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The IDC Monograph

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Federal Preemption Defenses in Product Liability Suits: A Continuing Evaluation

Introduction

Federal Preemption has been an effective defense to product liability actions for some time. Since the landmark U.S. Supreme Court case of *Cipollone v. Liggett Group, Inc.*,[1] made it clear that the concept of Federal Preemption applies to state common law tort actions, courts in Illinois as well as federal courts and other states' courts have looked to this doctrine increasingly as a means by which common law tort actions can be dismissed where Congress, either itself or through delegation to federal agencies, has decided that federal law should control.

Product manufacturers have been frustrated too often by the variability of potentially applicable laws of the various states, the District of Columbia, and other U.S. territories. This frustration is particularly apparent where juries evaluate design and manufacturing decisions, while facing the prospect of sending a severely injured plaintiff away with nothing. Often, these design or manufacturing decisions were made years before the accident, notwithstanding best efforts and consideration of all potentially relevant safety factors at the time. Sometimes, these decisions turn out in retrospect to be short of optimal based on the unique facts of a particular incident.

Federal Preemption recognizes the utility of having one set of guidelines, designs or manufacturing techniques used to provide a measure of uniformity to products and their regulation. The guidelines are often based on consideration of a multitude of factors and uses throughout the United States. Such uniformity can have the benefit of increasing overall society safety and product performance. In the 21st Century, more and more products are coming to the consuming public from outside Illinois and outside the United States. Manufacturers and distributors need to know that once their products meet a governmentally mandated standard or guideline established after rigorous evaluation and testing, designs, materials, and manufacturing techniques that have been explicitly approved will not be subject to second guessing by an emotionally charged jury facing the unique circumstances of a particular occurrence.

But, as will be seen, Federal Preemption is not an all-encompassing defense with universal application. Simply because Congress has spoken generally regarding a general product type, such as an automobile or a solvent, does not automatically give rise to preemption. Instead, Congress must speak clearly in expressing its desire to set both a floor and a ceiling regarding the regulation of product design, materials, packaging, and related features. Sometimes, Congress expresses its intentions clearly as to this issue. At other times, Congress's intent must be inferred by an encompassing set of related laws and agency regulations.

This Monograph will discuss the preemption defense including, its basic concepts and operation, as well as Illinois cases where preemption has been asserted. It will provide some examples and case law discussion of various statutes where preemption might be available to the defendant. This Monograph builds upon and updates a Monograph published in the IDC Quarterly more than 14 years ago.[2] The U.S. Supreme Court and other courts have added much to the jurisprudence of Federal Preemption since that time. Looking both back and forward since 1996 should help defense counsel in protecting their clients' interests going forward.

I. Federal Preemption – The Concept, the Law, and the Basics

The basis for Federal Preemption comes from the Supremacy Clause of the U.S. Constitution. It states:

> This 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.[3]

It is this clause that enables the acts of Congress (and regulations promulgated by its designees) to control over laws enacted by states or local governments. As will be seen, this also applies to common law tort suits, as verdicts and the award of money damages can have the same regulatory effect as locally enacted laws, statutes, and regulations.[4]

The cases discuss three types of preemption, noting that they are not always easily separated depending on the circumstances. Regardless of type, there is one major concept that pervades the analysis. This concept remains the most important policy issue involved in determining whether preemption will operate: the courts' focus at all times on the intent of Congress. Did Congress intend for the statutory regime at issue (or regulations enacted pursuant to congressional authority) to so totally control over the issue involved in the lawsuit such that the states' police powers – their traditional role in health and safety of their residents – should be supplanted by the federal government?

A. "3½" Types of Preemption

The United States Supreme Court is well aware that historically it has been the states that used their police powers to protect health and safety of their citizens. This subject has been seen largely as a matter of local concern.[5] Given the states' historical role, the Court has indicated that preemption provisions should be read narrowly, with a presumption against their application.[6] As tort litigation often involves health and safety issues, the impact of preemption on notions of federalism in this context are clear. For preemption to operate, it must be determined that federal control over the issues that arise in the litigation at issue was the "clear and manifest" purpose of Congress. From the attempts to answer this all-important question, the types of preemption were developed.[7]

The first type is "express preemption," which exists when Congress's intent is stated clearly within the statute enacted.[8] Typically, such enactments provide that a state or local government cannot legislate regarding the stated matters or even the general subject matter of the statute.

The next two types of preemption fall into the general category of implied preemption. The second type is called "conflict in fact"[9] or "conflict preemption,"[10] where either the federal statutory scheme or regulatory

regime, or both, conflict with that of a state or local government, such that a choice must be made regarding with which to comply. Under this scenario, compliance with both federal and state law would be impossible.

The third type is called "field preemption," which is arguably the most difficult to apply.[11] This third method looks at the federal regulatory regime and attempts to determine whether the degree of pervasiveness reaches a level such that it reasonably can be inferred that Congress intended to occupy the entire regulatory field. In such an instance, there is no room left for the states to exercise their police powers. This third method often operates within the context of silence on the subject of preemption in the original law passed by Congress.[12]

A review of the cases suggests that some of these seemingly separate preemption types actually operate in conjunction with one another.[13] The courts do not always apply each in a discrete fashion. Further, the lack of an express preemption provision by itself is not seen by the courts as itself an expression of intent by Congress not to preempt state law.

Lastly, although not a separate "type" of preemption per se, in the last few years, commentators have discussed something dubbed "agency preemption." This preemption occurs where a federal regulatory agency expresses its view or perception regarding the scope of preemption within a formal rulemaking, often in the preamble of such a rulemaking contained in the Federal Register.

Note that preemption provisions often are not the only relevant components of expressions of congressional intent regarding the role of the states in areas where Congress has chosen to regulate. Some statutes contain "savings clauses" in addition to preemption provisions.[14] Such savings clauses address the balance Congress is attempting to reach relative to its desire to completely supplant the role of state and local governments in their exercise of traditional police powers, and the use of these same police powers to enhance public safety and the efficacy of products used by both consumers and industry.

To determine whether a case or claim is preempted, it is important to examine carefully the allegations being made in the action, as well as the multiple theories of liability being pursued. The examples below discuss several U.S. Supreme Court cases in the context of products liability. The Court, in some instances, found some liability theories preempted (mostly negligence and strict liability claims). But, the Court has allowed other theories of recovery, such as express warranty claims, to proceed based on the fact that express warranty claims are contractual claims between the parties themselves. As such, express warranty claims do not involved in the exercise of state police powers.[15]

B. Preemption Cases Decided by the U.S. Supreme Court in the Context of Products Liability Claims, since 1990

Since the 1990s, the United States Supreme Court has spoken to the issue of preemption in the context of products liability claims a number of times. A discussion of these cases helps to understand how this doctrine operates, and can assist defense counsel in formulating strategy to enable preemption to operate in the desired manner. Practitioners should be mindful of the observation made by the Court over 60 years ago:

> It is often a perplexing question whether Congress has precluded state action or by the choice of selective regulatory measures has left the police power of the States undisturbed except as the state and federal regulations collide.[16]

This Section explores six cases that have developed the Court's jurisprudence regarding preemption within the context of products liability claims.

1. *Cipollone v. Liggett Group, Inc.*

Cipollone v. Liggett Group, Inc.[17] is a good starting point, as it touches on multiple aspects of the preemption doctrine. The Court's decision in that case laid the groundwork for subsequent decisions with ramifications for products liability cases. *Cipollone* was a products liability case filed in federal district court in New Jersey, alleging that Rose Cipollone developed lung cancer due to smoking cigarettes. Later she died (and eventually her spouse died too) and the suit was pursued by her estate. The plaintiff's complaint asserted several bases of recovery by alleging of a number of theories of liability commonly used in products cases: negligence, strict liability, express warranty, and intentional tort.

The bases asserted for recovery are important in that the Court applied the preemption principles separately to each. These bases included: (1) design defect claims arising out of the failure to use a safer alternative, and the use of the risk utility test; (2) failure to adequately warn of the hazards of smoking; (3) negligent testing, research, sale, and advertising of cigarettes; (4) breach of express warranty based on statements in advertising that minimized the dangers of smoking; (5) fraudulent misrepresentation regarding the hazards of smoking; and (6) conspiracy related to dissemination of health and safety information.[18]

At the district court level, the defendants argued that two statutes, the Federal Cigarette Labeling and Advertising Act of 1965[19] (the 1965 Act) and its successor, the Public Health Cigarette Smoking Act of 1969[20] (the 1969 Act) preempted the plaintiff's suit in its entirety. The trial court rejected this argument and struck the defendants' preemption affirmative defenses. The Second Circuit Court of Appeals found no express preemption. But that court did hold that the plaintiff's warning and advertising based claims were preempted to the extent that they asserted that some wording or message different than what was mandated by federal regulations.

After the Court denied a petition for certiorari, the case was remanded and tried by the district court. The district court found that the failure to warn, express warranty, fraudulent misrepresentation, and conspiracy claims were preempted to the extent they relied on the defendants' actions after the effective date of the 1965 Act. A verdict for the plaintiff was obtained, and the Supreme Court eventually granted a petition for certiorari.[21]

The Court focused on the two statutes listed above, discussing their history and the reasons for their enactment. From this exercise, Congress's intent was discerned. In tracing the history of the legislation, the Court discussed the differences between the two statutes and the evolution of their regulatory effect. Each of these statutes had express preemption provisions, although their text differed. The fact these provisions were present, however, led the Court to conclude that their mere presence, coupled with the belief that their presence was a reliable expression of congressional intent to supplant state authority, meant that there was no need to infer an intention to preempt state law from looking to the other provisions of the legislation. As such, those issues not expressly preempted by the statutes were not preempted.[22]

As for the 1965 Act, the Court found that the preemption provision prohibited requiring a different warning than was mandated in the Act itself. The relevant provisions were as follows:

> (a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.
> (b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.[23]

Section 4 of the 1965 Act contained the required warning language.[24]

Given the narrow reading used, the Court found that this provision was focused only on the content of the warning label and was simply a prohibition against other state and local governments mandating any other language. This ruling did not preempt other aspects of the litigation, including common law damages claims.[25]

The Court then looked to the 1969 Act. The relevant provision regarding preemption in the 1969 Act was as follows:

(b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.[26]

The Court juxtaposed the preemption provisions of each act. In so doing, the Court found the preemption provision in the 1969 Act to be broader in that it prohibited not only different "requirements" related to warnings and advertising, but also addressed "prohibitions" imposed by state law. Further, unlike the 1965 Act, the preemption provision of the 1969 Act also focused on advertising and promotion, not just advertising. The Court decided there was a distinction between a "regulation" which it said was a positive enactment by a legislative body and a "prohibition" which the Court found encompassed common law tort actions. The Court found that common law tort cases were based on the existence of a "legal duty" and as such imposed "requirements or prohibitions."[27]

The key to *Cipollone* is the notion that common law actions, where concepts of legal duty are an integral part, can be preempted just like a state or locally enacted statute, law, or ordinance. This conclusion regarding potential preemption of common law actions was made by a plurality of the Court. In fact, the remainder of the opinion applying preemption principles to the various theories of liability was also contained in the plurality. Yet, as seen below, the concept of legal duties defined in common law actions being subject to preemption analysis now has evolved into a majority view at the Court.

The Court nonetheless was unwilling to find all of the common law claims preempted and to sweep them all aside. Instead, the Court carefully examined each claim and theory of recovery alleged with a view towards a narrow construction of the relevant preemption statute and a strong presumption against preemption. The Court used the following test:

> The central inquiry in each case is straightforward: we ask whether the legal duty that is the predicate of the common-law damages action constitutes a "requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion," giving that clause a fair but narrow reading.[28]

The Court found any warnings-related claims which focused on conduct after the effective date of the 1969 Act alleging any different warning be used other than the congressionally mandated warning, or the lack of warnings in advertising or promotion, to be preempted. It found claims unrelated to advertising or promotion to be not preempted.[29]

As for the express warranty claims, the Court observed that express warranties were a private contractual matter. They did not involve a "requirement or prohibition" imposed by state law. Such agreements were found to be undertaken voluntarily and as such not preempted. It was of no matter that the basis of such claims was the advertising itself, and it did not matter that the courts were used to enforce such agreements.[30]

As for the fraudulent misrepresentation claims, the Court found the plaintiff's theory asserting that the way the defendants advertised negated the effect of the mandated warning to be preempted, as this was the converse of requiring a warning in advertising, which the 1969 Act had forbidden. Another of the plaintiff's theories of recovery alleged intentional concealment of material information. The Court found that so long as these claims did not focus on advertising or promotions (that is, a duty to disclose such information using means other than advertising or promotion), they would not be preempted. The Court found the latter to be grounded in a more general type of duty, a duty not to deceive, as opposed to a duty based on smoking and health which was the subject of the 1969 Act. This same rationale was used to save the plaintiff's conspiracy claims.[31]

In sum, the Court in *Cipollone* used express preemption to find that the 1969 Act preempted the plaintiff's common law claims, which necessarily would have involved a different warning or required a warning in advertising or promotional materials. To the extent the defendants' writings or statements could be construed

as creating an express warranty, such claims were not preempted. Tort claims based on more general duties consistent with the goals of the 1969 Act and the actions of the Federal Trade Commission in regulating consistent with the 1969 Act were also found not to be preempted.[32]

2. *Medtronic, Inc. v. Lohr*

In 1996, the Court again addressed preemption in a products liability context with its decision in *Medtronic, Inc. v. Lohr*.[33] There, plaintiff Lora Lohr had undergone a procedure to insert a pacemaker manufactured by the defendant. Eventually, the pacemaker had to be replaced on an emergency basis. The plaintiff attributed the failure of the device to a lead, an electrical connection between the device itself and Mrs. Lohr's heart. The plaintiff filed a suit in Florida state court alleging that defects in the pacemaker necessitated the emergency surgery. The complaint sounded in both negligence and strict liability. The defendant removed the case to federal district court. Later, the defendant moved for summary judgment asserting the preemption provisions of the Medical Device Amendments of 1976[34] (MDA), an act of Congress that amended the Federal Food and Drug Cosmetic Act[35] to add medical devices to the list of items previously subject to at least some oversight by the federal government. The Food and Drug Administration (FDA) was the agency designated to regulate under these acts.[3] The Court outlined the history of congressional action in the area of drug and medical devices and observed that the MDA contained a preemption provision which provided in relevant part:

> (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.[37]

MDA also created a hierarchy of regulation by classifying various medical devices based on perceived risk to the public. Pacemakers were listed as Class III devices and as such were to receive the most scrutiny. Class III devices were required to pass a rigorous pre-market evaluation called "pre-market approval" before being allowed to be sold. The Court, however, recognized that, because medical devices were added later to the list of regulated products, and because it would be impractical to require their sale to be ceased while the FDA performed a pre-market approval for each one, some were allowed to remain on the market pending evaluation.[38]

Also, new, unapproved devices could be sold absent the more intense pre-market approval process so long as the manufacturer certified that any such new device was "substantially equivalent" to a device already on the market. The approval process associated with the "substantially equivalent" standard was less rigorous than the regular standard, and sales could begin before this less encompassing equivalency approval process began. The Court observed that, because of the volume of time needed to complete the pre-market approval in combination with the volume of devices in need of pre-market approval, most medical devices were reaching the market by way of the less rigorous "substantially equivalent" process. It was through this method that the pacemaker at issue reached the market.[39]

The district court initially denied the defendant's summary judgment motion as to the case in its entirety based on preemption. Later, it reconsidered in light of then-new Court of Appeals for the Eleventh Circuit precedent and granted the summary judgment motion as to all claims. At the time, some courts of appeals, including the Eleventh Circuit, had begun to hold that FDA "approval" pursuant to MDA was enough to

trigger preemption.[40] On appeal from the district court's ruling, the Eleventh Circuit reversed in part and affirmed in part. In so doing, it found the preemption provisions of MDA to be vague. It then focused on regulations issued by the FDA, the agency statutorily designated to perform pre-market approvals and the "substantially equivalent" inquiry. It held that the plaintiff's negligent design claims were not preempted, but that negligent manufacturing and failure to warn claims were. It applied the same analysis and ruled similarly as to the strict liability based claims.[41]

At the Supreme Court, the defendant argued that using express preemption, the plaintiff's case was preempted in its entirety. This argument was rejected. The Court held that the preemption provision in MDA did not clearly prohibit all common law claims. The Court looked to the language of the preemption provision, focusing on the term "requirement." It decided that the use of this term suggested that Congress actually was concerned with states enacting laws that created duties focused on specific devices or aspects of devices, and not with common law actions or duties that may derive from such actions.

