life.[21] Examples of such devices include pacemakers, soft contact lenses and prosthetic heart valves.

Actions involving Class III devices have been given the greatest latitude when preemption is considered. Before *Lohr*, federal appellate courts usually held that all state law causes of action which relate to the safety of these devices were preempted by the Medical Device Amendments.[22] Whether a preemption defense is available for a Class II device is dependant upon whether the FDA has issued specific requirements with respect to the manufacture and/or sale of that device.[23] Product liability claims for Class I devices have not been preempted.

The Supreme Court's decision in *Lohr* now creates serious questions as to what, if any, state law claims will be preempted by the MDA. The Supreme Court was specifically called upon to determine whether the MDA preempted negligence and strict liability claims for a product which was marketed and sold as "substantially equivalent" to pre-existing devices on the market.

First, the Supreme Court ruled that negligent design claims are not preempted by the MDA. The Court noted that §360k[24] provides no basis to support a complete preclusion of all common law causes of action. In reviewing the MDA's history, the Court observed:

> [N]owhere in the materials relating to the Act's history have we discovered a reference to a fear that product liability actions would hamper the development of the medical devices. To the extent that Congress was concerned about protecting the industry, that intent was manifested primarily through fewer substantive requirements under the Act, not the preemption provision; furthermore, any such concern was far outweighed by concerns about the primary issue motivating the MDA's enactment: the safety of those who use medical devices.[25]

The Court went on to note that the mere finding by the FDA that the subject product was substantially equivalent to pre-existing devices on the market, does not necessarily preempt a negligent design claim. The substantial equivalency examination by the FDA was intended to preserve the status quo with respect to the marketing of existing medical devices and their equivalents. This status quo included the possibility of a manufacturer defending itself against state law claims of negligent design. The Court concluded that the Act's history and Congressional intent did not provide support for the preemption of negligent design claims.

Second, the Supreme Court held that state law causes of action can be pursued if the alleged violation of common law duties are parallel with federal requirements. Specifically, the Court held that a plaintiff may bring a common law action against a device manufacturer for negligently failing to comply with duties "equal to, or substantially identical to, requirements imposed"[26] under federal law.

More specifically, the Court noted that although the Code of Federal Regulations set forth general requirements for labeling[27] and "Good Manufacturing Practices"[28] they will not preempt state common law actions for damages.[29] Common law actions for negligent manufacture or failure to warn do not

threaten these federal requirements. Unless a federal requirement is device specific, the general requirement will not preempt these actions.

In sharp contrast to prior federal appellate decisions, the Supreme Court's ruling in *Lohr* provides large avenues for the pursuit of state common law product liability actions against medical device manufacturers. In fact, the plurality opinion predicted:

> [G]iven the critical importance of device-specificity in our (and the FDA's) construction of §360k, it is apparent that few, if any, common-law duties have been preempted by this statute. It will be rare indeed for a court hearing a common-law cause of action to issue a decree that has "the effect of establishing a substantive requirement for a specific device." 21 CFR §808.1(d)(6)(ii)(1995).[30]

Thus, in each case, the specific medical device will need to be evaluated to determine if federal regulations exist concerning it, the extent of its FDA approval, and whether a potential for preemption of a state common law action still exists.[31]

The Illinois appellate courts have considered the preemption defense in two medical device cases. Most recently in *Haudrich v. Howmedica, Inc.*, 169 Ill.2d 525, 662 N.E.2d 1248 (1996), the product defendant argued that Section 360(k) of the MDA deprived the state court of jurisdiction to render a judgment for damages. Upon review, the Supreme Court held that the issue of preemption is not jurisdictional but is in the nature of an "affirmative defense." Since preemption was not raised below, the court concluded that the preemption argument was waived on appeal.[32] In *Kus v. Sherman Hosp.*, 268 Ill.App.3d 771, 644 N.E.2d 1214 (1995), the Illinois Appellate Court for the Second District held that MDA does not preempt claims under Illinois law relating to the lack of informed consent for intraocular lens implantations since those claims do not relate to the safety or efficacy of the lenses.

Arguably, the defense of preemption for product liability claims involving prescription drugs and medical devices was severely eroded by the Supreme Court's decision in *Lohr*. The Supreme Court found that the MDA's preemption provision is highly ambiguous and that the Act lacks clear Congressional command for preemption. Without such clear command, state actions will only be preempted when there are specific federal requirements applicable to a particular device which are divergent from or conflict with the federal requirement. Defining the parameters of preemption under the MDA will be litigated for many years.

Part IV
Childhood Vaccines

In a very real sense, the National Childhood Vaccine Injury Act[33] is not a preemption statute at all. Passed in 1986, but effective October 1, 1988, the NCVIA establishes a preliminary step through which product liability claimants must go before they are allowed to file a civil tort action in either state of federal court. The statute provides certain different procedures for actions which were already pending in October 1988 or with respect to injuries sustained before October 1988, but given the passage of time, this section will only address the requirements for injuries and actions filed after October 1988.

The statute was passed in response to a perceived crisis with respect to various childhood vaccines, and the potential effect of product liability claims upon their availability. Many governmental entities, and most schools, require certain childhood vaccines, such as DPT, measles, mumps and rubella, as a predicate to allowing children in school. The basis of these requirements is the benefit to society from the decrease of incidents of certain serious diseases in the general population. However, it is scientifically known that a relatively small percentage of individuals who receive these vaccines have

serious but unavoidable adverse consequences. Fearing for the availability of these vaccines due to manufacturers refusing to produce them as a result of the threat of product liability claims, and believing that the benefits to society of the availability of these vaccines outweighed the possible losses to victims of the vaccines, Congress passed the NCVIA as an accommodation between these conflicting principles. The trade-off involved providing a no-fault-type of recovery to victims of certain identified vaccines established by a Vaccine Injury Table.[34]

Section 300aa-11(2) provides that no action may be brought in a state or federal court unless a petition has been filed under the NCVIA. The statute itself provides that it only applies to a person who has sustained a vaccine-related injury or death and is qualified to file a petition for compensation under the program.[35] The statute, therefore, applies only to a limited subset of vaccines and a limited subset of individual claimants.

The statute establishes a detailed set of procedures to be followed in determining whether the claimant is entitled to compensation under the Act and, if so, how much. The details of this procedure are beyond the scope of this section. However, exclusive jurisdiction of these proceedings is given by Section 300aa-12 to the United States Claims Court, dubbed by at least one court as the "Vaccine Court."[36]

Under several circumstances, a claimant may still bring a civil action in state or federal court, but these primarily involve the inadequacy of the results in the NCVIA petition proceeding, either because of the judgment awarded or the time it takes to get the judgment. Specifically, Section 300aa-21(a) permits the claimant to reject the judgment of the Vaccine Court and to file a civil action. Rejection must be made within 90 days of the Vaccine Court's final judgment. If not filed within 90 days, or if the person accepts the judgment of the Vaccine Court, a civil action is barred.