Further, the Court noted that one policy behind MDA was to provide for the safety and effectiveness of regulated devices. Congress was aware that common law cases had been litigated for years before MDA was enacted. In that sense, the Court found that parallel common law claims were both consistent with and an augmentation of this policy. The Court's belief was that the potential of an award of money damages would help motivate safety consciousness and increase device effectiveness, notwithstanding the capacity of such claims having a possible chilling effect on product innovation. In essence, the Court found that Congress was mostly concerned with inhibiting additional, positive regulation by states, not curtailing preexisting duties under common law.[42]

After disposing of the more general preemption argument, the Court focused on the specific claims. The Court found that the "substantially equivalent" inquiry was not nearly as rigorous as the pre-market approval process, and was an inquiry focused on "equivalence" not "safety." Thus, this "equivalence" inquiry provided no protection to the consumer of the device. Instead it was simply intended to maintain the status quo. For this reason, the Court found that the design defect claims were not preempted. Further, the Court found that claims based on the federal requirements themselves, that is, the failure of the device to meet applicable federal requirements for similar devices, were likewise viable and not preempted. This result occurred because the preemption statute prohibited only those "requirements" that were not equal to or substantially similar to federal requirements.[43]

Among the factors the Court relied on for its rulings in *Lohr* were the FDA-issued regulations as well as information about the medical device approval process the FDA promulgated. The Court noted that Congress had delegated to the FDA the right to implement MDA. Congress left it to the FDA to determine the scope of scrutiny a given medical device would receive. In this sense, it appears that the plurality decided that Congress effectively gave the FDA the right to determine the potentially preemptive effect MDA would have on claims concerning a particular device. This result was due to the fact that whether a claim would be preempted was found to be dependent on whether the FDA actually created a federal "requirement" applicable to that device. Thus, the scope of the FDA scrutiny turned out to be the thing that defined the potential for preemption in *Lohr*. As will be seen below, the role of published agency views on the issue of preemption and any regulatory actions is itself a potential quagmire as it relates to the preemption doctrine.

The role of the FDA clearly was important in the Court's decision not to preempt the *Lohr* plaintiff's common law manufacturing defect and warnings claims. In finding no preemption, the Court looked closely at the MDA preemption statute. That statute indicated that preemption existed only with respect to requirements for a device that related to its safety or effectiveness. The FDA's position, as stated in its statement regarding the regulations it issued, was that it believed there was preemption only with respect to regulations issued that pertained to a particular device or counterpart regulations. Further, the regulations indicated that preemption was not intended to operate where state and local requirements at issue applied to products other than regulated devices or to unfair labor practices with requirements not limited to devices. According to the FDA,

preemption should be available only when there was potential for conflict between the federal regulations and state and local requirements. Claims based on the Uniform Commercial Code warranties were unaffected.[44]

Thus, the Court found that preemption would operate only with regard to conflicts relating to health and safety issues and where there were specific regulations (or counterpart regulations) focused on a particular device. The defendant had argued that there were regulations that governed manufacturing (called Good Manufacturing Practices[45]), and that claims regarding manufacturing defects should be preempted. Because the Court characterized these regulations as general and not necessarily specific to a particular device, it found that they did not provide a basis for preemption. In fact, the Court saw such general duties as providing no greater burden or duty on the defendant as would a general common law duty to use due care. In that sense, a common law duty to use due care would not be "different from, or in addition to" the FDA regulations. These general regulations' lack of specificity meant that the preemption provision of the MDA was inapplicable to Lohr's manufacturing defect claims.[46]

3. ***Riegel v. Medtronic, Inc.***

Several years later, the Court revisited medical-device-related products liability litigation in *Riegel v. Medtronic, Inc.*,47 this time with a different result. *Riegel* involved a catheter that failed during a cardiac angioplasty. The plaintiffs filed a products liability suit asserting common law claims in a United States district court in New York. The defendant successfully argued preemption at the trial court level, and this result was affirmed by the Second Circuit Court of Appeals.48 The Supreme Court examined the preemption issue under the same analysis used in *Lohr*, and concluded that the plaintiffs' claims in this instance were preempted.[49]

One key distinction between *Lohr* and *Riegel* noted by the Court was that the catheter in *Riegel* actually underwent the rigorous pre-market approval process, and was not simply scrutinized under the "substantially equivalent" regulation as had been the device in *Lohr*. As such, the regulatory issue for the catheter in *Riegel* was not just "equivalency," but instead was "safety." The catheter was actually determined by the FDA to be both safe and effective, meeting the standard for obtaining pre-market approval. It was not simply found to be equivalent to other similar devices. The FDA regulations prohibited changes to its approved design, absent a resubmission to the FDA for pre-market approval. The FDA also approved the device's labeling, finding it neither false nor misleading.[50]

Given that the device in *Riegel* went through the rigorous pre-market approval process, the Court found that the common law action asserting the typical tort theories of recovery such as negligence, strict liability, and breach of implied warranty were preempted. It reasoned that a verdict against the defendant based on these theories would mean that the FDA's judgment about safety was second-guessed. The Court held that allowing claims asserting common law duties different from what the FDA imposed were state "requirements" different from what Congress intended, and thus preempted. The Court observed that the FDA performed an overall cost-benefit analysis as part of its work in determining whether a medical device would be allowed to be sold. It compared this analysis to a trial court verdict where juries are often focused on the individual plaintiff and costs to that individual, not the benefits to other persons or society as a whole.

Although the result of a verdict for the plaintiff in a common law action was damages, and not injunctive relief or a directive that mandates specific conduct as a statute or regulation would, the Court nevertheless saw an award of money damages as way to govern conduct.[51] In fact, it would appear that anytime the regulatory body engages in a congressionally mandated balancing between health and safety on one end, and efficiency and other commerce-related interests on the other, a common law claim that touches upon the balance reached usually would involve a measure of second-guessing and so be subject to preemption.[52]

The Court rejected the notion that the FDA regulatory activity involved in *Riegel* amounted to no more than giving rise to general, common law duties. It accepted the FDA's view on its own regulatory activity as substantive and focused, not general in nature.[53] One important difference between *Cipollone* and the more recent decision on *Riegel* is that the notion of common law duties being scrutinized as potentially creating

duties conflicting with congressional intent is no longer the view of a plurality of the Court, but instead enjoys a solid majority.

The Court did observe that, had the plaintiffs alleged that the defendant's device did not comply with FDA regulations for the catheter in question, such claims would not be preempted. Such claims would not have involved state regulation which was "different from, or in addition to" the applicable FDA regulations. In other words, the Court would have allowed so-called "parallel claims" notwithstanding the degree of regulation that it found so important to its decision. The Court also somewhat reiterated the discussion in *Lohr* regarding deference to the FDA's own conclusions about the preemptive effect of its own actions.[54]

4. ***Bates v. Dow Agrasciences, LLC***

In a decision unrelated to medical devices, the Supreme Court in *Bates v. Dow Agrasciences, LLC*55 discussed preemption in the context of a tort case involving damage from the use a pesticide. In that case, some Texas peanut farmers sued the manufacturer, Dow, after their peanut crop was damaged from the application of a Dow pesticide. This pesticide was subject to regulation by the United States Environmental Protection Agency (EPA) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act[56] (FIFRA). The product was submitted for registration under FIFRA, a process including a submission of the pesticide's label to enable the EPA to determine whether the product was "misbranded." This process involves an assessment that determines whether the label contains false or misleading statements, whether it contains adequate instructions for use, and whether there are no omissions of necessary warnings or other important information. Under FIFRA, selling mislabeled products regulated by that act is illegal. FIFRA also provides for a continuing duty to submit reports of incidents involving a regulated product's toxic effects that may not be addressed in an earlier, approved label.[57]

The issue with the pesticide in *Bates* was that it apparently damaged crops under certain soil conditions. At the time of sale in this case, there was no warning advising against its use under such conditions. After the crops were damaged, and before the next growing season, Dow sought to change the label to add a warning regarding use in such soil conditions. After unsuccessful pre-suit settlement negotiations, the farmers notified Dow of their intention to sue pursuant to the Texas Deceptive Trade Practices Act.[58] In response, Dow filed a suit in federal district court, seeking a declaratory judgment of preemption of the farmers' claims. In turn, the farmers filed a products liability counterclaim for damages based on negligence, strict liability, fraud and breach of warranty. The district court found almost all of the farmers' claims preempted. The Court of Appeals for the Fifth Circuit affirmed.[59]

The Supreme Court discussed the preemption provision at issue in FIFRA, which the Court noted was added well after FIFRA and its predecessor were passed by Congress decades earlier. Initially, these statutes focused largely on labeling. In 1972, FIFRA was amended to make it a more comprehensive regulatory statute. As a result, manufacturers were required to submit information regarding use, effectiveness and safety, not just proposed labeling. A preemption provision was also added, and provided as follows:

> (a) In general–
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> (b) Uniformity–
>
> "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.

(c) Additional uses–

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 136a of this title for all purposes of this subchapter, but shall authorize distribution and use only within such State . . . .[60]

In 1978, FIFRA was again amended, this time to authorize the EPA to waive the requirement that product efficacy information be provided to the EPA, a waiver the EPA put into place in 1979. It was under this regulatory framework that Dow's pesticide was registered. In this case, the EPA never substantively evaluated Dow's claims regarding the lack of use restrictions based on soil conditions for the pesticide in question.[61]

The Court's focus here was whether the farmer's common law claims were an additional or different "requirement" and thus preempted under the circumstances of this case. In so doing, the Court looked at two questions it saw raised by the wording of the newly added preemption provision: (1) whether the requirement was focused on "labeling or packaging" and (2) whether such a labeling or packaging requirement was in fact additional or different than the previous one.[62]

The first observation the Court made was that common law claims that focused on design or manufacturing defects, negligent testing or breach of express warranty did not impose any requirements that focused on labeling or packaging. Thus, such claims were not preempted. The court of appeals had reasoned that a money-damages judgment based on these particular theories of recovery could induce a label change. It thought any liability theory on which tort recovery involved potential inducement for change to the label was enough for preemption to operate. The Supreme Court found a distinction between a law or statute and a verdict adverse to the defendant. It indicated that a requirement was a mandate that must be obeyed; and that a jury verdict, while potentially motivating action, was not a mandate. A verdict merely suggested optional behaviors that may avoid such verdicts in the future. The Court was critical of what it called "an inducement test" used by the court of appeals. It found this test overbroad and inconsistent with congressional intent as expressed in the preemption provision, which it believed contemplated at least some state regulatory activity.[63]

The Court next addressed the warnings-based claims that focused on labeling. Unlike the preemption language in *Cipollone*, the Court in *Bates* observed that the prohibition instituted by Congress in FIFRA was on requirements "in addition to or different from" what Congress or the regulatory agency imposed, and was not a complete ban on any requirements. Thus, to the extent that failure-to-warn claims asserted only duties that were the equivalent of FIFRA-imposed duties, they could survive preemption. The Court emphasized that "equivalent" did not mean "identical." The Court remanded the case for a determination on this point.[64]

It is this ruling that initially gave rise to the notion that there can be "parallel requirements" in tort cases, whereby the duties imposed under common law are the same as those imposed by statute or regulation and so not preempted. To reach this conclusion, the Court relied not only on the language of the preemption statute, but also on the notion of narrowly reading such provisions. The Court found its narrow reading in *Bates* particularly appropriate, given the long history of tort litigation involving products regulated under FIFRA. Significant was that, despite this historical background of common law tort litigation, Congress had not done more in terms of expressing its preemptive intent. The Court found that tort claims involving labeling could aid the function of FIFRA, not hinder it. The Court brushed aside concerns about state tort litigation giving rise to a "crazy-quilt" of state-imposed warning and labeling requirements.[65]

Regardless, the Court suggested that claims asserting that different fonts or colors or word choices likely would be preempted, as would claims that involve divergence from specific FIFRA mandated labeling requirements.[66] It appears that a warnings claim alleging something other than literal non-compliance with an EPA regulation issued under FIFRA likely would be preempted.

5. *Wyeth v. Levine*

More recently, the Court dealt with a preemption situation that involves what has become known as "agency preemption." In the Court's decision in *Lohr*, it relied in part on comments made by the regulatory agency (in that instance the FDA) as part of the process of determining exactly what its regulations would be. Thereafter, some agencies began to opine expressly about preemption in the preamble of regulatory announcements and otherwise. Those opinions apparently were made to try to influence the outcome of cases where preemption could become an issue.

In *Wyeth v. Levine*,[67] the Court dealt with a preemption claim involving a drug label that had been initially approved by the FDA in 1955, with some later approved changes. The Plaintiff made failure to warn claims in Vermont state court relating to the way the drug at issue was administered to her. Her claim focused on the alleged lack of warning to physicians about how it should be administered. The drug caused injuries because it was injected or pushed directly into an IV tube rather than using what was known as the IV drip method. Apparently, the IV was mistakenly placed in an artery rather than a vein. Had the drip method been used, the medication would not have entered the artery. It was well known that arterial administration of this medication rather than venous administration could have drastic, negative side effects.

The drug company sought summary judgment based on preemption. It argued that the drug and its label had been approved by the FDA, and so no other warning could have been provided. The trial court rejected the preemption argument. It reviewed evidence of the interaction between the FDA and the drug company regarding labeling issues, noting that the drug company was told that any changes to the drug's label, which were eventually approved, had to be identical to what was actually approved. At trial, the court instructed the jury that it could consider the drug company's compliance with the FDA regulations, but that compliance was not dispositive on the issue of liability. The trial court also instructed the jury that the FDA regulations allowed for unapproved changes to warnings so long as such changes were additions to or a strengthening of approved warnings, and that the defendant advised the FDA of its actions. A seven figure verdict for the plaintiff was rendered, and the case made its way through the Vermont appellate and supreme courts.[68]

In its arguments before the United States Supreme Court, the drug company asserted implied preemption in two ways. First it argued that it was impossible to comply with both the state common law duty relating to modification of its warnings and the FDA regulation, that is, conflict in fact. At trial, the plaintiff argued for a stronger warning about using the IV push method of drug administration. Second, the defendant argued that allowing the plaintiff's state court tort claim itself created an obstacle to the accomplishment of Congress' objectives, that is, field preemption. In response, the Court applied the standard analysis discerning the intent of Congress and deciding whether there was some conflict between federal and state law.[69]

In discussing the intent of Congress, the Court noted the difference between the Federal Food and Drug Cosmetic Act[70] (FDCA) and its amendments, and the Medical Device Amendments of 1976[71] at issue in *Lohr* and *Riegel* which governed medical devices. Unlike the Medical Device Amendments, there was no express preemption provision in FDCA. The Court found that Congress acted to preserve the potential applicability of state law by inserting a savings clause into FDCA when it was amended in 1962.[72]

In addressing the first preemption argument, the Court observed that "impossibility preemption" was a very demanding defense. Although the regulations did prohibit unilateral label changes, there was a provision to allow changes that strengthened or added instructions to pre-existing, approved warnings, so long as the manufacturer submitted a supplemental application to the FDA regarding the changes. The defendant argued this regulation was limited to changes necessitated by wholly new information, not a revisiting of information that was part of the initial application to the FDA. In rejecting the defendant's interpretation of this regulation, the Court found the defendant's reading too narrow, given the FDA requirement that adverse reactions be consistently reported even for previously approved medications. For this reason, the Court found that state law warnings claims were not preempted based on "impossibility," as warning changes without explicit approval

by the FDA were allowed. The Court found that state common law simply reinforced the existing FDA regulatory scheme.[73]

The Court also disposed of the second preemption argument, that the state tort claim was an obstacle to the FDA drug-labeling scheme. The drug company argued that the obstacle it faced was allowing a state court action that assessed the warning's adequacy when the warning in question was specifically approved by the FDA, after the FDA's assessment and rejection of alternative warnings. In rejecting this position, the Court looked to Congress's intent in enacting FDCA. It found that Congress had consumer protection in mind. In failing to provide a remedy to consumers for mislabeling, Congress intended for consumers to be able to avail themselves of traditional state law remedies, that is, common law actions for damages. The fact that Congress had amended FDCA in the interim yet failed to totally preclude common law actions despite its awareness of such suits being filed was seen as evidence of Congress's intent to allow common law suits to exist in parallel to FDA oversight.[74]

It is at this point where the issue of agency preemption is discussed and perhaps resolved. The Court observed that notwithstanding its assessment of congressional intent, the FDA itself, in the preamble to amended regulations issued in 2006, opined about the preemptive effect of its regulatory actions. The FDA indicated that its regulations created both a floor and a ceiling relating to drug labels. It decided that its actions in approving drugs and drug labels left no room for state action. According to the FDA, suits under state common law that effectively challenged the FDA's expertise in approving drug warnings were thus preempted.[75]

The Court recognized that in the past it had given regulatory bodies' self-assessment defining the scope of regulatory action, including the potential effect on preemption, a measure of weight. But, the Court in *Levine* observed that it never totally deferred to an agency's own conclusion regarding the preemptive effect of its own regulatory activity. The Court recognized an agency's potential expertise in evaluation of products and unique understanding of the regulations issued and actions taken by that agency. But the Court said it still examined the regulatory action as a whole in combination with Congress's intent relating to the degree to which a body of regulation would control some or an entire aspect of regulatory reach. It was through this analysis that the Court would determine whether and to what degree regulatory action could serve to preempt all or part of a suit for damages based state common law.[76]

In *Levine*, the Court looked at the FDA's 2006 preemption statement, and found that it was not consistent with the positions on preemption the FDA had historically taken. It found the statement that accompanied the FDA's 2006 amended regulations to be more of a unilateral declaration, without any opportunity for input by the States or affected persons. It also found it to be inconsistent with Congress's intent. The Court found that the FDA historically had seen state common law suits as complementary to the FDA's regulatory actions. Such suits helped to identify unknown hazards, and reinforced the notion that the manufacturers, not the FDA, had primary responsibility for drug labels. In essence, the Court seemed to ignore the 2006 FDA pronouncement on preemption given the position the FDA had taken for years prior to that time. In the end, the Court found the plaintiff's state common law claims not preempted.[77]

6. ***Geier v. American Honda Motor Co.***

The Court juxtaposed the situation in *Levine* with a prior decision, *Geier v. American Honda Motor Co.*,[78] where it looked at the regulatory actions of the Department of Transportation in promulgating Federal Motor Vehicle Safety Standard 208.[79] This standard provided options to vehicle manufacturers as to whether to provide airbags as part of a passenger restraint system. The issue in *Geier* was whether this Standard preempted claims by persons asserting lack of airbags as a design defect in vehicles. Because an exclusive choice of restraint mechanisms was given vehicle manufacturers, the Court in *Geier* preempted claims where one authorized choice regarding passenger restraint was made over another. The Court relied on the history of such regulatory actions and the agency's explanation as to its rationale for their promulgation.[80]

As it relates to agency statements regarding preemption, if the agency statement is consistent with its historical position, consistent with its specific regulatory actions, and consistent with congressional intent, it is likely to get more deference than new declarations to the contrary. Note that President William Clinton issued an Executive Order on August 4, 1999 that discussed his administration's view on federalism and the potential impact agency regulatory conduct had on preemption.[81]

On May 20, 2009, President Barack Obama issued a memorandum to agency heads that was more focused on preemption. It essentially prohibits agencies from issuing statements regarding preemption in the preambles of regulatory announcements unless there is a specific regulation in place regarding preemption. It also advised agency heads to review regulations issued over the prior 10 years that discuss preemption and determine whether such regulations or statements are justified under the law.[82] Given that the executive branch controls most of the regulatory agencies, it is unlikely agency preemption will arise for some time.

The discussion above shows some recent actions by the U.S. Supreme Court in the area of Federal Preemption. When considering whether an action or parts of an action are preempted, a careful examination of Congress's actions over time will help to discern its intentions relative to preemption. Suits based in common law clearly can act as "requirements" which can be preempted depending on the scope of the preemption provision of a given statute or regulation; or if it can be argued that Congress intended that the federal government be the sole regulator of a product or product type involved. Further, the actions of the authorized federal regulatory agency should also be examined to see the degree to which regulated products are actually scrutinized in combination with the issue of whether a common law action serves to second guess the decisions of the agency involved.

II. Preemption Cases Decided by Illinois Courts

Illinois courts have decided a number of preemption cases over the last 15 years, although not many strictly focused on products liability. Before discussing some cases, a practice caveat is in order. One trap that the defense practitioner should avoid in Illinois is failure to raise preemption as an affirmative defense at the earliest opportunity. A failure to do so can result in it being waived. In *Haudrich v. Howmedica, Inc.*,[83] the Illinois Supreme Court held that the preemption defense was waived as it was not pled as an affirmative defense. There, the plaintiff claimed injury from a prosthetic device. The device had been subjected to pre-market approval by the FDA. After trial and an adverse verdict, the defendant argued preemption for the first time on appeal. The defendant asserted that the plaintiff's claim was preempted by the preemption provision in the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act,[84] the same statute at issue in *Lohr*[85] and *Riegel*.[86] The appellate court did not address the preemption issue. The Illinois Supreme Court, however, found that the issue was waived because it was not raised in the trial court. It rejected the argument that preemption was jurisdictional in nature and so could be raised at any time.[87]

1. *Busch v. Graphic Color Corp.*

The Illinois Supreme Court has dealt substantively with preemption in tort cases a few times in the last several years. In *Busch v. Graphic Color Corp.*,[88] a special administrator brought a wrongful death claim arising out of the decedent's use of paint stripper while cleaning ink vats. The decedent had no training in the use of paint stripper. She was married to one of the workers for the company that had contracted to clean the vats, and for unknown reasons began to clean them herself. She apparently died after being overcome by the fumes from the paint stripper. There were issues relating to the way she used the product and whether the work area had been properly ventilated. The paint stripper came in cans on which a warning was affixed. The warning label warned about the risk of overexposure to vapors and the need to use the product in a properly ventilated area.[89] The paint stripper was subject to regulation pursuant to the Federal Hazardous Substances Act[90] (FHSA).

The product supplier defendants moved for summary judgment asserting that the plaintiff's claims, which were largely focused on the adequacy of the warnings on the cans, were preempted by an express preemption provision contained in FHSA. FHSA was passed initially to create uniform requirements for warnings on packaging for hazardous products sold for household use. When FHSA was initially effective, it did not contain a preemption provision. Later in 1966, it was amended to reflect congressional concerns about warnings related claims and the notion of having 50 separate warning labels based on regulation by all the states. A preemption provision was added to prohibit requirements involving warnings and labeling that were not identical to requirements promulgated under the FHSA.[91]

In *Busch*, the defendants argued that there could not be common law claims that established a duty to provide different or other warnings than those approved by the Consumer Product Safety Commission (CPSC), the regulatory body to which Congress had delegated regulatory responsibility to regulate warning labels on products containing methylene chloride, the chemical in the paint stripper at issue. While the label in question had not been specifically approved by the CPSC, it was virtually the same as the suggested warning issued by the CPSC for products containing methylene chloride.[92]

Consistent with the United States Supreme Court's decisions discussed above, the Illinois Supreme Court examined the history of FHSA and the intent of Congress as it relates to the preemptive effect of the FHSA. It also examined the actions of the CPSC in enforcing FHSA. It noted the history and rationale for the CPSC regulatory action involving methylene chloride containing products, and its rulemaking in the face of competing interests of industry and consumer groups that gave rise to the model labeling. It determined that the CPSC had essentially decided what subjects paint stripper labels should address, that nothing different or additional need be included, and that Illinois courts should defer to this judgment. The court also expressed a willingness to defer to the CPSC's own conclusions about the preemptive effect of its actions on warning claims, as it was not contrary to the congressional intent as determined by the court. Also important to the court were decisions of the federal courts interpreting the preemption provision in FHSA as amended. It indicated that such decisions were controlling on Illinois courts so that federal statutes and regulations can be given uniform application.[93]

Finally, the court rejected the plaintiff's claims in *Busch* that there was no preemption because the information the plaintiff claimed was absent from the label in question related to a different risk of injury (asphyxiation) than that addressed by the model warning the CPSC issued (cancer). Although the court agreed that this issue fell under the subject preemption provision, it still held that the plaintiff's claims were preempted. The court found that the actions of the CPSC in creating the model language had more than one purpose even if communication of the carcinogenic risk was the primary reason for the rulemaking. The model language addressed the risk of asphyxiation and so it did address the risk that the plaintiff's decedent confronted.[94]

2. ***Sprietsma v. Mercury Marine***

A few years later, the United States Supreme Court reversed the Illinois Supreme Court in a preemption decision involving boats and outboard motors. In *Sprietsma v. Mercury Marine*,[95] the plaintiff brought a products liability action against an outboard boat motor manufacturer after the plaintiff's decedent was killed when struck by the propeller after falling out of a ski boat. The plaintiff asserted that the motor was defective because it did not have a propeller guard. The trial court found the action expressly preempted by the Federal Boat Safety Act of 1971[96] (FBSA), and the Illinois appellate court affirmed on this basis. The Illinois Supreme Court also found preemption, but not through express preemption. Instead, the court affirmed based on its finding implied preemption. It believed that the relevant regulatory agency's decision not to require propeller guards was an affirmative decision that guards not be required at all, which created the conflict between state and federal law.[97]

The U.S. Supreme Court reversed and found no preemption, express or implied. As it has in the other cases involving preemption, it discerned congressional intent relating to preemption and examined the regulatory work of the Coast Guard; the agency ultimately delegated regulatory authority for outboard motors for boats. It looked first to the preemption provision contained in the FBSA, which prohibited the establishment and enforcement of performance or safety standards different from issued regulations. But, it also noted a savings clause within the FBSA that provided compliance with such standards would not relieve a person from liability at common law.[98]

The United States Supreme Court traced the history of regulatory action under the FBSA. It noted that when the FBSA was signed into law, the United States Secretary of Transportation advised that all state laws were exempt from preemption until new regulations relating to boating safety could be issued. Over time, the Coast Guard began to issue regulations, and the United States Secretary of Transportation limited the scope of the blanket exemption from preemption consistent with the regulations as they were issued. Although the Coast Guard studied the propeller guards issue extensively, no requirement for propeller guards were ever put into place.[99]

The Court rejected the application of express preemption. It found the language of the provision at issue applied to positive state legislative or regulatory enactments only, and not to common law actions. This conclusion was supported by the existence of the savings clause.[100]

As for implied preemption, the United States Supreme Court took issue with the notion that the decision of the Coast Guard not to require propeller guards was a mandate that guards not be required at all. The Court found that decision of the Coast Guard not to act was not an affirmative decision that no guards should be required. Instead, the Court decided that the Coast Guard's decision not to act was simply a decision not to weigh in on this issue. It was not an authoritative statement against the use or requirement of propeller guards. The Court stated that, although a congressional or agency decision not to regulate could have preemptive effect, it did not in this instance. Although the Court recognized that one of FBSA's goals was to create uniform manufacturing standards, the lack of regulation on this subject in combination with the broad exemptions to preemption and the belief that allowing common law actions would promote safety necessitated a finding that the plaintiff's claims here were not preempted.[101]

3. *Mejia v. White GMC Trucks, Inc.*

There are other examples of Illinois courts dealing with preemption arguments. In *Mejia v. White GMC Trucks, Inc.*,[102] the estate of a garbage truck driver filed a wrongful death suit after the decedent was found dead on the passenger side of the truck after an accident. He was driving a garbage truck that hit a median, collided with another vehicle, and became airborne. This truck could be operated from either side. The passenger-side door was of a type that folded back, and was not a regular type of door. The passenger-side door was designed for low speed operation with the person on the passenger side being able to frequently exit. The plaintiff alleged that the passenger-side door was defective in that the latch handle on the passenger door was exposed, such that incidental contact could cause the latch to release, that the door itself was flimsy, and that the interior latch was such that it too could release with incidental contact, causing the door to open unexpectedly.[103] The defendant asserted preemption as to the plaintiff's door and door latch design claims, and the trial court entered summary judgment as to those claims.[104]

On appeal, the plaintiff argued that preemption did not apply, but the court rejected this position and affirmed the grant of summary judgment. The appellate court looked at the applicable statute, the National Traffic and Motor Vehicle Safety Act[105] (Traffic Safety Act), and found that Congress delegated the creation and promulgation of safety standards to the National Highway Transportation Safety Administration (NHTSA). The NHTSA, in turn, issued safety standards for door latches and locks with a mind toward minimizing the likelihood of occupant ejection. Although specific standards were promulgated, there was an

exemption to those standards for the type of door in this instance. The plaintiff argued that the exception did not apply to the suit, given the complaint's focus on the latches and not the door itself.[106]

The court looked at the preemption provision in the Traffic Safety Act, in conjunction with the savings clause in the statute. This clause provided compliance with the NHTSA safety standards did not relieve anyone of liability under common law. The court found the plaintiff's reading of the regulations to be too narrow, and decided that they did focus on occupant retention issues. It then found that the door at issue was specifically exempt from the regulations at issue as this door was not designed to retain occupants. As such, the court determined that this exception was evidence of an intentional decision to allow such doors, not merely a decision to simply not take action as in *Sprietsma*.[107]

4. *Osman v. Ford Motor Co.*

In *Osman v. Ford Motor Co.*,[108] the plaintiff appealed a grant of summary judgment to Ford Motor Co. (Ford) in a case where the plaintiff's decedent was killed in a one-vehicle accident. The decedent was ejected during the accident, as she was not wearing a manual lap seatbelt. The plaintiff argued that the vehicle was defective in that it did not have a different restraint system, nor did it provide a warning of the need to wear the manual lap seatbelt in addition to the automatic shoulder belt. Ford filed a summary judgment motion, arguing that the relevant safety standard issued by the NHTSA provided several options to vehicle manufacturers in terms of passenger restraint systems, and that the system in place in the decedent's vehicle was in compliance with the standard.

Ford argued implied preemption in that common law claims that a different system be used or that warnings related to such systems were preempted by virtue of the fact the NHTSA specifically regulated the issue of restraint devices to be used in passenger vehicles. The court agreed that the plaintiff's action was preempted. It found that the facts that the relevant regulation gave options to vehicle manufacturers, and that Ford complied with the regulation, meant that a common law action that would create a duty to choose one option over another was preempted. This decision also included warning claims that would require Ford to warn that the restraint option it chose was unsafe.[109]

Clearly, Illinois courts are willing and able to consider preemption claims where appropriate. Aside from the necessary statutory enactment and body of applicable regulations, one must be certain to plead a preemption affirmative defense as soon as possible so as to preserve this very important and effective defense for a dispositive motion. Beware of how the United States Supreme Court's analysis has changed over time. Just because an Illinois court decision of just a few years ago might suggest a lack of preemption does not mean the same regulatory scenario would not now give rise to a different result.

III. Discussion of Specific Federal Statutes

As federal preemption involves an examination of federal statutes and related regulations, it is useful to examine various statutes under which litigation has arisen so as to provide examples of court action and to serve as a resource for the defense practitioner. Below is by no means an exhaustive list of statutes in relation to which preemption has been used or discussed. Instead, these statutes are ones as to which a fair amount of court activity has occurred to provide useful examples of the operation of preemption, and hopefully an opportunity to continue to expand its use.

A. Federal Cigarette Labeling and Advertising Act

The Federal Cigarette Labeling and Advertising Act[110] (the FCLAA) was enacted by Congress with the intention of providing comprehensive labeling and advertising requirements for cigarettes manufactured, imported, and sold within the United States.[111] Specifically, the Act requires manufacturers use particular warning labels on packages. Section 1334(b) reads: "No requirement or prohibition based on smoking and

health shall be imposed under State law with respect to advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter."[112] These requirements necessarily preempt various state common law products liability claims.

Courts have evaluated the preemption issue with various state law claims involving cigarettes, including claims for failure to provide adequate warnings,[113] claims for design defect,[114] claims alleging conspiracy by cigarette manufacturers,[115] and state-law "Good Samaritan" claims.[116] Courts have reached similar conclusions on some of these issues and differing conclusions on others.