The second ground for avoiding the effect of the mandatory Vaccine Court petition is a delay by the Vaccine Court in reaching its decision. Section 300aa-21(b) provides that the special master must make a decision within a specified time, and that the Vaccine Court must enter judgment within a specified time. If those limits are not met, the petitioner may withdraw the petition, and then file a civil action in state or federal court.

The statute does, however, preempt certain common law doctrines as to any civil actions which are eventually filed. It seems that the purpose of these statutes is to encourage the use of the no-fault Vaccine Court forum, and acceptance of its judgments. Section 300aa-22, entitled "Standards of Responsibility," applies to all civil actions for vaccine-related injury or death. It provides that no vaccine manufacturer shall be liable if side effects were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings; creates a presumption that the vaccine was accompanied by proper directions and warnings if it complied with FDA requirements unless the plaintiffs shows by clear and convincing evidence that the manufacturer failed to exercise due care or that the manufacturer engaged in fraudulent or intentional conduct in withholding information pertaining to the safety and efficacy of the vaccine. (Such conduct might also subject it to punitive damages under Section 300aa-23(d).) The Standards of Responsibility provisions also provide that there is no duty to give warning directly to the injured party or the injured party's legal representative. 42 U.S.C. §300aa-22(c).

Section 300aa-23, in addition to limiting the occasions on which punitive damages can be awarded, also sets up a bifurcated trial procedure, mandated for all civil actions against vaccine manufacturers. The bifurcation involves a first stage in which liability alone is determined, a second stage in which compensatory damages alone are considered, and a third stage in which, if applicable, punitive damages alone are considered.

As this discussion discloses, the statute is very detailed in many respects. Despite the fact that it has been in effect for eight years, there is very little case law construing it in the context of civil actions filed after rejection of the Vaccine Court's judgment. One such case is *Schafer v. American Cyanamid*

Co., 20 F.3d 1 (1st Cir. 1994). That court notes that the Act requires that the person injured directly by a vaccine *first* bring a Vaccine Court proceeding, and then gives that person the choice to either accept or reject the Vaccine Court's award.

The more interesting part of the case, however, is the fact that the claim before the court was brought not by the injured person (Lenita Schafer), but by her family members. Lenita herself brought a claim before the Vaccine Court for her own injuries, and accepted the judgment award entered by the Vaccine Court in her favor. Her family members, however, had withdrawn their petition, with permission of the Vaccine Court, and instead brought the civil lawsuit for their own loss of consortium injuries. The First Circuit held that the acceptance by Lenita of the Vaccine Court judgement for her own award did not bar the separate civil action, if otherwise recognized by state law, by her family members. Preemption, therefore, was inapplicable by the terms of the statute itself.

The applicability of the NCVIA is especially important for vaccine manufacturers because earlier courts had ruled that other statutes did not preempt state common law tort actions. *See e.g. Weddel v. Secretary of DHHS*, 23 F.3d 388 (Fed.Cir. 1994); *Martinkovic v. Wyeth Laboratories, Inc.*, 669 F.Supp. 212 (N.D.Ill. 1987) (holding that neither the Public Health Service Act, 42 U.S.C. §262, *et seq.*, nor the FDA Act, 21 U.S.C. §301, *et seq.* preempted tort remedies in the vaccine arena).

Part V
Federal Insecticide, Fungicide and Rodenticide Act

The operative preemption language in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) provides: "Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter."[37] Claims which are potentially preempted under FIFRA typically fall into two different categories. The first are claims made by farmers who argue that crops have been damaged, or that a yield has not been as big as it should have been, because of improper representations, instructions, warnings, or warranties about the qualities of the product. The second category are personal injury claims based upon exposure to the product.

Interestingly, the most significant and influential case in this area was not a FIFRA case at all, but instead involved the Public Health Cigarette Smoking Act, 15 U.S.C. §§1331-1340. That case is *Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 120 L.Ed.2d 407, 112 S.Ct. 2608 (1992), (discussed in Part II). Every federal appellate court which has considered the question of FIFRA preemption since *Cipollone* has recognized the similarity between the language considered by the Court in *Cipollone* and the FIFRA preemptive language. Each court has construed FIFRA as preempting any claim seeking tort recovery based upon a failure to warn or improper labeling.

Typical of these cases is *Shaw v. Dow Brands, Inc.*, 994 F.2d 364 (7th Cir. 1993). The plaintiff claimed that his lungs were permanently damaged when he tried to clean his bathroom using a mildew stain remover manufactured by Dow. The court ruled that Shaw's claim for failure to warn, based upon any defect in the labels or warnings of the product, was preempted by FIFRA. It specifically recognized that state common law findings would be included as a "requirement" that might be contrary to the labeling and packaging requirements established by federal law. Similar rulings, based upon similar reasoning, have been made by every post-*Cipollone* federal appellate court to consider the question. *King v. E.I. Dupont De Nemours & Co.*, 996 F.2d 1346 (1st Cir. 1993) (a failure to warn and to instruct claim arising out of bodily injury allegedly caused by exposure to herbicides); *Worm v. American Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993) (rejecting a claim brought by farmers for alleged injury to corn corp, but noting that claims for negligent testing, manufacturing and formulating are <u>not</u> preempted); *MacDonald v. Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994) (a personal injury claim based

upon failure to warn); *Bice v. Leslie's Poolmart, Inc.*, 39 F.3d 887 (8th Cir. 1994) (preempting a common law claim for failure to warn of the hazardous nature of swimming pool supplies); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555 (9th Cir. 1995) (rejecting claims by farmers for crop damage based upon inadequate warnings, negligent testing to the extent that it involved a claim of inadequate product label, and claims for breach of warranty, and noting "the rigorous label-approval process under FIFRA," even though FIFRA does not prescribe the exact contents of labels. The court noted that where warranties are made outside of the content of the actual labels, warranty arguments based upon statements made in the labels are preempted); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir. 1993) (finding preemption of a landowner's claim against a chemical manufacturer alleging failure to warn of potential environmental risks); and *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993) (finding preemption in a bodily injury claim by a worker exposed to the defendant's product based upon inadequate labeling for the alleged dangers arising out of exposure. The court rejected plaintiff's attempt to avoid preemption by arguing that point of sale signs, consumer notices, and other informational materials did not contain appropriate warnings, because such claims implied that the language of the labeling and packaging failed to warn the user).

State courts have been less uniform in their preemption analysis. Iowa (*Schuver v. E.I. Dupont De Nemours & Co.*, 546 N.W.2d 610 (Iowa 1996)), Washington (*Goodwin v. Bacon*, 896 P.2d 673 (Wash. 1995)), and Kansas (*Jenkins v. Amchem Prods., Inc.*, 256 Kan. 602, 886 P.2d 869 (1994)), have all held that FIFRA preempts claims brought by farmers for either bodily injury or crop loss. By contrast, the Wisconsin Supreme Court in *Gorton v. American Cyanamid Co.*, 194 Wis.2d 203, 533 N.W.2d 746 (1995), held that there was no preemption, at least where the claims were based upon promotional materials, advertisements, technical reports, and oral statements.