The United States Supreme Court first addressed the scope of the FCLAA's preemption power in *Cipollone v. Liggett Group, Inc.*,[117] where a cigarette smoker who contracted lung cancer brought claims against the manufacturer based on failure to warn, express warranty, intentional fraud, and conspiracy. A two-prong test required the Court first to examine the purpose of the FCLAA, and second to analyze the effect of the operations of the state law. The Court determined that the scope of the preemption provision was limited to the express language in the provision.[118]

Because Congress expressly defined the FCLAA's preemptive scope, matters beyond the statute's clearly defined reach are not preempted. In so reasoning, the Court held that the plaintiff's claims based on a failure to warn theory, to the extent they relied on the manufacturer's advertising or promotions, were preempted by the FCLAA.[119] The claims based on express warranty, intentional fraud and conspiracy, however, were not preempted.[120] Many courts have analyzed and applied *Cipollone* to federal preemption products liability cases; the case remains authoritative.[121]

In analyzing whether, and to what extent, courts have decided to preempt common law products liability claims relating to tobacco, various points of agreement are recognized. Congress may impliedly or expressly preempt state common law claims. If there is no such express language in the statute, preemption may be implied where the issue established by Congress is so pervasive as to "occupy the field."[122] A state law claim, however, may still be preempted, even if it does not occupy the entire field, if the state law makes compliance with the federal law impossible or if the state law would even be an obstacle to such compliance. In assessing preemption, courts have analyzed Congressional intent before superseding the state law claims.

1. Inadequate-Warning Claims

When confronted with failure-to-warn claims, many courts have held that such state law claims are preempted by the FCLAA. Some courts, however, have held that state law claims arising out of a manufacturer's alleged failure to provide adequate warnings of health risks associated with smoking prior to January 1, 1966 (the effective date of the FCLAA), are *not* preempted by the federal law.[123]

Consistent with *Cipollone*, the United States District Court for the Western District of Pennsylvania in *Stitt v. Phillip Morris Inc.* held that preemption applied to post-1969 strict liability and negligence claims to the extent they were based on concealment, failure to warn, or failure to disclose.[124] Also like *Cipollone*, this court refused to preempt state law claims based solely on the manufacturer's research, testing, or other practices unrelated to promotion or advertising.[125] A recent case from the United States District Court for the Northern District of Illinois Court held similarly in *Espinosa v. Phillip Morris*.[126] There, the court held that preemption applied to state law claims based upon failure to warn, which would require a showing that the manufacturer failed to include additional warnings, or at least failed to articulate them more clearly.[127]

State law claims of fraudulent misrepresentation also have been preempted by the FCLAA. In *Cipollone*, the United States Supreme Court held that preemption applied to claims that the manufacturer minimized the risk of negative health effects related to smoking, through the use of advertising. It, however, also stated that claims of fraud and misrepresentation are *not* preempted if they arise from a state-imposed requirement related to advertising where the underlying duty is not to deceive and not based on health.[128] Like *Cipollone*, the Texas Supreme Court in *American Tobacco Co. v. Grinnell*[129] held preemption applied to a state law claim based on allegations that the manufacturer should have provided additional or more clearly stated warnings.[130]

In *Cipollone*, the Court clarified that the plaintiff's state law claims based on a failure-to-warn theory prior to the FCLAA's effective date in 1966 were viable claims and not preempted. Other courts have followed the same reasoning. In *Tompkins v. R.J. Reynolds Tobacco Co.*,[131] the United States District Court for the Northern District of New York held that only failure-to-warn claims against the cigarette manufacturer post-1969 were preempted by the FCLAA.[132]

In some circumstances, courts have refused to preempt state common law claims under the FCLAA. The United States District Court for the District of Massachusetts in *Johnson v. Brown & Williamson Tobacco Corp.* did not hold state law claims to be preempted where the manufacturer intentionally misrepresented false statements in its advertising.[133] The United States District Court for the District of Maryland in *Shaw v. Brown & Williamson Tobacco Corp.* allowed state law claims where the plaintiff developed cancer from secondhand smoke exposure.[134] The court in that case reasoned that the FCLAA's preemption provision regarding warnings only applied to one's own smoking.[135]

2. Design Defect Claims

Generally, courts have held that design defect claims based on strict liability and negligence are not preempted by the FCLAA. For example, a federal district court in Connecticut held that the plaintiff's claim based on the allegedly defective nature of the manufacturer's cigarettes was not preempted.[136] Similarly the Eighth Circuit declined to hold that the FCLAA preempted a design-defect claim brought against a cigarette manufacturer.[137]

3. Conspiracy Claims

In this context, a conspiracy claim against a manufacturer relates to the manufacturer's alleged prevention of other parties from releasing information to the public regarding the dangers of smoking cigarettes. In *Cipollone*, the United States Supreme Court reasoned that, because conspiracy claims are based on a duty not to conspire to misrepresent or commit fraud, which is not in and of itself based on smoking and health, the FCLAA does not preempt such claims.[138] In accordance with this reasoning, the Florida District Court of Appeals in *Lashke v. Brown & Williamson Tobacco Corp.* refused to hold that the FCLAA preempted the plaintiff's claim based on the cigarette manufacturer's alleged conspiracy to conceal information.[139]

4. Good Samaritan Claims

A "Good Samaritan" claim works under the presumption that one who provides services to another, which that person should recognize are necessary to protect his life or possessions, must undertake these services exercising reasonable care. In *Gunsalus v. Celotex Corp.*, a plaintiff who developed lung cancer from smoking cigarettes brought a "Good Samaritan" claim against the cigarette manufacturer.[140] The United States District Court for the Eastern District of Pennsylvania held that the FCLAA preempted the state law "Good Samaritan" claim.[141] It applied the reasoning in *Cipollone* and found the "Good Samaritan" claim to be premised on the plaintiff's assertion that the manufacturer owed a duty to the plaintiff to provide information about the hazards of smoking.[142] The success of the state law claim necessarily depended upon a duty to warn and therefore was preempted by the FCLAA.[143]

B. Federal Food and Drug Cosmetic Act

As discussed in the prior IDC Monograph on this statute, the Federal Food and Drug Cosmetic Act of 1938[144] (the FFDCA) was enacted to regulate all matters related to pharmaceuticals. The Food and Drug Administration (FDA) enforces the FFDCA. Drug manufacturers must obtain approval from the FDA (based on a showing that a proposed new prescription drug is safe and effective) before marketing that drug.[145]

Further, for all prescription drugs, the FDA must approve the content and format of the labeling and warnings contained on the packaging.[146] Both pre and post-approval, manufacturers are required by the FFDCA to disclose to the FDA both the results of product testing and any reports of adverse reactions to the marketed drug.[147] A manufacturer's failure to comply with the FFDCA could constitute evidence of negligence in a products liability suit.[148] The FFDCA does not contain an express pre-emption provision.

1. Prescription Drugs

Until the United States Supreme Court decision in *Wyeth v. Levine*,[149] there was a split of authority among lower courts regarding whether or not the Act impliedly preempted state law cases alleging failure to warn against the manufacturers of pharmaceuticals.[150] Among the majority of cases where lower courts found the Act did not preempt state law claims, In Re *Zyprexa Products Liability Claims Litigation*,[151] illustrates the reasoning of these courts on the issue. That group of cases was initiated in the United States District Court for the Eastern District of New York due to thousands of products liability cases being filed against Eli Lilly based on failure to warn of side effects of the use of the drug, including the increased risk of hyperglycemia and diabetes. In 2000, the FDA studied whether persons taking these types of antipsychotic drugs, including Zyprexa, were at an increased risk of these conditions.[152] In 2003, based on the results of the study, the FDA mandated that the manufacturers of these drugs give warnings about the connection between use of the drugs and these possible side effects.[153] In response to this directive, Eli Lilly included such a warning in Zyprexa's labeling.[154]

Some of the plaintiffs alleged their pre-existing diabetes was made worse from taking the drug, some that they were diagnosed with diabetes after taking the drug, and one that use of the drug caused her hyperglycemia.[155] All plaintiffs asserted that the warnings placed on Zyprexa's labeling that had been approved by the FDA were not sufficient to warn their doctors about the increased risk of the side effects of hyperglycemia and diabetes. Lilly argued that the plaintiffs' claims that FDA approved warnings were inadequate should not be allowed.

The United States District Court for the Eastern District of New York focused on two issues in its decision: first, the presumption against preemption mandated by the United States Supreme Court and second, despite this presumption, whether it should give deference to the FDA's claim of preemption set forth in the preamble to a final rule made in 2006 on the labeling of prescription drugs.[156] The FDA asserted in the preamble that, because state tort law claims threatened its charge as the agency that is responsible for evaluating and regulating drugs, in situations where the FDA had approved a particular warning, failure-to-warn claims should be preempted based on conflict with federal law.[157]

After discussing various cases regarding the deference that should be given to an agency's interpretation of its own rules, the court determined that the preamble to the final FDA rule was entitled to only some deference because it was not persuasive, and was inconsistent with its previous interpretations of the FFDCA. Further, other courts had held that the FDA approval process for labeling did not preempt state law failure-to-warn claims and that the preamble was merely an advisory statement that could be changed without public involvement and that bound the FDA only.[158] As a result, the court held the defendants had not overcome the presumption against preemption, as there was no real conflict between federal law and plaintiffs' state law failure-to-warn cases and there was no clear congressional intent to preempt.[159]

Horne v. Novartis Pharmaceuticals Corp.[160] is a case that typifies the other group of decisions finding that the FFDCA preempts state law failure to warn cases. *Horne* was a case that arose when the plaintiff sued the manufacturer of Lotensin HCT, an ACE inhibitor drug used to treat hypertension. The plaintiff claimed that she took the drug while she was pregnant, until her doctor changed her prescription, and that it caused her son to be born with birth defects that caused his death.[161] Her suit alleged the labeling on Lotensin HCT should have warned that the drug could cause fetal injuries if taken in the first trimester of pregnancy.[162] The FDA had approved labeling for Lotensin HCT, which warned that taking the drug during the second and third trimesters

could cause fetal injury and stated that no link had been established between use of the drug and fetal injuries if taken in the first trimester.[163] The plaintiff's cause of action sounded in negligence, wantonness, failure to warn, breach of warranty, fraudulent misrepresentation, and concealment.[164]

The court in *Horne* agreed with the defendant's contention that the plaintiff's claims conflicted with the "pregnancy category classifications and warnings approved and mandated by the FDA for products containing ACE inhibitors, such as Lotensin HCT" and held that the plaintiff's failure-to-warn claims were preempted.[165] The court spoke to the issue of how much deference to give to the FDA's preamble regarding preemption. It agreed with the plaintiff that it would usually look to Congress's intent in the absence of express preemption and assume in that situation that Congress did not intend to preempt state law.[166] The court, however, also stated that federal law may preempt state law in the event of actual conflict, even if Congress had no intent to preempt.[167]

In deciding that the plaintiff's claims were preempted, the court compared the *Horne* situation to the facts of *Sykes v. Glaxo-SmithKline*,[168] wherein the United States District Court for the Eastern District of Pennsylvania found that when the FDA had approved drug labeling, the plaintiff's proposed warning would directly conflict with the FDA-approved warning and held that federal law preempted state law claims for failure to warn.[169] Similar to the findings in *Sykes*, the court in *Horne* found, regarding the plaintiff's proposed warning, that the plaintiff had not presented any studies from the time she was pregnant that showed that birth defects could be caused if Lotensin HCT was used in the first trimester; nor had she shown that the defendant had any "reasonable evidence" at the time she was pregnant that would have required a change in Lotensin HCT's labeling.[170]

It is against this backdrop that the United States Supreme Court decided *Wyeth v. Levine* and rejected the drug company Wyeth's preemption arguments.[171] The Court based its holding on the defendant's failure to show that it was impossible for it to follow both the proposed state standard and the applicable federal standards regarding its labeling of the drug at issue and on its finding that the possible state-court-imposed standard was not an obstacle to the FDA's labeling scheme.[172]

The Supreme Court's holding in *Wyeth*, however, left unanswered preemption issues that remain unresolved. First, it is undecided whether or not state tort law claims are preempted on conflicts grounds if the FDA is aware of a risk and does not require a change in labeling. Next, the Court's holding in *Wyeth* does not speak to the issue of whether claims against generic drug manufacturers are preempted because FDA regulations do not allow the labels for those drugs to deviate from those of the drugs for which they are substitutes.

Colacicco v. Apotex, Inc.[173] was a case decided before *Wyeth* in which the United States District Court for the Eastern District of Pennsylvania found that failure-to-warn claims were preempted in situations where the FDA had reviewed issues with a particular drug but had determined there was insufficient scientific evidence to warrant a change in the drug's label. The United States Court of Appeals for the Third Circuit affirmed the decision of the district court and the plaintiffs filed a writ of certiorari with the United States Supreme Court.[174]

The Supreme Court, after its decision in *Wyeth*, vacated the *Colacicco* decision and remanded the case to the Third Circuit to further consider the case in light of holding in *Wyeth*.[175] The Third Circuit vacated its judgment and remanded the case back to the district court for the same purpose.[176] That case currently is pending and it is unclear whether the Court's opinion in *Wyeth* will cause the district court to reconsider its holding, taking into account the Supreme Court's declaration in that case that a strong presumption against preemption should be used in implied preemption cases and reconsider its refusal to give the FDA's preamble on preemption much deference. The Court's holding that it is primarily a drug manufacturer's responsibility to assure its drugs' safety should weaken the defense argument regarding field preemption.

2. Generic Drug Cases

Since the United States Supreme Court's decision in *Wyeth*, several courts have addressed the issue of whether the Act FFDCA preempts state law failure-to-warn claims against the manufacturers of generic drugs who fail to make the labeling on their products stronger. Most of these have found against preemption.[177]

Mensing v. Wyeth, Inc.[178] was one such case where the United States Court of Appeals for the Eight Circuit held that the FFDCA did not preempt failure-to-warn cases against generic drug manufacturers.[179] The plaintiff sued the manufacturer of the drug, Reglan and generic iterations of that drug, asserting that the drug caused her to develop tardive dyskenesia and that the drug's label failed to warn about the risk of development of that condition when the drug was used long term.[180] The district court found the claims preempted under the FFDCA and the plaintiff appealed.[181]

On appeal the Eighth Circuit considered the Supreme Court's prescribed presumption against preemption in *Wyeth*, and stated that brand name drug manufacturers were not the Supreme Court's only focus. The Eighth Circuit noted that it must be skeptical about any claim that Congress intended to impliedly grant tort immunity to the majority of prescription drug manufacturers.[182] The defendant argued it was impossible for it to modify existing FDA-approved labeling. The court again invoked the Supreme Court's language in noting that impossibility was a demanding defense. The Eighth Circuit noted that generic drug manufacturers are unable to make a change in labeling that is inconsistent with the brand name drug's label. Unconvinced that this showed impossibility, the court held that the company could have proposed a label with adequate warnings. The FDA would have considered such a proposal and possibly imposed it uniformly upon all manufacturers of the drug.[183]

Absent clear evidence that the FDA would not have approved the proposed language, the Eighth Circuit could not conclude it was impossible for the defendant to comply with both state and federal requirements.[184] The court also cited federal regulations related to generic drug manufacturers that require them to revise their labels "as soon as there is reasonable evidence of an association of a serious hazard with a drug."[185] Finally, the Eighth Circuit determined, considering the same factors that the relied upon by the Supreme Court in *Wyeth*, that field preemption did not apply in this case.[186]

C. Medical Device Amendments of 1976

At the time of the last IDC Monograph on the subject of preemption pursuant to the Medical Device Amendments of 1976 (MDA) to the Federal Food and Drug Cosmetic Act (FFDCA),[187] *Medtronic, Inc. v. Lohr*[188] had just been decided by the United States Supreme Court and its effects were not yet known. As discussed above, in that case, the Court held that state law claims alleging defective products are not always preempted by the MDA. The case was remanded to the Court of Appeals for the Eleventh Circuit.[189] On remand, the Eleventh Circuit reversed the dismissal of the plaintiff's complaint and remanded the case to the district court. [190]

The MDA groups medical devices into three classes: Class I are devices that do not present an unreasonable risk of illness or injury and are only minimally regulated. Class II devices are those that have the potential to be more harmful and are required to comply with federal regulations known as "special controls." Finally, the devices which are the subject of most litigation in this area, Class III devices, are "for a use in supporting or sustaining human life," or present "a potential unreasonable risk of illness or injury."[191]

Class III devices are highly regulated and subject to one of two sorts of pre-market review by the FDA before they can be placed on the market for sale. Class III devices proposed after the enactment date of the MDA must clear the FDA's pre-market approval (PMA) process.[192] PMA procedures require an entity applying for FDA approval of such a device to disclose to the FDA "all information, published or known . . . or which should reasonably be known . . . concerning investigations which have been made to show whether or not such device is safe and effective,"[193] and make a statement fully explaining the design, components, and intended use of the device, describing the methods of manufacturing and processing, describing proposed

labeling plus any other information the FDA may request.[194] The FDA may request that a panel of experts review a proposed device's application and file a report with its recommendations.[195]

The FDA will grant PMA only if it is reasonably assured that the product is both effective and safe under the conditions of use described on its label and if it has decided the label is not false or misleading.[196] Manufacturers of medical devices are also subject to the FDA's "current good manufacturing practice" requirements (CGMP requirements).[197] These requirements describe detailed quality control measures that must be taken during the manufacturing process, the labeling, the packaging, the storage, and the installation of the device, to be sure the device is safe and effective. The manufacturers of the device must adopt practices in conformance with these requirements, which include inspection and quality assurance, design and manufacturing specifications, and others related to cleanliness, timing, and preventive and corrective action.[198] Post-approval reporting of device failure that might have caused death or serious injury is also required.[199]

Medical devices can obtain FDA approval through a less onerous process known as premarket notification or the "501(k)" process. Through this process, clearance from the FDA can be sought and granted by submitting a "premarket notification" application which assures the FDA that the proposed product is either "substantially equivalent" to a Class I or a Class II device already being marketed or to a Class III device being sold before the MDA was enacted in 1976 if the FDA has not decided whether to reclassify the device as either Class I or Class II or to require PMA approval.[200] The FDA will not grant 501(k) approval unless it is convinced that the proposed device will be used in the same way and is as safe and effective as the device already on the market.[201]

Regarding preemption, the FFDCA contains a provision that expressly preempts state law claims that impose any "requirement" that is "different from, or in addition to, any requirement applicable under this chapter" and "which relates to the safety or effectiveness of the device."[202] The United States Supreme Court has addressed the issue of preemption pursuant to the FFDCA in three seminal cases: *Buckman Co. v. Plaintiffs' Legal Committee*,[203] *Riegel v. Medtronic, Inc.*,[204] and *Medtronic, Inc. v. Lohr*.[205]

In *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court determined that the United States was the only possible plaintiff in a "fraud on the FDA" state law claim and that such claim, therefore, was preempted by the regulatory scheme.[206] The Court distinguished between the FDA "policing against fraud" and a private litigant's state common law causes of action against the manufacturers of medical devices: the former, not entitled to a presumption against preemption, and the latter entitled to such a presumption.[207] *Buckman* should be read, in the context of *Lohr* and *Riegel*, as a narrow holding that applies to fraud on the FDA only.

Medtronic, Inc. v. Lohr[208] was the Supreme Court's first interpretation of the FFDCA, and the Court decided that the FFDCA's express preemption language does not preempt state law claims of negligence and strict liability regarding a device that was approved via the 501(k) process.[209] The Court held that this process was not a "requirement" under the FFDCA's provisions, and that state law claims were not preempted by the general manufacturing requirements of the FDA, as they were not specific to a particular device.[210]

Years later, in *Riegel v. Medtronic, Inc.*,[211] the Supreme Court had the opportunity to decide the meaning of the FFDCA's express preemption provision in the context of a Class III device for which the FDA had granted PMA. The Court concluded that states may impose different or additional remedies than those imposed under federal law with no preemption, but may not impose different or additional requirements.[212] The Court noted that Class III devices that had been granted PMA had to be manufactured with "almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness."[213]

The Court, therefore, found that state law claims are preempted only in so far as they require something different than federal law requires and that if conduct proscribed by state law is the same as that which is prohibited by the FDA, state law claims are not expressly preempted.[214] Reading *Lohr* and *Riegel* together, along with the FDA's regulations regarding certain claims exempted from preemption, might indicate that

there are some state law claims regarding devices that comply with the CGMP requirements and that would not be preempted.

Since *Riegel*, the decisions on preemption issues reiterate the Court's holding that parallel state common law actions based on alleged violations of federal regulations are not preempted. Many courts, however, continue to find preemption based on imposition of ultra-stringent pleading standards pursuant to the Court's holding in *Bell Atlantic Corp. v. Twombly*[215] or by incorrectly requiring that state causes of action be based on CGMP requirements. Below are some courts' holdings regarding various sorts of state law claims.

1. Design Defect

Regarding design defect claims, any such claim that calls into question the FDA's findings as to the safety of a device's design is preempted, as it would impose requirements different or in addition to those of the FFDCA.[216]

2. Failure to Warn

After being granted PMA, a manufacturer must follow strict reporting requirements so the FDA is assured that the device in question continues to be safe and effective and is not adulterated or misbranded. State causes of action for failure to warn usually are not preempted if they are based on a manufacturer's failure to follow the regulations regarding labeling or failure to report problems with a device.[217]

Before *Riegel*, several courts had held that state law claims based on a duty to warn after the sale of a device were preempted. *Gomez v. St. Jude Medical Daig Division, Inc.*,[218] *McMullen v. Medtronic, Inc.*,[219] and *Cupek v. Medtronic, Inc.*[220] are examples of such holdings. Relevant is the fact that the court in *McMullen* did not find a regulatory violation when a drug manufacturer failed to issue a warning before FDA approval of proposed labeling changes, despite the fact that federal regulations (21 C.F.R. 814.49 and 21 C.F.R. 821.1) allow manufacturers to "enhance" previously approved labels and require tracking recipients of the device at issue.[221] A salient common factor in these cases is that the manufacturers involved apparently reported adverse events in a timely manner. Had the cases involved a scheme to evade or delay a recall or failure to timely report adverse effects pursuant to federal regulations, a different result could have been appropriate in light of *Riegel*.[222]

The preemption issue also arises in cases regarding medical devices for which the FDA approves a device and labeling for a particular use or condition but which are actually used for some purpose other than that for which they are approved. Those cases concern failure to provide adequate label content to cover the other uses to which the device may be put.[223] The FDA is cognizant that "off label" uses for medical devices occur and regulates labeling accordingly. The regulation requires a manufacturer who knows, "or has knowledge of facts that would give him notice" that a particular device will be used for some condition or purpose other than that for which it is approved, draft labeling adequate to take those other uses into account.[224]

To be sure these requirements were clear, the FDA issued a proclamation guiding the labeling for "off label" uses which distinguishes between the desired dissemination of information regarding unapproved uses for a device and "promotion" of the device for "off label" uses.[225] *Riley v. Cordis Corp.*[226] is a case where plaintiff avoided preemption by basing his case on the illegal promotion of a device for which adequate warnings and directions for "off label" use were not given.[227]

3. Breach of Warranty

Regarding express warranty claims, courts have held consistently that claims that a device failed to live up to the promises made in its labeling and package inserts are not preempted. These cases, based in a bargain between the parties, are not found to be at odds with the premarket approval process. In *Mitchell v. Collagen Corp*.[228] the court found that the plaintiff was not claiming that the FDA-approved label for a hip replacement

was defective, but rather that the hip implanted did not fit the description given on the label and that this discrepancy resulted in harm. For that reason, the plaintiff's claim was not preempted.[229]

D. The National Childhood Vaccine Injury Compensation Act

The National Childhood Vaccine Injury Compensation Act[230] (Vaccine Act), created a system whereby individuals injured by vaccines typically administered to children can obtain compensation without the costs of litigation. Under this approach, victims file a petition to the "Vaccine Court" and can recover damages from a trust without having to prove causation, negligence, or defect. In addition, vaccine manufacturers avoid the expenses of litigation and potentially large tort awards, which could otherwise cause manufacturers to withdraw from the childhood vaccine production industry.

Although the Vaccine Act is intended to prevent plaintiffs from filing traditional tort actions, it includes the following provision: "State law shall apply to a civil action brought for damages for a vaccine-related injury or death."[231] Despite this savings clause, courts nevertheless have held that the Vaccine Act preempts certain state law actions. For example, the Court of Appeals for the Third Circuit in *Bruesewitz v. Wyeth Inc.*[232] decided that the Vaccine Act preempted claims of strict liability and negligent design defect.[233] In *American Home Products Corp. v. Ferrari*,[234] the court found that the Vaccine Act does not necessarily preempt all design defect claims, but rather protects manufacturers from liability for design defect claims for vaccines deemed "unavoidably unsafe."[235] Unavoidably unsafe products are those which, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use."[236] Whether a product is unavoidably unsafe is a question to be determined using case-by-case scrutiny.[237]

Uncertainty regarding the Vaccine Act's preemptive scope could be clarified soon. In March 2010, the United States Supreme Court, after granting certiorari from *Bruesewitz*, agreed to consider whether the Vaccine Act preempts all strict liability and negligent design defect claims against manufacturers of childhood vaccines.[238] In analyzing this case, the Third Circuit held that the Vaccine Act creates a mandatory forum for claims against vaccine manufacturers.[239] The ambiguity within the Vaccine Act, however, exists because, although Section 300aa-22(a) permits state law claims, Subsection (b) prevents claims against manufacturers if the injury or death results from unavoidable side effects arising from a properly prepared vaccine. Because the Vaccine Act is ambiguous as to the scope of preemption of state law, the Third Circuit in *Bruesewitz* analyzed legislative history and concluded that the Vaccine Act's purposes would be futile if design defect claims were permitted.[240] The appellate court concluded that, taking on case-by-case analyses of whether a manufacturer conceivably could have developed a safer vaccine, which is effectively what the plaintiff in that case suggested, would be costly, time-consuming, and would frustrate congressional intent in enacting the Vaccine Act.[241]

The Supreme Court heard oral arguments in *Bruesweitz* on October 12, 2010, but as of the date of this printing has not issued an opinion. The determination, when made, should offer insight into the current scope of the Vaccine Act's preemptive power.

E. Federal Insecticide, Fungicide and Rodenticide Act

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[242] was transformed by amendment in 1972 from a "labeling law into a comprehensive regulatory statute."[243] "As amended, FIFRA regulated the use, as well as the sale and labeling, of pesticides; regulated pesticides produced and sold in both intrastate and interstate commerce; provided for review, cancellation, and suspension of registration; and gave [the Environmental Protection Agency (EPA)] greater enforcement authority."[244] These amendments also added environmental safety as a criterion for registration.[245]

The EPA is given authority, pursuant to FIFRA, to register covered products, thus regulating their sale.[246] A manufacturer that desires to register a pesticide must submit to the EPA a proposed label along with certain

data that supports the request.[247] The EPA will register the proposed pesticide if, after review, it decides that: the pesticide is effective,[248] the pesticide will not cause unreasonable adverse effects on people or the environment,[249] and its label does not contain language that constitutes "misbranding."[250] "Misbranding" occurs if a pesticide's label contains any statement that is "false or misleading in any particular" (including a false or misleading statement about a pesticide's efficacy).[251] A pesticide is also considered "misbranded" if its label omits adequate instructions for the product's use or omits needed warnings or cautionary statements.[252]

FIFRA contains an express preemption clause, which states: "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."[253] Historically, there have been two types of claims that potentially are preempted pursuant to FIFRA: first, that due to improper representations, warnings, instructions, or warranties given by a manufacturer about a product's quality, crops have been damaged or a crop's yield was not as large as it should have been; and second, claims alleging that a personal injury occurred due to exposure to a product.

Cipollone v. Liggett Group, Inc.,[254] a seminal case interpreting the Public Health Cigarette Smoking Act,[255] was most significant and had the most influence on interpretation of FIFRA's preemption clause. Virtually all federal courts that considered FIFRA preemption after the decision in *Cipollone* noted the similarity between the preemption language considered by the United States Supreme Court in that case and FIFRA's preemption language. Each of those courts determined that FIFRA preempted any tort claim based on improper labeling or failure to warn.[256] State courts, however, were not as single minded in their analysis of FIFRA's preemption clause.[257]

The lack of uniformity among the state courts on the issue,[258] the United States Supreme Court's decision in *Medtronic, Inc. v. Lohr*,[259] and the resulting decision on remand[260] set the stage for the Supreme Court to analyze FIFRA's preemption language and to clarify its application. *Lohr* dealt with regulation of medical devices under the Medical Device Amendment and the applicable preemption language was very similar to that contained in FIFRA. However, the Medical Device Amendment analyzed in *Lohr* did not provide a detailed process for evaluation of a proposed device as opposed to FIFRA's very detailed format for regulating the content of labels. This difference in the two statutes decreased the significance of *Lohr*'s impact on evaluation of FIFRA preemption.

The United States Supreme Court clarified preemption pursuant to FIFRA with its decision in *Bates v. Dow Agrosciences, LLC.*[261] The Court's pronouncements in *Bates* have informed both state and federal court decisions since that time.

One such case, *Peterson v. BASF Corp.*,[262] was decided by the Minnesota Supreme Court. The case dealt with claims by farmers who were parties to a class action suit alleging that the defendant violated New Jersey state law when it deceptively marketed two herbicides. The farmers alleged that each of the herbicides at issue contained equal amounts of its active ingredients and were both registered for use on the same crops. The defendant, to pursue a marketing strategy designed to maximize profits, allegedly sought to prevent the farmers from learning that the lower priced herbicide was equal to the higher priced one.[263]

The Minnesota Supreme Court had the case on remand from the United States Supreme Court, which had granted the defendant, BASF Corp. (BASF), a writ on the preemption issue in light of the recently decided *Bates* case.[264] On remand, BASF argued that the plaintiffs' consumer fraud claims formed the basis of the case and were preempted by FIFRA.[265] In considering BASF's position, the court surveyed both FIFRA and prior case law and engaged in a detailed discussion of *Bates*. From the court's reading of *Bates*, it concluded that the standards for finding preemption pursuant to FIFRA adopted by the United States Supreme Court in that case were narrower than the Minnesota Supreme Court had applied in its earlier decision in the case. The Minnesota Supreme Court had applied an "effects-based" test (whether one could reasonably foresee that the manufacturer, in order to avoid liability, would choose to alter the product or its label).[266] The United States Supreme Court in *Bates* rejected that test as too broad.[267] The Minnesota Supreme Court noted the United States Supreme Court's rejection of an effects-based test, along with its determination that warranty and fraud claims based on oral representations, even those that were equal to statements on the product's label, were not

preempted because they were not requirements for labeling or packaging.[268] Based on this reasoning, the Minnesota Supreme Court concluded that "state regulation must be very directly related to labeling and packaging in order to invoke FIFRA preemption."[269]

The Minnesota Supreme Court found that the activities in which BASF engaged, although violative of the New Jersey Consumer Fraud Act,[270] did not concern the labeling or packaging of the products at issue, but rather concerned deceptive advertising, literature, and misrepresentations to state authorities.[271] The court found that this conduct was the same as the oral representations in *Bates*, which the United States Supreme Court found not to be preempted by FIFRA.[272] The farmers' claims, therefore, were not preempted.

Another recent case regarding FIFRA preemption arose in the United States District Court for the District of Idaho. The plaintiffs in *Adams v. United States of America*[273] alleged that the United States Bureau of Land Management (BLM) chose and used an herbicide on range and non-crop land that, due to wind drift, damaged crops on the plaintiffs' land. The manufacturer of the herbicide at issue, DuPont, sought summary judgment based on preemption under FIFRA for claims that the labels it used on the herbicide were misleading, or false, or both, because they "did not contain adequate instructions and omitted necessary warnings."[274] The court cited *Bates* for the proposition that "[a] state rule that is 'equivalent to, and fully consistent with, FIFRA's misbranding provisions' need not explicitly incorporate FIFRA's standards to avoid preemption."[275] The court found that the plaintiffs' claims "appear[ed] to track FIFRA" requirements and rejected DuPont's argument that because the EPA had reviewed the product's label and approved it, the plaintiffs' claims were an attempt to impose requirements in addition to those required by FIFRA.[276]

F. The Federal Hazardous Substances Act

The Federal Hazardous Substances Act[277] (FHSA) was enacted 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."[278] In 1966 an amendment to the FHSA included a "limited preemption" provision, which states:

> [I]f a hazardous substance or its packaging is subject to a cautionary labeling requirement under Section 2(p) or 3(b) [15 U.S.C. § 1261(p) or § 1262(b)] 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 designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under 2(p) or 3(b).[279]

This provision seeks to prevent various states from creating their own cautionary labeling standards, while still allowing states to regulate the sale and use of hazardous substances.[280] Courts have held that "when a statute only preempts state requirements that are different from or in addition to those imposed by federal law, plaintiffs may still recover under state tort law when defendants fail to comply with the federal requirements."[281]

In *Moss v. Parks Corp.*, the court concluded that a plaintiff may bring a common law tort action based on a failure to warn only if the claim is based on non-compliance with the existing federal regulations.[282] A plaintiff, however, cannot seek more stringent labeling requirements.[283] Such a claim would be preempted by the FHSA.