The distinction, between words on labels, and words in other communications, has frequently been used by plaintiffs in an attempt to avoid preemption. While some courts, such as *Gorton* and the Illinois Fourth District in *Malone v. American Cyanamid Co.*, 271 Ill.App.3d 843, 649 N.E.2d 493 (4th Dist. 1995),[38] have accepted this distinction, most courts have rejected it. The most recent discussion of this subject is in *Kuiper v. American Cyanamid Co.*, 913 F.Supp. 1236 (E.D.Wis. 1996). *Kuiper* is notable since it purports to be applying Wisconsin law, yet expressly disagrees with the earlier Wisconsin Supreme Court decision in *Gorton*, noting that it is not bound by that Court's decision. Defendants in Wisconsin, therefore, should seek to have a federal court determination, rather than a state court determination, of their claims. The *Kuiper* court expressly rejected an attempted distinction by the plaintiffs between failure to warn claims based upon labeling and packaging on one hand, and misrepresentation claims based upon false statement in advertising and promotional materials.

The impact of the recent United States Supreme Court decision in *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240 (1996) to these doctrines is uncertain. At the time of this writing, the plaintiff farmers in the Iowa *Schuver* case have filed a petition for *certiorari* to the United States Supreme Court, based upon *Medtronic*. It may be significant to note, however, that one of the bases for the plurality opinion in *Medtronic* was the lack of detailed evaluation of medical devices under the Medical Device Act.[39] By contrast, several of the cases in the FIFRA preemption area have noted the very detailed scheme for regulating the content of labels in this area.[40] Thus, pending ultimate United States Supreme Court determination of this issue, a legitimate argument can be made that the *Medtronic* rationale does not apply to FIFRA preemption claims.

Part VI
The Federal Hazardous Substances Act

In 1960, Congress enacted the Federal Hazardous Substances Act (FHSA),[41] in order to "provide nationally uniform labeling requirements for adequate cautionary labeling of packages of hazardous substances which are sold in interstate commerce and are intended or suitable for household use."[42]

As enacted, it did not contain a specific preemption provision. "However, when the Act was amended in 1966, the legislative history discussed the impracticality of having the states produce potentially fifty different labels for a particular hazardous substance. Congress recommended, 'a limited preemption amendment which would encourage and permit states to adopt requirements identical with the federal requirements for substances subject to the federal act, and to enforce them to complement federal enforcement ...'"[43]

The 1966 amendments to the FHSA added a qualified preemptive provision which provides:

> [I]f a hazardous substance or its packaging is subject to a cautionary labeling requirement under Section 2(p) or 3(b) [subsection (p) of this section or Section 1262(b) of this title] designed to protect against a risk of illness or injury associated with the substance, no state or political subdivision of a state may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and design to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under Section 2(p) or 3(b) [subsection (p) of this section or Section 1262(b) of this title].[44]

The Ninth Circuit Court of Appeals, in *Chemical Specialties Manufacturers' Assn., Inc. v. Allenby*, 958 F.2d 941 (9th Cir. 1992), reviewed the purpose for enacting the FHSA's preemption provisions by noting that although a national safety standard would ease the burden of product manufacturers from complying with 51 separate regulatory schemes set forth by each state and the federal government, such a standard would also take the police powers away from the states who best know how to serve the interests of their citizens. "The preemption clause in [the] FHSA balances these competing concerns by leaving cautionary labeling requirements to the federal government while allowing states to regulate the sale and use of hazardous chemicals." *Allenby*, 958 F.2d at 950.

In *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992), the Court stated that "[c]onsideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by ... Federal Act unless that [is] the clear and manifest purpose of Congress.'" *Busch v. Graphic Color Corp.*, 169 Ill.2d 325, 334, 662 N.E.2d 397, 214 Ill.Dec. 831, 836-837 (1996), *quoting Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608 (1992).

The most current and thorough discussion of FHSA as it applies in Illinois is the recent Illinois Supreme Court opinion of *Busch v. Graphic Color Corp.*, 169 Ill.2d 325, 662 N.E.2d 397, 214 Ill.Dec. 831 (1996). The Court concluded that Congress intended to preempt all non-identical state legislation setting forth cautionary labeling requirements addressing the same risk of illness or injury as the FHSA.[45] Consistent with this Congressional intent, the FHSA has been held to preempt and preclude a plaintiff from bringing a common law "warning" claim which seeks to impose requirements different from those imposed by the Act.

In *Busch*, the Illinois Supreme Court held that a common law action against a paint thinner supplier was preempted. The claim was based upon a failure to warn of the dangers of inhaling the paint thinner. The toxic ingredient was methylene chloride, a hazardous substance which fell within the scope of the FHSA. The paint thinner was labeled in accordance with the recommendations of the Consumer Product Safety Commission (CPSC), the federal agency responsible for administering the FHSA. In looking at the recommended label of the CPSC, the Court noted that nothing more is required of labels under the FHSA other than what is stated in the CPSC example. Consequently, the plaintiff's common law tort action based upon failure to warn was preempted by the FHSA because

the plaintiff was seeking to impose additional labeling requirements which were not required by the FHSA.

The CPSC has detailed labeling examples for many substances which fall within the scope of the FHSA. These labeling examples are available to the public. In many instances, manufacturers prepare labels which are identical to these CPSC examples. The CPSC example labels usually address the content of warnings rather than the design of the labels.

Other federal and state courts have held that state law failure to warn and failure to provide adequate warning claims are preempted unless the plaintiff pleads that the defendant failed to follow the federal labeling regulations contained within the FHSA. *Moss v. Parks Corp.*, 985 F.2d. 736, 740-741 (4th Cir. 1993) (state law tort action based on failure to warn theory seeking to impose labeling requirements different from those of the FHSA are preempted, however, consumers could bring state law tort actions based on violations of the federal labeling requirements.) *DeHaan v. Wink Products Co.*, WL 24322 at 6 (N.D.Ill. 1994) (an Illinois claim that a manufacturer's warning, complying with the FHSA's requirement, was inadequate, was held preempted.) *Salazer v. Whink Products Co.*, 881 P.2d 431 (Colo. 1994) (affirmed summary judgment holding the FHSA preempted a common law duty to warn.)

A plaintiff's common law tort action for damages is not preempted where he charges a manufacturer with violations of the FHSA labeling requirements and in the course of doing so does not seek to compel more stringent labeling demands on the manufacturer.[46] However, summary judgment is properly granted in favor of defendant where the court determines that the label complied with federal law.[47].