In a recent decision, a federal district court in the state of Washington similarly concluded that a state law failure-to-warn claim existed only if the state law labeling requirements are identical to those under the FHSA.[284] More specifically, the court decided that to the extent the Washington Products Liability Act[285] (WPLA) required more extensive labeling requirements than those under the FHSA, the plaintiff's failure-to-warn claim would be preempted.[286] On the other hand, to the extent the WPLA had the same requirements as under the federal regulations, the plaintiff's claims would not be preempted.

G. The National Manufactured Housing and Safety Standards Act

The National Manufactured Housing Construction Safety Standards Act[287] of 1974 (the Manufactured Homes Act) was enacted to decrease deaths, injuries, property damage, and insurance costs incurred due to accidents in "manufactured homes," and to upgrade quality and durability of those homes.[288] The Manufactured Homes Act contains two preemption provisions. First, an express preemption provision, Section 5403(d), provides that "no State or political subdivision of a State shall have the authority either to establish, or continue in effect, with respect to any manufactured home covered, any standard regarding the 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."[289] Second, the savings clause, Section 5409(c), states that "compliance with any Federal manufactured home construction or safety standard issued under this chapter [of the Manufactured Homes Act] does not exempt any person from liability under common law."[290]

Further, regulations made by the Department of Housing and Urban Development (HUD) pursuant to the Manufactured Homes Act contain similar preemptive language wherein no state or locality may establish or enforce any rule or regulation that "stands as an obstacle to accomplishment and execution of the full purposes and objectives of Congress."[291]

The prior IDC Monograph on this subject reported that the effect of these two sections on the issue of preemption of claims based on state law had been the subject of conflicting interpretation in both state and federal courts. The issues and holdings have not changed significantly since that time, although both state and federal courts generally have found that state common law claims are not preempted, as long as the claims do not seek to enforce state manufactured home standards that are not identical to a federal standard applicable to the same aspect of performance. One group of cases holding that state law failure-to-warn claims are not preempted is typified by the holdings in *Shorter v. Champion Home Builders Co.*[292] and *Mizner v. North River Homes, Inc.*[293]

In *Shorter*, the United States District Court for the Northern District of Ohio found that state common law failure-to-warn claims for injury due to dangerous levels of formaldehyde in a mobile home were not preempted. The court determined that, based on the legislative history of the Manufactured Homes Act, Congress's intent of reducing personal injuries in mobile homes would not be frustrated by allowing state law claims to proceed.[294] Further, the court found that reading the preemption provisions contained in the Manufactured Homes Act together indicates that they preempt state law standards but not state law claims.[295]

The Supreme Court of Missouri, in *Mizner*, allowed claims based on state laws to proceed, reading the two preemption provisions together and finding that the first provision prohibited state "standards" (legislative or administrative standards), while the second did not affect the state's common law.[296] Similarly, the United States District Court for the Eastern District of Texas, in *Richard v. Fleetwood Enterprises, Inc.*,[297] held that the Manufactured Homes Act generally does not preempt causes of action based in state law, and noted that Section 5409(c) of the Manufactured Homes Act states that compliance with it does not exempt anyone from liability under common law.

In *Choate v. Champion Home Builders Co.*,[298] the Court of Appeals for the Tenth Circuit found that the Manufactured Homes Act does not expressly preempt common law actions nor exclusively occupy the area of construction and safety of manufactured homes so as to impliedly preempt common law actions. The court in *Choate* compared the preemption clauses contained in the Manufactured Homes Act to those contained in the statute interpreted by the United States Supreme Court in *Geier v. American Honda Motor Co.*,[299] and in keeping with the Court's interpretation of that statute, declared that the preemption clause in the Manufactured Homes Act was meant to expressly preempt only state statutes and regulations and not actions brought under state common law.[300]

The other group of cases includes courts that have found that common law claims against a manufacturer of mobile homes are preempted. Most notably, the Texas Court of Appeals in *Macmillan v. Redman Homes,*

Inc.,[301] found that, although claims could be brought in state court for a manufacturer's violation of formaldehyde standards set by HUD, claims based on formaldehyde standards other than HUD's were preempted. The court in *Macmillan* explained how the two preemption sections could be read in harmony in its holding that state courts may litigate only those safety issues not covered by federal standards and that compliance with federal law does not protect a mobile home manufacturer from claims concerning areas not covered by federal law.[302] Similarly, in *Gianakakos v. Commodore Home Systems Inc.*,[303] the Court of Appeals of the State of New York held that claims regarding failure to comply with state regulations were preempted.

Preemption under the Manufactured Homes Act has come up quite often in the context of state law claims for injury due to exposure to formaldehyde in manufactured homes. Both state and federal courts have found that the Manufactured Homes Act does not explicitly preempt those claims. In *Richard*, plaintiffs alleged there was excessive formaldehyde in the manufactured home they had purchased from the defendant and that they had been sickened by it. The district court determined that state law strict liability, gross negligence, and breach of warranty claims were not preempted.[304]

In its consideration of the preemption issue, the district court discussed that the Manufactured Homes Act did not preempt state causes of action explicitly, nor was there any indication of "clear or manifest congressional intent for the federal regulation of the safety and sale of manufactured housing to completely occupy the field."[305] While giving dealers and distributors a remedy against the manufacturer of a mobile home, the court noted, the Manufactured Homes Act does not provide a remedy for the purchaser of such a home. The purchaser has remedies at common law, which are not preempted.[306]

The Supreme Court of Appeals of West Virginia analyzed the preemption issue in *Harrison v. Skyline Corp.*,[307] where the plaintiffs claimed that the defendant manufacturers negligently left debris containing formaldehyde-treated floor decking in the ductwork of their manufactured home. The plaintiffs alleged they were exposed "to toxic levels of formaldehyde" from the heated forced air moving over the debris.[308] The court held that the plaintiffs' state law negligence claim was not preempted, either expressly or impliedly.[309]

The court reviewed the Manufactured Homes Act, and citing the courts' holdings in *Geier* and *Richard*, determined that, although HUD had specific regulations regarding the acceptable level of formaldehyde in a manufactured home, it had not established a standard for "the proper disposal of formaldehyde treated materials during the manufactured home construction process."[310] The plaintiffs, by their claim, the court concluded, were proposing a state common law performance standard for disposal of formaldehyde-treated materials. Because this standard was unregulated by HUD and would not "thwart" the Manufactured Homes Act's objectives of "protecting the quality, durability safety and affordability of manufactured homes" the court held that their state law claim was not preempted.[311]

Another group of formaldehyde exposure cases, *In re: FEMA Trailer Formaldehyde Products Liability Litigation*,[312] concerned the use of Federal Emergency Management Agency (FEMA) trailers after hurricanes Katrina and Rita. The plaintiffs, tenants who lived in FEMA trailers, claimed that they were exposed to high levels of formaldehyde that was present in the trailers and were damaged due to the exposure and the lack of adequate warnings about the dangers of formaldehyde exposure in the trailers.[313] The plaintiffs asserted that an "ambient air standard" should have been used to minimize emissions of formaldehyde in manufactured housing rather than the HUD-approved "product standard."[314]

The United States District Court for the Eastern District of Louisiana held that HUD's formaldehyde regulations for trailers were meant to preempt state and local regulations on that substance, and that if the states desired to regulate those same matters then the state regulations had to be identical to the federal.[315] The court determined that, pursuant to the preemption provisions set forth in the Manufactured Homes Act, state courts may regulate matters not covered by federal standards, and that compliance with federal standards does not protect a defendant from claims regarding matters not covered by federal law. Because plaintiffs sought to enforce a standard for measuring legally permissible levels of formaldehyde in manufactured homes, which differed from that required by federal regulations, that claim was preempted.[316]

H. The National Traffic and Motor Vehicle Safety Act

The National Traffic and Motor Vehicle Safety Act (Traffic Safety Act) was enacted in 1966 with the intention of establishing unified standards of automobile safety[317] to reduce traffic related injuries and death.[318] Under the Traffic Safety Act, a state "may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle . . . only if the standard is identical to the standard prescribed under this chapter."[319] Along with this preemption provision, the Traffic Safety Act includes a savings clause, which reads: "Compliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law."[320] Courts have struggled with interpreting these two provisions together and therefore have both preempted and preserved state law claims related to the Traffic Safety Act.

To better understand how the Traffic Safety Act has been held to preempt common law claims expressly, to preempt common law claims impliedly, or to not preempt claims, the following analysis focuses on cases involving the installation of airbags. Standard 208, promulgated under the Traffic Safety Act, provides automobile manufacturers with three options for protecting front-seat passengers, any of which the manufacturer could implement and be in compliance with the federal standard.[321]

In *Johnson v. General Motors Corp.*, a plaintiff asserted a state law claim against an automobile manufacturer for failure to install airbags in the vehicle.[322] The United States District Court for the Western District of Oklahoma found the claim to be preempted expressly by the Traffic Safety Act. It reasoned that the purpose of creating uniform motor vehicle standards would be frustrated if individual states were able to impose liability on manufacturers for failing to install airbags.[323] In interpreting the savings clause, the court stated that the clause applies to matters not covered by the federal standards for design or manufacturing defects. Similarly, the Seventh Circuit in *Hurley v. Motor Coach Industries, Inc.*[324] held that a claim was preempted under Illinois products liability law that was in conflict with Standard 208 of the Traffic Safety Act.[325] Under the tenets of Illinois products liability law, the plaintiff was required to, and did, propose an alternative design to the alleged unreasonably dangerous condition. The proposed design would have precluded the manufacturer from exercising an option under Standard 208.[326] The court concluded that the state suit is preempted when a state law forecloses one or more options under Standard 208.

Some courts have reached the same conclusion, but instead have found preemption of state law claims implied through the Traffic Safety Act. The United States Supreme Court in *Geier v. American Honda Motor Co.*[327] found that the state tort law was an obstacle to Standard 208 and posed an actual conflict to this regulation.[328] As such, the Court held that the plaintiff's claims were preempted.[329] In *Wood v. General Motors Corp.*,[330] a plaintiff filed suit against an automobile manufacturer for failing to install airbags in a vehicle in which she was injured.[331] Although the goal of the design defect claim was the same as that of the Traffic Safety Act – to increase motor safety – the court concluded that the theory of recovery is preempted by Standard 208 and the Traffic Safety Act. Because the claim interfered with the methods of achieving the Traffic Safety Act's purpose, the court held it impliedly was preempted.[332]

In some situations, courts have concluded that the Traffic Safety Act does not preempt state law claims. For example, in the recent decision of *Durham v. County of Maui*,[333] the United States District Court for the District of Hawaii permitted a state law claim alleging negligence for failing to equip an automobile with side-impact airbags. The court held that federal law did not preempt the claim, because the Traffic Safety Act does not address side-impact airbags.[334] Other courts simply have interpreted the savings clause as preserving common law actions in claims relating to airbags.[335]

I. The Locomotive Inspection Act

The Locomotive Inspection Act[336] (LIA), originally known as the Boiler Inspection Act,[337] was passed in 1911, and amended in 1915 and 1924. It provides, among other things, that a railroad carrier may use or allow to be used a locomotive or tender on its railroad line only where the locomotive or tender and its "parts and

appurtenances . . . are in proper condition and safe to operate without unnecessary danger of personal injury."[338] The LIA does not contain any express preemption language.

The United States Supreme Court specifically considered the scope of preemption pursuant to the LIA in *Napier v. Atlantic Coast Line Railroad Co.*[339] The Court concluded that the Boiler Inspection Act "extends to the design, the construction and the material of every part of the locomotive's tender and of all appurtenances."[340] The Court held that "state legislation is precluded, because the Boiler Inspection Act, as we construe it, was intended to occupy the field."[341] The Court reasoned that the fact that the "[Interstate Commerce] Commission has not seen fit to exercise its authority to the full extent conferred . . . has no bearing upon the construction of the act delegating the power."[342]

Preemption pursuant to the LIA was considered recently by the United States Court of Appeals for the Third Circuit in *Kurns v. A.W. Chesterton Inc.*,[343] and the LIA's preemptive effect, established under the provisions of its precursor, was reaffirmed.[344] In *Kurns*, the wife and estate of a railroad worker who died from mesothelioma filed a products liability suit in a Pennsylvania state court. The plaintiffs alleged that their decedent was exposed to asbestos from the various defendants' products, including exposure to asbestos from railroad brake shoes and engine valves used on locomotives and that this exposure caused decedent's mesothelioma.[345] After all but two defendants were granted summary judgment, the case was removed to the United States District Court for the Eastern District of Pennsylvania due to the lack of diversity.[346] The manufacturers of the railroad brake shoes and engine valves filed motions for summary judgment on the grounds that the plaintiffs' claims were preempted by the LIA.[347] The district court granted the defendants' motions for summary judgment, deciding that the plaintiffs' state law tort claims were preempted by the LIA. Based on *Napier*, the district court held that the LIA "occupies the field of regulating locomotives and locomotive parts used in Interstate Commerce."[348]

The plaintiffs appealed from the district court's order. On appeal, the Third Circuit considered the plaintiffs' assertions that state law claims sounding in failure to warn and design defect are not preempted by the LIA. The plaintiffs attempted to distinguish between regulations of locomotive equipment and railroad workers' state law claims for personal injury due to a manufacturer's failure to warn about hazardous substances released during repair of locomotives. The distinction was rejected by the court.[349] The Third Circuit affirmed the district court's holding that the LIA preempted all state law claims pursuant to field preemption and quoted *Law v. General Motors Corp.*:[350] "It has long been settled that Congress intended federal law to occupy the field of locomotive equipment and safety, particularly as it relates to injuries suffered by railroad workers in the course of their employment."[351]

The appellate court in *Kurns* held that brake pads and engine valves were "clearly locomotive equipment" and fell within the LIA's scope.[352] The court also discussed the LIA's rationale and intent to "prevent the paralyzing effect on railroads from prescription by each state of the safety devices obligatory on locomotives that would pass through many of them."[353]

The appellate court then noted that, although the specific issue regarding whether a state law claim arising out of workplace exposure to asbestos while working with railroad parts was one of first impression for a federal appeals court, the supreme courts in a number of states had considered the issue and virtually all held such claims to be preempted.[354] The appellate court specifically discussed the Supreme Court of Appeals of West Virginia's complete survey of all relevant case law and its conclusion that:

> In spite of the strong presumption against federal preemption . . . , an overwhelming body of case law persuades us that, through passage of the Boiler Inspection Act, Congress has occupied the field of railroad safety so pervasively that Plaintiffs' claims against the defendants are preempted.[355]

The appellate court in *Kurns* agreed with "the vast majority of courts that have been called upon to decide the issue of the scope of LIA preemption."[356] The court held that because the plaintiffs' state law claims involved the material used in locomotive parts, they were preempted.[357]

J. The Flammable Fabric Act

The Flammable Fabric Act[358] (FFA) was enacted to prevent states from establishing their own individual standards or regulations for flammable fabrics that are not identical to federal standards,[359] unless the state standard provides a higher degree of protection than the federal standard.[360] The scope of remedies available under the FFA for violations of flammability standards is limited to injunctive relief, criminal penalties and seizure of materials.[361] Courts, therefore, have held that the FFA does not preclude the pursuit of private remedies. In considering Congress' concern for the plight of burn victims, courts have permitted state court recognition of civil remedies based on standards different from federal standards.[362]

In *Raymond v. Riegel Textile*, the Court of Appeals for the First Circuit held that the application of New Hampshire's strict liability standard in tort actions involving flammable fabric was not inconsistent with the FFA's purposes.[363] The court recognized that the FFA was created as a means by which the United States Secretary of Commerce may continually update flammability standards when necessary.[364] Such intent should not prevent strict liability standards from being applied in these types of cases. Courts have also decided that the fact that fabric surpasses flammability standards under the FFA is not conclusive evidence that the fabric is not unreasonably dangerous.[365]

In cases involving the FFA, courts typically allow state law claims to go forward. For example, in *Davis v. New York City Housing Authority*, the Appellate Division of the Supreme Court of the state of New York held that the FFA did not preempt claims of negligence, strict liability, or breach of implied warranty.[366] Although courts generally have chosen not to hold that the FFA preempts state common law claims, the United States District Court for the Eastern District of California in *Upholstered Furniture Action Council v. California Bureau of Home Furnishings*[367] did just that. The court reasoned that Congress intended the non-regulation by states of this particular area of law and therefore Congress sought to prohibit states from imposing statutes inconsistent with the FFA.[368] As such, the court decided that a California statute governing flammability of certain upholstered furniture was in conflict with the FFA and therefore was preempted.[369] Note that this result is inconsistent with the decision of courts to permit state common law claims relating to the FFA.[370]

Conclusion

Federal preemption can be an extremely valuable defense. Rather than filing broad based, sweeping motions to dismiss or summary judgment motions, defense counsel should look carefully at the applicable federal statutes and regulations in conjunction with the allegations in the suit to determine if some or all of the plaintiff's claims are preempted. Once congressional intent is determined, and all applicable regulations are identified and examined, defense counsel should juxtapose the allegations against the backdrop of congressional and agency regulatory action. Look to see whether some or all of the plaintiff's claims attempt to deviate from the regulatory framework imposed at the federal level. Then, decide whether Congress, through its enactments or the regulations or opinions of the relevant regulatory agency, determined whether claims that deviate from the existing federal regulatory framework are permitted. If not, then seek dismissal of any such claims. Courts have a receptive ear toward the applicability of preemption should the right scenario be presented.

(Endnotes)

[1] *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608 (1992).

[2] Daniel K. Cray et al., *The IDC Monograph: Federal Preemption Defenses in Product Liability Cases*, IDC QUARTERLY, Vol. 6, No. 3 (1996).

[3] U.S. CONST., art. VI, cl. 2.

[4] *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 125 S. Ct. 1788 (2005); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S. Ct. 2240 (1996); *Cipollone*, 505 U.S. at 504.

[5] *Lohr*, 518 U.S. at 475.

[6] *Cipollone*, 505 U.S. at 518.

[7] *Id.* at 516; *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 229-31, 67 S. Ct. 1146, 1151-52 (1947).

[8] *See Cipollone*, 505 U.S. at 516, 520-522.

[9] *See Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 204, 103 S. Ct. 1713, 1722 (1983).

[10] *See Rice*, 331 U.S. at 230.

[11] *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S. Ct. 399, 404 (1941).

[12] *Cipollone*, 505 U.S. at 516.

[13] *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485-91, 116 S. Ct. 2240, 2250-53 (1996).

[14] *Sprietsma v. Mercury Marine*, 537 U.S. 51, 59-63, 123 S. Ct. 518, 524-27 (2002).

[15] *Cipollone*, 505 U.S. at 525-26.

[16] *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230-31, 67 S. Ct. 1146, 1151-52 (1947).

[17] *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608 (1992).

[18] *Cipollone*, 505 U.S. at 508-10.

[19] Pub. L. No. 89-92, 79 Stat. 282 (1965), codified as amended at 15 U.S.C. §§ 1331-1340.

[20] Pub. L. No. 91-222, 84 Stat. 87 (1969), codified as amended at 15 U.S.C. §§ 1331-1340.

[21] *Cipollone*, 505 U.S. at 510-12.

[22] *Id.* at 516-17.

[23] Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, § 5 (1965) (current version at 15 U.S.C. § 1334).

[24] *Id.* § 4; *see also Cipollone*, 505 U.S. at 514.

[25] *Cipollone*, 505 U.S. at 518-20.

[26] Pub. L. No. 91-222, 84 Stat. 87 (1969), codified at 15 U.S.C. § 1334(b); *Cipollone*, 505 U.S. at 515.

[27] *Cipollone*, 505 U.S. at 520-22.

[28] *Id.* at 523-24.

[29] *Id.* at 524-25.

[30] *Id.* at 525-27.

[31] *Id.* at 527-30.

[32] *Id.* at 530-31.

[33] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S. Ct. 2240 (1996).

[34] Pub. L. No. 94-295, 90 Stat. 539 (1976).

[35] 21 U.S.C. §§ 301 to 399 (2007); *see also infra* Section III.B.

[36] *Lohr*, 518 U.S. at 475-81.

[37] 21 U.S.C. § 360k(a) (1993), *quoted in Lohr*, 518 U.S. at 481-82;.

[38] *Lohr*, 518 U.S. at 477-48.

[39] *Id.* at 475-80.

[40] *See Duncan v. Iolab Corp*., 12 F.3d 194 (11th Cir 1994); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992).

[41] *Lohr*, 518 U.S. at 482-84.

[42] *Id.* at 486-91.

[43] *Id.* at 492-94.

[44] *Id.* at 497-501.

[45] *Id.* at 497-98, n.17.

[46] *Id.* at 500-02.

[47] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S. Ct. 999 (2008).

[48] *Riegel*, 552 U.S. at 320-21.

[49] *Id.* at 330.

[50] *Id.* at 317-23.

[51] *Id.* at 324-26.

[52] *See infra* Sections III.B.1 and III.C.1.

[53] *Riegel*, 552 U.S. at 327-29.

[54] *Id.* at 328-30.

[55] *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 125 S. Ct. 1788 (2005).

[56] 7 U.S.C. § 136, *et seq.* (2000).

[57] *Bates*, 544 U.S. at 434-39, 128 S. Ct. at 1792-95.

[58] Tex. Bus. & Com. Code Ann § 17.01, *et seq.* (West 2002).

[59] *Bates*, 544 U.S. at 435-36.

[60] 7 U.S.C. §136v, *et seq.* (2001), quoted in *Bates*, 544 U.S. at 439.

[61] *Bates*, 544 U.S. at 437-40.

[62] *Id.* at 443-44.

[63] *Id.* at 443-46.

[64] *Id.* at 451-54.

[65] *Id.* at 451-52.

[66] *Id.* at 449-54.

[67] *Wyeth v. Levine*, __ U.S. __, 129 S. Ct. 1187 (2009).

[68] *Levine*, 129 S. Ct. at 1191-93.

[69] *Id.* at 1193-95.

[70] 21 U.S.C. §§ 301 to 399 (2007); *see also supra* Section I.B.2; *infra* Section III.B.

[71] Pub. L. No. 94-295, 90 Stat. 539 (1976).

[72] *Levine*, 129 S. Ct. at 1196-97.

[73] *Id.* at 1194-97.

[74] *Id.* at 1199-1200.

[75] *Id.* at 1199-1200.

[76] *Levine*, 129 S. Ct. at 1200-01.

[77] *Id.* 129 S. Ct. at 1201-04.

[78] *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S. Ct. 1913 (2000).

[79] 49 C.F.R. § 571.208 (1997) (Standard 208).

[80] *Geier*, 529 U.S. at 875-86.

[81] Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (1999).

[82] Preemption, Memorandum for the Heads of Executive Departments and Agencies (May 20, 2009), 74 Fed. Reg. 24,693 (May 22, 2009).

[83] *Haudrich v. Howmedia, Inc.*, 169 Ill. 2d 525, 662 N.E.2d 1248 (1996).

[84] 21 U.S.C. §§ 301 to 399 (2007); *see also supra* Section I.B.2; *infra* Section III.B.

[85] *See supra* Section I.B.2.

[86] *See supra* Section I.B.3.

[87] *Haudrich*, 169 Ill. 2d at 535-40.

[88] *Busch v. Graphic Color Corp.*, 169 Ill. 2d 325, 662 N.E.2d 397 (1996).

[89] *Busch*, 169 Ill. 2d at 345.

[90] 15 U.S.C. § 1261, *et seq.* (1988).

[91] The preemption provision provided in relevant part:

> [I]f a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) 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 designed 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).

Pub. L. No. 94-284 (codified at 15 U.S.C. § 1261(b)(1)(A) (1988)).

[92] *Busch*, 169 Ill .2d at 341-45.

[93] *Id.* at 335-45.

[94] *Id.* at 345-47.

[95] *Sprietsma v. Mercury Marine*, 537 U.S. 51, 123 S. Ct. 518 (2002).

[96] 46 U.S.C. §§ 4301-4311 (1971).

[97] *Sprietsma*, 537 U.S. at 54-55.

[98] *Id.* at 57-59.

[99] *Id.* at 57-62.

[100] *Id.* at 62-64.

[101] *Id.* at 64-70.

[102] *Mejia v. White GMC Trucks, Inc.*, 336 Ill. App. 3d 702, 784 N.E.2d 345 (1st Dist. 2002).

[103] *Mejia*, 336 Ill. App. 3d at 703-04.

[104] *Id.* at 704.

[105] 49 U.S.C. § 30101, *et seq.* (2000).

[106] *Mejia*, 336 Ill. App. 3d at 707.

[107] *Id.* at 705-10.

[108] *Osman v. Ford Motor Co.*, 359 Ill. App. 3d 367, 833 N.E.2d 1011 (4th Dist. 2005).

[109] *Osman*, 359 Ill. App. 3d at 372-80.

[110] 15 U.S.C. § 1333 (2010).

[111] *Lacey v. Lorillard Tobacco Co.*, 956 F. Supp. 956, 959 (N.D. Ala. 1997) (*citing* 15 U.S.C. §§ 1333 to 1340 (2010)).

[112] 15 U.S.C. § 1334(b) (2010).

[113] *See infra* Section III.A.1.

[114] *See infra* Section III.A.2.

[115] *See infra* Section III.A.3.

[116] *See infra* Section III.A.4.

[117] *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608 (1992); *see also supra* Section I.B.1.

[118] *Cipollone*, 505 U.S. at 517.

[119] *Id.* at 530-31.

[120] *Id.* at 531.

[121] *Farina v. Nokia Inc.*, 625 F.3d 97, 118-21 (3d Cir. 2010).

[122] Beverly L. Jacklin, Annotation, *Federal Pre-emption of State Common-law Products Liability Claims Pertaining to Tobacco Products*, 97 A.L.R. Fed. 890 (1990).

[123] *See, e.g., Gunsalus v. Celotex Corp.*, 674 F. Supp. 1149 (E.D. Pa. 1987); *Laschke v. Brown & Williamson Tobacco Corp.*, 766 So.2d 1076 (Fla. Dist. Ct. App. 2000).

[124] *Stitt v. Philip Morris Inc.*, 245 F. Supp. 2d 686, 692 (W.D. Pa. 2002).

[125] *Stitt*, 245 F. Supp. 2d at 692.

[126] *Espinosa v. Phillip Morris USA, Inc.*, 500 F. Supp. 2d 979 (N.D. Ill. 2007).

[127] *Espinosa*, 500 F. Supp. 2d at 983 (*citing Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 524, 112 S. Ct. 2608 (1992)).

[128] *Cipollone*, 505 U.S. at 529.

[129] *American Tobacco Co. v. Grinnell*, 951 S.W.2d 420 (Tex. 1997).

[130] *Grinnell*, 951 S.W.2d at 440.

[131] *Tompkins v. R.J. Reynolds Tobacco Co.*, 92 F. Supp. 2d 70, (N.D.N.Y. 2000).

[132] *Tompkins*, 92 F. Supp. 2d at 86.

[133] *Johnson v. Brown & Williamson Tobacco Corp.*, 122 F. Supp. 2d 194, 203 (D. Mass. 2000).

[134] *Shaw v. Brown & Williamson Tobacco Corp.*, 973 F. Supp. 539, 547 (D. Md. 1997).

[135] *Shaw*, 973 F. Supp. at 545.

[136] *Izzarelli v. R.J. Reynolds Tobacco Co.*, 117 F. Supp. 2d 167, 175 (D. Conn. 2000).

[137] *Boerner v. Brown & Williamson Tobacco Corp.*, 394 F.3d 594, 600 (8th Cir. 2005).

[138] *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530, 112 S. Ct. 2608, 2624-25 (1992); *see also supra* Section I.B.1.

[139] *Laschke v. Brown & Williamson Tobacco Corp.*, 766 So.2d 1076, 1078 (Fla. Dist. Ct. App. 2000).

[140] *Gunsalus v. Celotex Corp.*, 674 F. Supp. 1149, 1155 (E.D. Pa. 1987).

[141] *Gunsalus*, 674 F. Supp. at 1157.

[142] *Id.*

[143] *Id*. at 1156-57 (*quoting Cipollone v. Liggett*, 789 F.2d 181, 187 (3d Cir. 1986)).

[144] 21 U.S.C. §§ 301 to 399 (2007); *see also supra* Section I.B.2.

[145] *Id.* § 355.

[146] 21 C.F.R. § 314.70(b)(3)(i) (2008).

[147] *Id.* §§ 314.80(c), (j); 314.81(b)(2)(i).

[148] 21 U.S.C. § 352 (2006).

[149] *Wyeth v. Levine*, __ U.S. __, 129 S. Ct. 1187 (2009); *see also supra* Section I.B.5.

[150] Courts in the following cases did not find preemption: *Horne v. Novartis Pharms. Corp.*, 541 F. Supp. 2d 768 (W.D.N.C. 2008); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289 (E.D. Pa. 2007); In Re *Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230 (E.D.N.Y. 2007); *Perry v. Novartis Pharms. Corp.*, 456 F. Supp. 2d 678 (E.D. Pa. 2006); *Adesina v. Aladan Corp.*, 438 F. Supp. 2d 329 (S.D.N.Y. 2006); *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006).

[151] In re *Zyprexa*, 489 F. Supp. 2d 230 (E.D.N.Y. 2007).

[152] In re *Zyprexa*, 489 F. Supp. 2d at 248.

[153] *Id.*

[154] *Id*. at 249.

[155] *Id.* at 253-62.

[156] *Id.* at 240.

[157] *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006).

[158] In re *Zyprexa*, 489 F. Supp. 2d 230, 272-74 (E.D.N.Y. 2007) (citing *Auer v. Robbins*, 519 U.S. 452, 117 S. Ct. 905 (1997); *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778 (1984); and *Skidmore v. Swift & Co.*, 323 U.S. 134, 140, 65 S. Ct. 161 (1944)).

[159] In re *Zyprexa*, 489 F. Supp. 2d at 274, 276.

[160] *Horne v. Novartis Pharms. Corp.*, 541 F. Supp. 2d 768 (W.D.N.C. 2008).

[161] *Horne*, 541 F. Supp. 2d at 772.

[162] *Id.* at 772-73.

[163] *Id.* at 773-75.

[164] *Id.* at 775.

[165] *Id.*

[166] *Id.* at 781 (quoting *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654, 115 S. Ct. 1671 (1995)).

[167] *Horne*, 541 F. Supp. 2d at 781.

[168] *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289 (E.D. Pa. 2007).

[169] *Horne*, 541 F. Supp. 2d at 782.

[170] *Id.* at 783.

[171] *See supra* Section I.B.5.

[172] *See supra* note 73 and accompanying paragraph.

[173] *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008), *judgment vacated by* 129 S. Ct. 1578 (2009) (mem.) (remanding the case for further consideration in light of *Wyeth v. Levine*, __ U.S. __, 129 S. Ct. 1187 (2009)).

[174] *Colacicco v. Apotex, Inc.*, 129 S. Ct. 1578, 1578 (2009) (mem).

[175] *Colacicco*, 129 S. Ct. at 1578.

[176] *See Colacicco v. Apotex, Inc.*, No. 05-5500, 2009 WL 4729883, at *1 (E.D. Pa. Dec. 10, 2009).

[177] *See, e.g., Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009); *Bartlett v. Mutual Pharm. Co.*, 659 F. Supp. 2d 279 (D.N.H. 2009); *Morris v. Wyeth, Inc.*, 642 F. Supp. 2d 677 (W.D. Ky. 2009); *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262 (W.D. Okla. 2009).

[178] *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009).

[179] *Mensing*, 588 F.3d at 614.

[180] *See Mensing v. Wyeth*, 562 F. Supp. 2d 1056, 1057 (D. Minn. 2008).

[181] *Id.* at 1064-65.

[182] *Mensing*, 588 F. 3d at 607.

[183] *Id.* at 608.

[184] *Id.* at 610-11.

[185] *Id.* at 608-09 (*quoting* 21 C.F.R. § 201.57(e) (2009)).

[186] *Id.* at 612; *see also Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010); *Stacel v. Teva Pharmaceuticals*, 620 F. Supp. 2d 899 (N.D. Ill. 2009).

[187] 21 U.S.C. §§ 301 to 399 (2007); *see also supra* Section I.B.2 and Section III.B.

[188] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S. Ct. 2240 (1996).

[189] *Lohr*, 518 U.S. at 503.

[190] *Lohr v. Medtronic, Inc.*, 98 F.3d 618 (11th Cir. 1996).