"Since the Supreme Court's decision in *Cipollone*, courts have essentially used a two-prong analysis to determine whether state claims are preempted by ... federal labeling requirement statutes, including the FHSA." *Wallace v. Parks Corp.*, 629 N.Y.S.2d 570, 212 A.D.2d 132, 137-138 (1995). This two-prong preemption analysis begins first with determining whether a plaintiff's claim is based upon a requirement imposed by the state and, secondly, whether the claim relates to labeling or packaging.[48]

In applying the two-prong test, the *Wallace* court held that the failure to warn claim and the implied warranty claim based upon labeling were barred. However, the express warranty claim was not barred because the express warranty did not arise from any requirement of state law, but from a promise voluntarily made by the manufacturer. Claims based upon the design of the container and manufacture of the fuel also were not preempted because these claims did seek to impose other or different labeling requirements than those imposed by the FHSA.

There are no Illinois cases which address whether the FHSA preempts design or express warranty claims, but it seems unlikely that an Illinois court would expand the qualified preemption provisions of the FHSA to do so.

Part VII
The National Manufactured Housing and Safety Standards Act

The National Manufactured Housing Construction Safety Standards Act of 1974 (Manufactured Home Act) was enacted to "reduce the number of personal injuries and deaths and the amount of insurance costs and property damage resulting from manufactured home accidents and to improve the quality and durability of manufactured homes."[49] The goal of the statute was to provide adequate and safe housing at a reasonable cost.

The Manufactured Home Act contains two preemption provisions. The first, §5403(d) states:

> Whenever a Federal manufactured home construction and safety standard established under this chapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any manufactured home covered, any standard regarding construction or safety applicable to the same aspect of performance of such manufactured home which is not identical to the Federal Manufactured home construction and safety standard.[50]

The second, §5409(c) mandates that compliance with these standards will not effect common law, specifically stating:

> Compliance with any federal manufactured home construction or safety standard issues under this chapter does not exempt any person from liability under common law.[51]

In addition, HUD regulations promulgated pursuant to the Act contain a similar preemptive statement mandating that no court, state or locality may establish or enforce any rule or regulation or take any action that stands as an obstacle to accomplishment and execution of the full purposes and objectives of Congress.[52]

The preemptive provisions of the Manufactured Home Act have been subject to conflicting interpretations. *Shorter v. Champion Home Builders Co.*, 776 F.Supp. 333 (N.D.Ohio 1991), held that a state common law personal injury claim based on dangerous levels of formaldehyde in a mobile home was not preempted because no evidence in the legislative history of the Act would suggest that a state law claim would frustrate the intent of Congress in reducing personal injuries in mobile homes. The two preemption provisions must be read together. The first preemption clause prohibits state "standards" which were interpreted to mean legislative or administrative standards while the second clearly leaves the common law unaffected. *Mizner v. North River Homes, Inc.*, 913 S.W.2d 23 (Mo. 1995).

Other courts have held that common law claims against a manufacturer are preempted. For example, in *MacMillan v. Redman Homes, Inc.*, 818 S.W.2d 87 (Tx.Ct.App. 1992), the Texas Court of Appeals held that state common law claims based on formaldehyde standards other than those promulgated by the Department of Housing & Urban Development are preempted, but claims could be brought for violation of these federal standards. The *MacMillan* court reconciled the two preemption provisions to mean that state courts can litigate safety issues not covered by federal standards, and that compliance with federal law does not shield a defendant from suits concerning matters not covered by federal law.[53]

State indoor air quality standards for formaldehyde in new mobile homes were the subject of a declaratory judgment action in *Liberty Homes, Inc. v. Department of Industry, Labor & Human Relations*, 125 Wis.2d 492, 374 N.W.2d 142 (1985), *affirmed*, 136 Wis.2d 368, 401 N.W.2d 805 (1987). The standards at issue predated the adoption of the HUD standards and they were different from the federal standards. The Court of Appeals held that federal regulation preempted the state rules from and after the effective date of the federal regulation.

Municipalities also sometimes seek to restrict or prohibit the location of mobile homes within its boundaries by enforcing building codes which manufactured or mobile homes cannot meet. The Manufactured Home Act precludes governmental bodies from imposing construction and safety standards upon mobile homes that differ in any respect from those developed by the Department of Housing and Urban Development. *Scurlock v. City of Lynn Haven, Fla.*, 858 F.2d 1521, 1524 (11 Cir. Fla. 1988).

Similarly, the Court of Appeals of Ohio, held that the Manufactured Home Act preempted state and local regulations of mobile homes or manufactured homes with respect to safety and construction,

while leaving land use or zoning aspects to the state and local governments. *Village of Moscow v. Skeene*, 65 Ohio App.3d 785, 789, 585 N.E.2d 493 (Ohio Ct.App. 1989). *See also Grant v. County of Seminole, Fla.*, 817 F.2d 731, 736 (11th Cir. 1987); *Pacific Gas & Electronic Co. v. State Energy Resources Comm.*, 461 U.S. 190, 204-16, 103 S.Ct. 1713, 1722-1728, 75 L.Ed.2d 752 (1983).

Part VIII
Motor Vehicles

In 1966, Congress enacted The National Traffic and Motor Vehicle Safety Act (Safety Act)[54] "to reduce traffic accidents and deaths and injuries resulting from traffic accidents"[55] and to ensure uniformity among automobile safety standards.[56] The Safety Act directs the Secretary of Transportation to prescribe "practicable" motor vehicle safety standards,[57] which define a "minimum standard for motor vehicle performance."[58]

The Safety Act contains two provisions relevant to preemption. The first is the preemption clause which reads:

> When a motor vehicle safety standard is in effect under this chapter, a State or a political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter.[59]

The other applicable section in the Safety Act is the savings clause which states, "Compliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law."[60]

A curious patchwork of decisions has made the task of extracting a consensus or predicting future outcomes in this area difficult. Nonetheless, this section will provide an overview of the history and status of federal preemption in the motor vehicle arena, using airbag claims as an illustration. Cases involving the installation of airbags[61] offer examples of how the preemption and savings clauses of the Safety Act can either preempt or preserve a state law claim, depending on court interpretation. Further, because there is no Illinois case law in this area, the newest Illinois Supreme Court's federal preemption pronouncement and its probable consequence in the motor vehicle area will be discussed.

Between 1973 and 1986, Standard 208[62] gave a manufacturer three options for protecting front-seat automobile occupants, compliance with any one of which would satisfy the federal standard.[63] A plaintiff in a typical airbag case alleges that the automobile manufacturer's failure to install an airbag rendered the vehicle defective in design.[64] The car maker responds that the vehicle complies with Federal Motor Vehicle Safety Standard 208 (which covers occupant crash protection) and, therefore, §30103(b) of the Safety Act preempts the claim. The car makers argue that under Standard 208 they consciously chose to install manual seat belts rather than airbags. It follows, contend the manufacturers, that recovery on a "no airbag" claim is prohibited by Standard 208. Otherwise, a state court action would effectively remove the element of choice explicitly provided in Standard 208 and subvert the legislative purpose of offering manufacturers the flexibility to choose among alternatives. The plaintiff's counter argument is the savings clause of the Safety Act expressly preserves common law tort claims.[65]

Prior to the United States Supreme Court's 1992 decision in *Cipollone v. Liggett Group, Inc.,*[66] automobile manufacturers successfully relied upon implied conflict preemption to defend product liability claims.[67] These defendants argued that an award of damages in a common law action has the same regulatory effect as an affirmative legislative enactment and thus any claim that could potentially impose restrictions not identical to those existing in federal law must be preempted. By

acknowledging that the savings clause explicitly preserved liability under common law while the preemption clause was silent on the issue, most courts failed to find express preemption.[68] Instead, implied preemption was found as a result of the inherent conflict between the options of Standard 208 and the implications of a common law judgment. These courts reasoned that common law tort actions would interfere with and frustrate the methods by which the federal regulations sought to accomplish the legislature's goal of uniformity.[69] Thus, the pre-*Cipollone* era was a friendly one for car makers in that most courts, including the U.S. Court of Appeals for the First, Third, Tenth, and Eleventh Circuits, used implied conflict preemption to halt "no airbag" common law tort claims.[70]

At first glance, *Cipollone* seemed to suggest that when Congress had enacted a provision in a statute defining preemptive reach, an implied preemption inquiry was improper.[71] The Court apparently reasoned a preemption clause constituted a "reliable indicium of congressional intent with respect to state authority"[72] and prevented a court from looking beyond the statute itself to determine whether a claim was preempted. As the Safety Act contained such an express preemption provision, and most courts at that point had ruled that the text of the statute, with its ambiguity between the savings and preemption clauses, precluded express preemption, commentators initially viewed *Cipollone* as sounding a death knell for the preemption defense in "no airbag" claims.[73] However, decisions in the immediate wake of *Cipollone* were not nearly conclusive. Courts continued to rule consistently against *express* preemption, but exhibited no such consensus with regard to the viability of the *implied* preemption defense.[74]

Three years later, in *Freightliner Corp. v. Myrick*,[75] the Supreme Court attempted to reduce this confusion by emphasizing that *Cipollone* did not foreclose implied preemption inquiry.[76] However, this clarification did not go far in alleviating the ambiguity. By the time *Myrick* reached the Supreme Court in 1995, many courts had begun to hold that "no airbag" claims were *expressly* preempted by §30103(b) of the Safety Act, perhaps in an effort to find preemption while circumventing the ostensible holding of *Cipollone*.[77] These courts found no conflict between the preemption and savings clauses in the Safety Act, narrowly construing the savings clause to preserve only matters not covered by the federal standards.[78]

The most recent trend in the motor vehicle context of federal preemption represents yet a third interpretation of the Safety Act. Rather than finding either express or implied preemption, courts recently have ruled that the Safety Act does not preempt such claims at all.[79] These courts interpret the savings clause broadly, holding that it preserves common law actions in "no airbag" claims.[80]

The above obscurity is further compounded for Illinois lawyers because no state or federal court in Illinois has addressed federal preemption in the motor vehicle context. However, the Illinois Supreme Court's recent interpretation of federal preemption with regard to hazardous substances offers some insight, albeit limited, as to how it might rule in a motor vehicle case.[81]

I n *Busch v. Color Graphic Corp.*,[82] (also discussed in Part VI) the Illinois Supreme Court held that the Federal Hazardous Substances Act (FHSA) preempted a failure-to-warn claim against a manufacturer of paint stripper. Because federal preemption is largely a matter of specific statutory interpretation, blind utilization of this decision as a tool to predict an outcome in the motor vehicle context would be unwise. Moreover, although the preemption clause of the FHSA is similar to that of the Safety Act, the FHSA does not contain a savings clause so one must be cautious in applying the holding in *Busch* to the motor vehicle context. Nonetheless, two principles from *Busch* are at least worth noting.

First, the Court stated at the outset of its analysis that in addressing the preemptive scope of the FHSA, it was bound by the decisions of the federal courts.[83] Given the lack of consensus in the federal courts regarding the preemptive scope of the Safety Act, this principle does not assist in the motor vehicle context at present. However, assuming a motor vehicle preemption case makes its way to the

Seventh Circuit, the Court's decision in that case will go a long way toward predicting the doctrine's fate in Illinois.

Second, the Court in *Busch* concluded that common law tort claims had the same effect as "requirements" for the purposes of FHSA preemption.[84] The Court cited *Cipollone* for the proposition that state regulation can be as effectively exerted through an award of damages in a common law action as through some form of positive legislative enactment.[85] This principle, because it is not statute-specific, is directly applicable to the motor vehicle context and seems to eliminate one major hurdle for a defendant invoking the federal preemption defense.

The livelihood of the federal preemption defense with respect to claims involving motor vehicles is unclear. Until a federal appeals court delineates the proper post-*Cipollone* and post-*Myrick* interpretation of the Safety Act, outcomes will depend largely on the views of a particular court.

Part IX
Federal Boat Safety Act

Unlike the Vehicle Safety Act, courts have uniformly interpreted the preemptive scope of the Federal Boat Safety Act (FBSA).[86] This Act gives the Secretary of Transportation authority to prescribe regulations which establish "minimum safety standards for recreational vessels and associated equipment."[87] The Secretary has delegated this power to the United States Coast Guard.[88]

The guiding principle with regard to federal preemption under the FBSA is the distinction between claims asserting liability for defectively designed products that are actually installed, and those claiming liability resulting from a failure to install. As discussed below, only the latter claims are preempted by the FBSA.

The FBSA contains two provisions relevant to preemption. The first is entitled "Federal preemption" and provides:

> Unless permitted by the Secretary under section 4305 of this title, a State or political subdivision of a State may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment (except insofar as the State or political subdivision may, in the absence of the Secretary's disapproval, regulate the carrying or use of marine safety articles to meet uniquely hazardous conditions or circumstances within the State) that is not identical to a regulation prescribed under section 4302 of this title.[89]

The FBSA also contains a savings clause: "Compliance with this chapter or regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under State law."[90]

The vast majority of claims litigated in this context involve propeller guards.[91] Plaintiffs typically allege that the design of a boat motor is defective or unreasonably dangerous because the propeller is not surrounded by a guard.[92] With only one exception,[93] courts have consistently held that these claims are preempted by the FBSA.[94] The only federal appellate court to address the issue, the U.S. Court of Appeals for the Eighth Circuit, recently ruled likewise.[95] The one Illinois case in this area, *Farner v. Brunswick Corp.*,[96] is in accord.