[191] 21 U.S.C. § 360c(a)(1)(A)-(C) (2006).

[192] *Id.* §§ 360c(a)(1)(C); 360e; 360e(b)(1)(A).

[193] *Id.* § 360e(c)(1)(A).

[194] *Id.* § 360(c)(1)(B)-(G); *see also* 21 C.F.R. § 814.20 (2010).

[195] 21 C.F.R. § 814.40 (1997).

[196] 21 U.S.C. § 360e(d)(1)(A), 360e(d)(2) (2006).

[197] *Id.* § 360j(f); 21 C.F.R. § 820, *et seq.* (2010).

[198] 21 C.F.R. § 820.1 (2010).

[199] *Id.* § 803.50(a)(1)-(2); *see also* 21 U.S.C. § 360(i)(a)(1) (2006).

[200] Medical Devices; Order for Certain Class III Devices; Submission of Safety and Effectiveness Information, 74 Fed. Reg. 16,214-02 (Apr. 9, 2009).

[201] *See* 21 U.S.C. § 360c(i)(1)(A).

[202] *Id.* § 360k(a) (2006).

[203] *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 121 S. Ct. 1012 (2001).

[204] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S. Ct. 999 (2008); *see also supra* Section I.B.3.

[205] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S. Ct. 2240 (1996); *see also supra* Section I.B2.

[206] *Buckman Co.*, 531 U.S. at 348.

[207] *Id.* at 349 (*quoting* 21 U.S.C. § 337(a)).

[208] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S. Ct. 2240 (1996); *see also supra* Section I.B.2.

[209] *Lohr*, 518 U.S. at 484, 502.

[210] *Id.* at 500-02.

[211] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S. Ct. 999 (2008); *see also supra* Section I.B.3.

[212] *Riegel*, 555 U.S. at 330 (citing *Lohr*, 518 U.S. at 495).

[213] *Id.* at 323.

[214] *See* 21 U.S.C. § 360k(a)(2) (2006).

[215] *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955 (2007); *see also Heisner* ex rel. *Heisner v. Genzyme Corp.*, No. 08-C-593, 2008 WL 2940811 (N.D. Ill. July 25, 2008) (dismissing claims of product defect but allowing plaintiff to amend complaint to plead sufficient facts regarding violation of FDA reporting requirements).

[216] *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009); *see also Bausch v. Stryker Corp.*, No. 08-C-4248, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008).

[217] *Riegel*, 552 U.S. at 334.

[218] *Gomez v. St. Jude Med. Daig Div. Inc*., 442 F.3d 919 (5th Cir. 2006).

[219] *McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005).

[220] *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005).

[221] *McMullen*, 421 F.3d at 489-90.

[222] *See Heisner* ex rel. *Heisner*, 2008 WL 2940811, at *5; *but see* In re *Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1159-61 (D. Minn. 2009).

[223] *See* 21 C.F.R. § 801.4 (1999).

[224] *Id.*

[225] 99 C.F.R. §§ 101(a)(3-4); 103(a)(4)(i).

[226] *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009).

[227] *Riley*, 625 F. Supp. 2d at 783-84.

[228] *Mitchell v. Collagen Corp.*, 126 F.3d 906, (7th Cir. 1997).

[229] *Mitchell*, 126 F.3d at 915.

[230] 42 U.S.C. §300aa-1.

[231] *Id.* § 300aa-22(a).

[232] *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009).

[233] *Bruesewitz*, 561 F.3d at 242.

[234] *American Home Prods. Corp. v. Ferrari*, 284 Ga. 384, 668 S.E.2d 236 (2008).

[235] *American Home Prods. Corp.*, 668 S.E.2d at 242.

[236] *Id*. at 239 (*quoting* Restatement (Second) of Torts § 402A cmt. K (2010)).

[237] *Id.*

[238] *Bruesewitz v. Wyeth Inc.*, ___ U.S. ____, 130 S. Ct. 1734 (2010).

[239] *Bruesewitz*, 561 F.3d at 235.

[240] *Id.* at 246.

[241] *Id.* at 249.

[242] 7 U.S.C. § 136, *et seq*. (2006).

[243] *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991, 104 S. Ct. 2862, 2867 (1984).

[244] *Ruckelshaus*, 467 U.S. at 991-92.

[245] *Id.* at 992.

[246] 7 U.S.C. § 136a(c)(1)(c) (2006).

[247] *Id.*

[248] *Id.* § 136a(c)(5)(a).

[249] *Id.* § 136a(c)(5)(c).

[250] *Id.* § 136(c)(5)(B); 40 C.F.R. § 152.112(f) (2009).

[251] 7 U.S.C. § 136(q)(1)(A) (2006); 40 C.F.R. § 156.10(a)(5)(ii) (2009).

[252] 7 U.S.C. §§ 136(q)(1)(F), (G) (2006).

[253] *Id.* § 136v(b).

[254] *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608 (1992); *see also supra* Section I.B.1.

[255] 15 U.S.C. §§ 1331-1340 (2006).

[256] *See Worm v. American Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993) (holding that a claim by farmers for injury to crops was preempted, but the claims for negligent testing, manufacturing, and formulating were not); *King v. E.I. DuPont De Nemours & Co.*, 996 F.2d 1346 (1st Cir. 1993) (finding that Maine tort law claims based on failure of herbicide manufacturer to provide adequate warnings on product labels were preempted); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364 (7th Cir. 1993) (finding that state failure-to-warn claims based on defect in label preempted); *Kuiper v. American Cyanamid Co.*, 913 F. Supp. 1236 (E.D. Wis. 1996) (rejecting distinction between failure-to-warn claims, which are based on labeling and packaging, and misrepresentation claims arising from false statements in advertising and promotional materials).

[257] *See Schuver v. E.I. DuPont De Nemours & Co.*, 546 N.W.2d 610 (Iowa 1996) (holding FIFRA preempts farmers' claims for injury or crop loss); *Jenkins v. Amchem Prods., Inc.*, 256 Kan. 602, 886 P.2d 869 (1994) (same); *Goodwin v. Bacon*, 896 P.2d 673 (Wash. 1995) (same); *Gorton v. American Cyanamid Co.*, 194 Wis. 2d 203, 533 N.W.2d 746 (1995) (holding, at least as to claims based on promotional materials, advertisements, and oral statements, that they were not preempted).

[258] See *Kuiper*, 913 F. Supp. at 1236; *Etcheverry v. Tri-Ag Serv., Inc.*, 22 Cal. 4th 316, 993 P.2d 366 (2000); *American Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002).

[259] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S. Ct. 2240 (1996); *see also supra* Section I.B.2.

[260] *Lohr v. Medtronic, Inc.*, 98 F.3d 618 (11th Cir. 1996).

[261] *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 125 S. Ct. 1788 (2005); *see also supra* Section I.B.4.

[262] *Peterson v. BASF Corp.*, 711 N.W.2d 470 (Minn. 2006).

[263] *Peterson*, 711 N.W.2d at 473.

[264] *Id.* at 474.

[265] *Id.* at 475.

[266] *Id.* at 478.

[267] *Bates*, 544 U.S. at 445; *see also supra* Section I.B.4.

[268] *Peterson*, 711 N.W.2d at 479.

[269] *Id.*

[270] N.J. Stat. Ann. § 56.8-2 (West 2001).

[271] *Peterson*, 711 N.W.2d at 479.

[272] *Id.* at 481.

[273] *Adams v. United States*, 622 F. Supp. 2d 996 (D. Idaho 2009).

[274] *Id.* at 1009.

[275] *Id.* at 1010 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447, 125 S. Ct. 1788, 1788 (2005)).

[276] *Id.*

[277] 15 U.S.C. § 1261, *et seq.* (1988).

[278] House Comm. on Interstate & Foreign Commerce, Federal Hazardous Substances Labeling Act, H.R. Rep. No. 1861, 86th Congress, 2d Session 3 (1966), *reprinted in* 1966 U.S.C.C.A.N. 4095, 4096; *Moss v. Parks*, 985 F.2d 736, 739 (4th Cir. 1993).

[279] Pub. L. No. 94-284 (codified at 15 U.S.C. § 1261(b)(1)(A) (1988)).

[280] *Chemical Specialties Mfrs.' Ass'n, Inc. v. Allenby*, 958 F.2d 941, 950 (9th Cir. 1992).

[281] *Mattis v. Carlon Elec. Prods.*, 295 F.3d 856, 862 (8th Cir. 2002) (citing *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988, 993 (8th Cir. 1994)).

[282] *Moss*, 985 F.2d at 740.

[283] *Id.*

[284] *Wilson v. Sherwin-Williams*, No. C09-5333, 2010 WL 2569179, at *6 (W.D. Wash. June 22, 2010).

[285] Wash. Rev. Code Ann. § 7.72.030 (West, Westlaw through Laws of 2011).

[286] *Wilson*, 2010 WL 2569179, at *7.

[287] 42 U.S.C. §§ 5401-5426 (2000).

[288] 42 U.S.C. § 5401 (2000).

[289] 42 U.S.C § 5403(d) (2000).

[290] *Id.* § 5409(c).

[291] 24 CFR § 3282.11(d) (2007).

[292] *Shorter v. Champion Home Builders Co.*, 776 F. Supp. 333, (N.D. Ohio 1991).

[293] *Mizner v. North River Homes, Inc.*, 913 S.W.2d 23 (Mo. Ct. App. 1996).

[294] *Shorter*, 776 F. Supp. at 338.

[295] *Id.*

[296] *Mizner*, 913 S.W.2d at 25.

[297] *Richard v. Fleetwood Enterprises, Inc.*, 4 F. Supp. 2d 650, 657 (E.D. Tex. 1998).

[298] *Choate v. Champion Home Builders Co.*, 222 F.3d 788, 796-97 (10th Cir. 2000).

[299] *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S. Ct. 1913 (2000); *see also supra* I.B.6.

[300] *Choate*, 222 F.3d at 793-94.

[301] *Macmillan v. Redman Homes, Inc.*, 818 S.W.2d 87 (Tex. Ct. App. 1991).

[302] *Macmillan*, 818 S.W.2d at 97.

[303] *Gianakakos v. Commodore Home Sys. Inc.*, 285 A.D. 2d 907, 727 N.Y.S.2d 806 (N.Y. App. Div. 2001).

[304] *Richard v. Fleetwood Enterprises, Inc.*, 4 F. Supp. 2d 650, 657 (E.D. Tex. 1998).

[305] *Richard*, 4 F. Supp. 2d at 657.

[306] *Id.* at 655, 657.

[307] *Harrison v. Skyline Corp.*, 224 W. Va. 505, 686 S.E.2d 735 (2009).

[308] *Harrison*, 686 S.E.2d at 739.

[309] *Id.* at 515-16.

[310] *Id.* at 745.

[311] *Id.* at 745-46 (citing 42 U.S.C. § 5401(b)(1)).

[312] *In re FEMA Trailer Formaldehyde Prods. Liab. Litig.*, 620 F. Supp. 2d 755 (E.D. La. 2009).

[313] *In re FEMA Trailer Formaldehyde Prods. Liab. Litig.*, 620 F. Supp. 2d at 756.

[314] *Id.* at 763.

[315] *Id.* at 765 (citing *Macmillan v. Redman Homes, Inc.*, 818 S.W.2d 87 (Tex. Ct. App. 1991)).

[316] *Id.* at 766.

[317] *See Pokorny v. Ford Motor Co.*, 902 F.2d 1116, 1122 (3d Cir. 1990).

[318] 49 U.S.C. § 30101 (1995).

[319] *Id.* § 30103(b)(1) (1995).

[320] *Id.* § 30103(e).

[321] 49 C.F.R. § 571.208 (1979).

[322] *Johnson v. General Motors Corp.*, 889 F. Supp. 451 (W.D. Okla. 1995).

[323] *Johnson*, 889 F. Supp. at 457.

[324] *Hurley v. Motor Coach Industries, Inc.*, 222 F.3d 377 (7th Cir. 2000).

[325] *Hurley*, 222 F.3d at 381.

[326] *Id.* at 383.

[327] *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S. Ct. 1913 (2000); *see also supra* I.B.6.

[328] *Geier*, 529 U.S. at 881.

[329] *Id.* at 886.

[330] *Wood v. General Motors Corp.*, 865 F.2d 395 (1st Cir. 1988).

[331] *Wood*, 865 F.2d at 396.

[332] *Id.* at 408.

[333] *Durham v. County of Maui*, 696 F. Supp. 2d 1150 (D. Haw. 2010).

[334] *Durham*, 696 F. Supp. 2d at 1160.

[335] *See, e.g., Nelson v. Ford Motor Co.*, 108 Ohio App. 3d 158, 670 N.E.2d 307 (Ct. App. 1995) (holding that the Traffic Safety Act preserves common law claims and therefore does not preempt a state claim against a manufacturer for failing to install airbag).

[336] 49 U.S.C. § 20701-20703 (2010).

[337] *Kurns v. A.W. Chesterton Inc.*, No. 09-1634, 2010 WL 3504312, at *4 n.3 (3d Cir. Sept. 9, 2010).

[338] 49 U.S.C. § 20701.

[339] *Napier v. Atlantic Coast Line R.R. Co.*, 272 U.S. 605, 47 S. Ct. 207 (1926).

[340] *Napier*, 272 U.S. at 611.

[341] *Id.* at 613.

[342] *Id.*

[343] *Kurns v. A.W. Chesterton Inc.*, No. 09-1634, 2010 WL 3504312, at *1 (3d Cir. Sept. 9, 2010).

[344] *Kurns*, 2010 WL 3504312, at * 7.

[345] *Id.* at *1.

[346] *Id*.

[347] *Id.*

[348] *Id.*

[349] *Id.* at *5.

[350] *Law v. General Motors Corp*., 114 F.3d 908 (9th Cir. 1997).

[351] *Kurns*, 2010 WL 3504312, at * 4 (quoting *Law*, 114 F.3d at 910).

[352] *Kurns*, 2010 WL 3504312, at *4.

[353] *Id.* (quoting *Oglesby v. Delaware & Hudson Ry. Co.*, 180 F.3d 458, 460 (2d Cir. 1999)).

[354] *Kurns*, 2010 WL 3504312, at *5; *see, e.g.*, *General Motors Corp. v. Kilgore*, 853 So.2d 171, 176-80 (Ala. 2002); *Schneiding v. General Motors Corp*., 22 Cal.4th 471, 993 P.2d 996, 998-1004 (2000); *Darby v. A-Best Prods. Co.*, 811 N.E.2d 1117, 1125-26 (Ohio 2004); In re *W. Va. Asbestos Litig.*, 215 W. Va. 39, 592 S.E.2d 818, 822 (2003).

[355] In re *W. Va. Asbestos Litig.*, 592 S.E.2d at 822.

[356] *Kurns*, 2010 WL 3504312, at *5.

[357] *Id.* at * 6.

[358] 15 U.S.C. § 1203 (2008).

[359] *Id.* § 1203(a).

[360] *Id.* § 1203(b).

[361] *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1026 (1st Cir. 1973).

[362] *Raymond*, 484 F.2d at 1028.

[363] *Id.* at 1027.

[364] *Id.*

[365] *Brech v. J.C. Penney Co., Inc.*, 698 F.2d 332, 334 (8th Cir. 1983).

[366] *Davis v. New York City Hous. Auth.*, 246 A.D.2d 575, 668 N.Y.S.2d 391 (1998).

[367] *Upholstered Furniture Action Council v. California Bureau of Home Furnishings*, 415 F. Supp. 63 (E.D. Ca. 1976).

[368] *Upholstered Furniture Action Council*, 415 F. Supp. at 65.

[369] *Id.*

[370] *See Wilson v. Bradlees of New England*, 96 F.3d 552, 559 (1st Cir. 1996) (concluding that the plaintiff's common law claims of design defect and failure to warn regarding shirts that caught fire was not preempted by the FFA); *Pack v. E.R.O. Industries*, 669 N.Y.S.2d 995, 996 (N.Y. App. Div. 1998) (holding the FFA does not preempt the plaintiff's claims for negligence, strict liability, and breach of implied warranties); *Askenazi v. Hymil Mfg.*, 648 N.Y.S.2d 895, 900 (N.Y. App. Div. 1996) (permitting the plaintiff's state law tort claims against fabric manufacturers despite the recent narrowing of the holding in *Cipollone* by the court in *Medtronic Inc. v. Lohr*).

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