Courts typically conduct the following analysis to arrive at their conclusion that claims premising liability on a failure to install propeller guards are preempted by the FBSA. First, judges note that the Coast Guard has specifically rejected proposed regulations requiring the use of propeller guards.[97] In 1990, the Coast Guard adopted the recommendation of the National Boating Safety Advisory Council that the "U.S. Coast Guard should take no regulatory action to require propeller guards,"[98] and the

official position that "available propeller guard accident data do not support imposition of a regulation requiring propeller guards on motorboats."[99] Courts give this decision not to regulate the same preemptive force as a decision to regulate.[100]

Turning next to the issue whether common law judgments constitute "laws or regulations" for preemption purposes, courts cite *Cipollone* for the proposition that state regulation can be as effectively exerted through an award of damages as through some form of preventive relief.[101] As this "regulation" via common law claims would not be identical to the Coast Guard regulatory position, the FBSA's preemption clause precludes them.[102]

The savings clause does not alter this analysis. In interpreting the savings clause, courts hold that it preserves only claims based on a manufacturer's installation of a defective or unreasonably dangerous propeller guard.[103] Ruling otherwise, courts reason, would allow the savings clause to supersede the specific substantive preemption provision.[104]

The federal preemption defense under the FBSA is a powerful tool to halt a claim alleging liability for a failure to install safety devices which the Coast Guard has determined are not mandated. However, the federal preemption defense does not apply to claims involving defective products actually installed.[105]

Part X
Flammable Fabric Act

The Flammable F a b r i c Act (the "Act") provides that whenever a federal flammability standard or regulation for a fabric, related material or product is in effect, a state cannot establish a standard or regulation for the same unless that standard or regulation is identical to the federal standard or regulation.[106] The exception is where the state standard or regulation provides a higher degree of protection for the consumer from the risk of fire due to such fabric.[107]

Many courts have held the Act does not preclude state courts from recognizing civil remedies based on standards or regulations different from federal standards or regulations, as the Act only provides for injunctive relief, seizure of material and criminal penalties as forms of remedy but did not expressly preclude states from developing other forms of remedy. *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025 (1st Cir. 1973). Thus, the Act does not preclude actions under a theory of strict liability for injuries resulting from burning clothing, even though such an action ultimately requires the jury to determine the appropriate safety standard, i.e., whether the fabric was sold in "a defective condition unreasonably dangerous to the public." *Raymond*, *supra*.

Moreover, the courts have acknowledged that Congress' intent in promulgating the Act was to increase protection for consumers. The Act created an avenue whereby the Secretary of Commerce may continually update flammability standards to accommodate new technologies and developments. Thus, in determining the Act's preemptive scope, the courts felt that Congress' concern for the plight of burn victims should be taken into consideration and as such, a strict liability standard of unreasonably dangerous was not "inconsistent" with the Act and its purposes. *Raymond*, *supra*.

Following this rationale, a number of courts have held that compliance with federal standards and regulations is not conclusive as a measure of defectiveness or unreasonable danger, rather it simply serves as evidence that the product is not defective. *Simien v. S.S. Kresge Co.*, 566 F.2d. 551 (5th Cir. 1978); *LaGorga v. Kroger Co.*, 275 F.Supp. 373 (W.D. Pa 1967), *affirmed*, 407 F.2d 671 (3d Cir. 1969); *Brech v. J.C. Penny Co., Inc.*, 698 F.2d 332 (8th Cir. 1983); *Raymond*, *supra*. Thus, even if the facts establish that a fabric meets and far exceeds the federal standard, a fabric may nonetheless be unreasonably dangerous for normal use; and a jury may consider additional evidence on the issue, even including the reliability of the flammability tests under the Act. *Howard v. McCrory Corp.*, 601 F.2d 133 (4th Cir. 1979). However, where the evidence establishes that the flammability

characteristics of the fabric meet the requirements of the Act, a court may properly refuse to give an instruction that the fabric is unreasonably dangerous. *Bellote v. Zayre Corp.*, 531 F.2d 1100 (1st Cir. 1979).

A survey of case law reveals that the Flammable Fabric Act is generally construed as not having preemptive effect. However, *Upholstered Furniture Action Council v. California Bureau of Home Furnishings*, 415 F.Supp. 63 (E.D. 1976), emphasized Congress' concern for nonregulation of industry. Regardless, the general consensus appears to be that the Flammable Fabric Act's preemptive role in civil litigation is limited, as the Act expressly authorizes states to impose more protective flammability standards and regulations in Section 1203(b). Also, it is uncertain whether an action based on state legislation which provides remedies similar to those provided by the Act, such as injunctive relief and criminal penalties, would be preempted as this issue has not come before any court.

Part XI
Conclusion

The field of product liability continues to be a fertile area of litigation. In recent years, federal preemption has developed into a formidable defense when appropriate. When considering a preemption defense for clients whose products are regulated by the federal government, defense counsel will want to research not only federal statutes but also regulations promulgated by various agencies. When applicable, summary judgment or dismissal is an appropriate remedy to dispose of an entire case or certain specific allegations of a defect.

Endnotes

[1] 735 ILCS 5/2-2103 provides that in a product liability action, the product or product components shall be presumed to be reasonably safe if the aspect of the product or component that allegedly caused the harm was specified or required "by a federal or state statute or regulation promulgated by an agency of the federal government responsible for the safety or use of the product . . ."

[2] United States Constitution, Article VI, Clause 2.

[3] *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 299-300, 108 S.Ct. 1145, 1150-51, 99 L.Ed.2d 316 (1988).

[4] *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69 (8th Cir. 1995) (held the Federal Insecticide, Fungicide and Rodenticide Act preempted express warranty claims based upon a federally-required and approved labeling statement); *Lynnbrook Farms v. Smithkline Beecham Corp.*, 887 F.Supp. 1100 (C.D. Ill. 1995) (held the Virus-Serum-Toxins Act preempted breach of implied warranty of merchantability against a cattle vaccine manufacturer); *Malone v. American Cyanamid Co.*, 271 Ill.App.3d 843, 649 N.E.2d 493, 208 Ill.Dec. 438 (4th Dist. 1995) (held the Federal Insecticide, Fungicide and Rodenticide Act preempted implied warranties of merchantability to the extent the claim relied upon inadequate labeling or packaging of defendant's herbicide); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992) (affirmed dismissal of negligence, strict liability and breach of implied warranty claims against the manufacturer of an intraocular lens holding the FDA "investigational device exemption regulations" preempted suits based upon state law.)

[5] 15 U.S.C. §1333.

[6] 15 U.S.C. §1334(a).

[7] 15 U.S.C. §1334(b).

[8] 15 U.S.C. §1334 (b).

[9] 21 U.S.C. §301 *et seq.*

[10] 21 U.S.C. §355.

[11] 21 U.S.C. §352.

[12] *See e.g. Abbot v. American Cyanamid Co.*, 844 F.2d 1108 (4th Cir. 1988); *Hurley v. Lederle Laboratories Division of American Cyanamid Co.*, 863 F.2d 1173 (5th Cir. 1988); and *Tobin v. Astra Pharmaceuticals Products, Inc.*, 993 F.2d 528 (6th Cir. 1993), *cert. denied*, 114 S.Ct. 304 (1993).

[13] *See e.g. Tobin v. Astra Pharmaceutical Products, Inc.*, 993 F.2d 528 (6th Cir. 1993), *cert. denied,* 114 S.Ct. 304 (1993); and *Tarallo v. Searle Pharmaceutical, Inc.*, 704 F.Supp. 653 (D.S.C. 1988). However, bear in mind the learned intermediary doctrine may afford a defense. *Martin v. Ortho Pharmaceutical Corp.*, 169 Ill.2d 234, 661 N.E.2d 352, 214 Ill.Dec. 498 (1996); *Kirk v. Michael Reese Hosp. & Medical Center*, 117 Ill.2d 507, 513 N.E.2d 387, 111 Ill.Dec. 944 (1987).

[14] 21 C.F.R. §310.510 which provides as follows:

> (a) Oral contraceptives. (1) The commissioner of Food and Drugs concluded that the safe and effective use of oral contraceptive drug products requires that patients be fully informed of the benefits and risks involved in the use of these drugs. Information in lay language concerning effectiveness, contraindication, warnings, precautions, and adverse reactions shall be furnished to each patient receiving oral contraceptives. This information shall be given to the patient by the dispenser in the form of a brief summary of certain essential information included in each package dispensed to each patient, and in longer, detailed labeling piece in or accompanying each package dispensed to each patient.

[15] 21 U.S.C. §360 *et seq*.

[16] 21 U.S.C. §301 *et seq.*

[17] 21 U.S.C. §360k(a).

[18] *See e.g. Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995); *Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994).

[19] 21 U.S.C. §360c(a)(1)(A).

[20] 21 U.S.C. §360c(a)(1)(B).

[21] 21 U.S.C. §360c(a)(1)(C).

[22] *See e.g. King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993), *cert. denied*, 114 S.Ct. 84 (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), *cert. denied*, 114 S.Ct. 86 (1993); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992), *cert. denied*, 113 S.Ct. 327 (1992).

[23] *See e.g. Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989); *Elbert v. Howmedica, Inc.*, 841 F.Supp. 327 (D. Haw. 1993).

[24] §360k. State and local requirements respecting devices:

> (a) General Rule. 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.

[25] 1996 WL 345805, *11 (U.S.Fla.).

[26] 1996 WL 345805, *14 (U.S.Fla.).

[27] 21 CFR §801.109 *et seq.*

[28] *See* 21 CFR §820 *et seq*.

[29] 1996 WL 345805, *15 (U.S. Fla.).

[30] 1996 WL 345805, *16 (U.S. Fla.).

[31] In his concurring opinion, Justice Breyer summarized the kind of analysis that must be applied:

> Consequently, I believe that ordinarily, insofar as the MDA preempts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also preempt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action. It is possible that the plurality also agrees on this point, although it does not say so explicitly. *Medtronics, Inc. v. Lohr*, 116 S.Ct. 2240 (U.S. 1996).

[32] At the appellate court level, the Illinois Appellate Court for the Fifth District conducted an extensive review of the prior decisions and statutory history of the MDA and concluded that Congress did not intend to preempt common law actions for damages by the passage of the MDA. *Haudrich v. Howmedica, Inc.*, 267 Ill.App.3d 630, 642 N.E.2d 206 (5th Dist. 1994).

[33] 42 U.S.C. §300aa-1, *et seq.*

[34] U.S.C. §300aa-14.

[35] 42 U.S.C. §300aa-11(9).

[36] *Schafer v. American Cyanamide Co.*, 20 F.3d 1, 2 (1st Cir. 1994).

[37] 7 U.S.C. §136v(b).

[38] *Burke v. Dow Chem. Co.*, 797 F.Supp. 1128 (E.D. N.Y. 1992).

[39] 21 U.S.C. §360.

[40] *See e.g. King*, 996 F.2d at 1346, *Worm II*, 5 F.3d at 747.

[41] 15 U.S.C. §§1261-1277.

[42] House Comm. On Interstate and Foreign Commerce, Federal Hazardous Substance Labeling Act, H.R. Rep. No. 1861, 86th Congress, 2nd Session 2 (1960), reprinted in 1960 U.S.C.C.A.N. 2833.

[43] House Comm. On Interstate and Foreign Commerce, Child Protection Act of 1966, H.R. Rep. No. 2166, 89th Congress, 2d Session 3 (1966), reprinted in 1966 U.S.C.C.A.N. 4095, 4096. *Moss v. Parks*, 985 F.2d 736 (4th Cir. 1993).

[44] 15 U.S.C. §1261 note (b)(1)(A) (1988).

[45] *Busch* at 838.

[46] *Moss*, 985 F.2d 736, 740-741 (4th Cir. 1993).

[47] *Id.* at 742.

[48] *Wallace* at 138.

[49] 42 U.S.C. §§5401-5426 (1983).

[50] 42 U.S.C. §5403(d).

[51] 42 U.S.C. §5409(c).

[52] 24 CFR 3282.11(d).

[53] *MacMillan* at 93.

[54] Congress has recently recodified the Safety Act at 49 U.S.C. §30101 *et seq*. The former citation was 15 U.S.C. §1381 *et seq*. Although Congress made technical improvements to promote clarity and consistency, the recodification does not reflect a substantive change in the law. H. Rep. No. 103-108, 103rd Cong., 2d Sess. 3 (1994).

[55] 49 U.S.C. §30101.

[56] *See e.g. Pokorny v. Ford Motor Co.*, 902 F.2d 1116, 1122 (3rd Cir. 1990), *cert. denied*, 498 U.S. 853 (1990) (secondary goal of the Safety Act was to promote nationwide uniformity among automobile safety standards).

[57] 49 U.S.C. §30111.

[58] 49 U.S.C. §30102(a)(9).

[59] 49 U.S.C. §30103(b)(1).

[60] 49 U.S.C. §30103(e).

[61] Readers should note the well-established principle that liability for defective design of, as opposed to failure to install, an airbag system is *not* preempted by the Safety Act. *See e.g. Perry v. Mercedes-Benz of North America, Inc.*, 957 F.2d 1257 (5th Cir. 1992).

[62] National Highway Traffic Safety Admin., Dept. of Trans. Standard 208, 49 C.F.R. §571.208 (1979).

[63] *Id.*; *See also Wood v. General Motors Corp.*, 865 F.2d 395, 399 (1st Cir. 1988), *cert. denied*, 494 U.S. 1065 (1990) (car makers have a choice between (1) passive protection from frontal and angular collisions, which would include automatic and shoulder harnesses without lap belts; (2) passive protection from head-on collisions, supplemented by seat belts and a belt warning system; or 3) lap and shoulder belts, plus a belt warning system). New regulations published in 1986, made applicable to all cars manufactured after September 1, 1989, mandate the installation of either of two passive restraint feature, an airbag, or an automatic seatbelt system with a warning light in event the belt is disengaged. 49 C.F.R. §571.208 (1990).

[64] *E.g. Pokorny*, 902 F.2d 1116 (3d Cir. 1990).

[65] *See e.g. Wilson v. Pleasant*, 660 N.E.2d 327 (Ind. 1995) (savings clause preserves common law tort actions in no airbag claims); *Tebetts v. Ford Motor Co.*, 140 N.H. 203, 665 A.2d 345 (1995), *cert. denied*, 116 S.Ct. 773 (1996).

[66] 505 U.S. 504 (1992).

[67] *See e.g. Wood*, 865 F.2d at 395; *Pokorny*, 902 F.2d at 1116; *Taylor v. General Motors Corp,* 875 F.2d 816 (11th Cir. 1989), *cert. denied*, 494 U.S. 1065 (1990); *Kitts v. General Motors Corp.*, 875 F.2d 787 (10th Cir. 1989), *cert. denied*, 494 U.S. 1065 (1990).

[68] *See e.g. Pokorny*, 902 F.2d 1116; *Kitts*, 875 F.2d 787.

[69] *See e.g.* Wood, 865 F.2d at 412 ("Congress decided that once the federal government had promulgated a standard, the states' usual role in setting safety standards was subordinated in the interest of national uniformity."); *Taylor*, 875 F.2d at 827 (finding that claim would frustrate regulatory scheme by removing manufacturer's choice among three different passenger restraint options); *Staggs v. Chrysler Corp.*, 678 F.Supp. 270 (N.D. Ga. 1987) (finding that an inconsistent standard on the state level via state tort claims would usurp the intent of Congress to have uniform automobile regulations).

[70] See note 67, *supra*.

[71] *Cipollone*, 112 S.Ct. at 2618.

[72] *Id.*

[73] *See e.g.* Kurt B. Chadwell, *Automobile Passive Restraint Claims Post-Cipollone: An End to the Federal Preemption Defense*, 46 Baylor L. Rev. 141, 153 (1994).

[74] *See e.g. Myrick v. Freuhauf Corp.*, 13 F.3d 1516 (11th Cir. 1994), *aff'd sub nom., Freightliner Corp. v. Myrick*, 115 S.Ct. 1483, 131 L.Ed.2d 385 (1995) (refusing to engage in implied preemption analysis); *Gills v. Ford Motor Co.*, 829 F.Supp. 894 (W.D. Ky. 1993) (held airbag claim impliedly preempted).

[75] 115 S.Ct. 1483 (1995).

[76] *Id.* at 1488.

[77] *See Boyle v. Chrysler Corp.*, 501 N.W.2d 865 (Wis.Ct.App. 1993); *Estate of Montag v. Honda Motor Co.*, 856 F.Supp. 574 (D.Colo. 1994), *affirmed*, 75 F.3d 1414 (10th Cir. 1996); *Tammen v. General Motors Corp.*, 857 F.Supp. 788 (D.Kan. 1994); *Miranda v. Fridman*, 645 A.2d 167 (N.J.Super.Ct.App.Div. 1994); *Johnson v. General Motors Corp.*, 889 F.Supp. 451 (W.D. Ok. 1995).

[78] *Id.*

[79] *Wilson v. Pleasant*, 660 N.E.2d 327 (Ind. 1995); *Hernandez-Gomez v. Leonardo*, 917 P.2d 238 (1996); *Tebetts v. Ford Motor Co.*, 140 N.H. 203, 665 A.2d 345 (1995), *cert. denied*, 116 S.Ct. 773 (1996); *Loulos v. Dick Smith Ford, Inc.*, 882 S.W.2d 149 (Mo. Ct. App. 1994).

[80] *Id.*

[81] *See also* the federal preemption discussion with regard to the Federal Hazardous Substances Act specifically, *supra.*

[82] 169 Ill.2d 325, 662 N.E.2d 397 (1996).

[83] *Busch*, 169 Ill.2d 325.

[84] *Id.*

[85] *Id.*

[86] 46 U.S.C. §§ 4301-4311.

[87] 46 U.S.C. §4302.

[88] The FBSA provides that the Secretary may delegate his authority under the FBSA to "a person, private, or public agency, or organization." 46 U.S.C. 4303(a).

[89] 46 U.S.C. §4306.

[90] 46 U.S.C. §4311(g).

[91] *See Farner v. Brunswick Corp.*, 239 Ill.App.3d 885, 607 N.E.2d 562 (2d Dist. 1992); *Carstensen v. Brunswick Corp.*, 49 F.3d 430 (8th Cir. 1995), *cert. denied*, 116 S.Ct. 182 (1996); *Lewis v. Brunswick Corp.*, 922 F.Supp. 613 (S.D. Ga. 1996); *Moss v. Outboard Marine Corp.*, 915 F.Supp. 183 (E.D. Cal. 1996); *Davis v. Brunswick Corp.*, 854 F.Supp. 1574 (N.D. Ga. 1993); *Shields v. Bayliner Marine Corp.*, 822 F.Supp. 81 (D. Conn. 1993); *Shields v. Outboard Marine Corp.*, 776 F.Supp. 1579 (M.D. Ga. 1991); *Mowery v. Mercury Marine, Div. of Brunswick Corp.*, 773 F.Supp. 1012 (N.D. Ohio 1991); *Ryan v. Brunswick Corp.*, 531 N.W.2d 793 (Mich. Ct. App. 1995).

[92] *Id.*

[93] *See Moore v. Brunswick Bowling and Billiards Corp.*, 889 S.W.2d 246 (Tex.), *cert. denied*, 115 S.Ct. 664 (1994).

[94] See note 59, *supra*.

[95] *Carstensen*, 49 F.3d 430 (8th Cir. 1995).

[96] *Farner*, 239 Ill.App.3d 885, 607 N.E.2d 562 (2d Dist. 1992) (affirmed summary judgment against a plaintiff who was injured when she was struck by a boat propeller).

[97] *See e.g. Carstensen*, 49 F.3d at 431; *Moss*, 915 F.Supp. at 185; *Lewis*, 922 F.Supp. at 614.

[98] Minutes of the 44th Meeting of the National Boating Safety Advisory Council 17-19 (Nov. 6-7, 1989).

[99] Letter from Robert T. Nelson, Rear Admiral, U.S. Coast Guard, Chief, Office of Navigation, Safety and Waterway Services to A. Newell Garden, Chairman, National Boating Safety Advisory Council 1 (Feb. 1, 1990).

[100] *See e.g.Carstensen*, 49 F.3d at 431.

[101] *See e.g. Farner*, 607 N.E.2d at 567; *Carstensen*, 49 F.3d at 432.

[102] *Id.*

[103] *See e.g.Carstensen*, 49 F.3d at 432; *Lewis*, 922 F.Supp. at 613; *Moss*, 915 F.Supp. at 187.

[104] *See e.g.Carstensen*, 49 F.3d at 432.

[105] *E.g. Mulhern v. Outboard Marine Corp.*, 432 N.W.2d 130 (Wis.Ct.App. 1988) (finding that the FBSA did not preempt a state tort action premised upon a defective throttle mechanism installed by the defendant manufacturer); *Rubin v. Brutus Corp.*, 487 So.2d 360 (Fla.Dist.Ct.App. 1986) (holding that the FBSA did not preempt a state tort claim based on injuries received when a seat installed by the manufacturer came loose and collapsed on impact).

[106] 15 U.S.C. §1203(a).

[107] 15 U.S.C. §1203(b).