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PREEMPTION

Recent Supreme Court decisions and announcements from the Obama administration indicate that courts and agencies may be increasingly reluctant to find preemption, say attorneys Brett H. Oberst and Matthew C. Wickersham in this BNA Insight. If preemption becomes less viable as a defense, companies will be left to guess, at great risk and expense, what they must do to satisfy their legal obligations and avoid liabilities.

The authors contend regulatory compliance may fill this gap, as its rationale in tort law is to reduce the risk of inconsistent state litigation where the defendant has complied with extensive regulations that were created to prevent the same risks and injuries at issue in the litigation. Agencies also have wide access to experts in the field, and through public comment, can draw upon additional expertise and viewpoints, a process that stands in stark contrast to litigation, where one or more experts on each side present their perspectives, and a judge or jury decides the issue based on limited information and in the context of an individual case, the authors say.

A New (and Old) Twist on Preemption—the Regulatory Compliance Defense

BY BRETT H. OBERST
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Companies that spend significant time and resources to comply with extensive federal and state regulations are understandably frustrated by tort lawsuits seeking to impose new liabilities and obligations on top of those regulations. While regulations are subject to notice, public comment and an extensive administrative record that define the legal obligations imposed, common law tort claims can proceed based on

the simple allegation that the defendant ''should have known better.''

Historically, corporate defendants have relied upon the doctrine of preemption to defeat such claims, arguing that a comprehensive scheme of regulations expressly or impliedly preempted common law tort claims. However, recent Supreme Court decisions and announcements from the Obama administration indicate that courts and agencies may be increasingly reluctant to find preemption. If preemption is a less viable defense, companies are left to guess, at great risk and expense, what else they must do to satisfy their legal obligations and avoid liabilities. In addition, if companies are forced to act in an *ad hoc* manner to avoid such claims, then the effectiveness and cohesiveness of our regulatory system may be undermined. In effect, the regulatory process moves from the halls of our federal and state agencies into the courtroom. As a result, all of the resources, experience and information that is weighed by regulators, out in the open and subject to public debate, is replaced by an adversarial process, limited evidence and time to review the issues, with a judge or jury deciding what is expected from that particular company.

Just as tort law has created this issue, it may also provide an answer to supplement the doctrine of preemption. The defense of regulatory compliance is recognized in the common law jurisprudence, and has been used by courts and state legislatures to reduce the risk of inconsistent state tort litigation where the defendant has already complied with extensive regulations that were created to prevent the same risks and injuries at issue in the litigation. While this doctrine has been seldom used, its underlying rationale offers some of the same benefits as a preemption defense.

Traditionally, regulatory compliance has been viewed as evidence of due care, but not conclusive as to whether the defendant acted negligently or not.[1] However, state courts and legislatures may recognize a stronger regulatory compliance defense, mandating that evidence of compliance with certain regulations shall be conclusive evidence that a defendant acted per se reasonable with respect to an injury or claim within the scope of the regulation. If a defendant can show compliance with regulations intended to protect against the type of injury at issue, then the court may hold that such compliance is conclusive on the issue of negligence, unless plaintiffs can show special circumstances, such as evidence of fraud by the defendant on the federal agency. In short, if violating a regulatory standard may establish negligence per se, then there should also be circumstances under which compliance is reasonable per se.

I. Diminishing Usefulness of the Preemption Doctrine

Defendants have used the preemption doctrine as a means to avoid a conflict between tort liability and agency determinations. Preemption holds that a federal standard or regulation governs over any inconsistent determinations made by courts.[2] This doctrine imposes an absolute bar against the imposition of any liability for conduct in compliance with the applicable standard set by the preemptive agency. While this doctrine still allows for a determination as to whether the defendant's conduct complied with the applicable standard, it does not allow courts to impose a more restrictive standard than that mandated by the relevant agency.

While preemption prevents the risk of conflicting tort outcomes, the scope of the preemption doctrine has been increasingly restricted. The Supreme Court has held in several recent opinions that tort litigation was not preempted by agency regulations that the defendants argued took into account the risks and injuries at issue.[3]

The preemptive effect of federal statutes and regulations has been further restricted by the policymakers themselves. During the George W. Bush administration, federal agencies regularly issued statements that their regulations were intended to have broad preemption effects.[4] However, the Obama administration has stopped this practice, and indicated that the current administration will take a more limited approach to preemption. In stark contrast to past practices, on May 20, 2009, the White House issued a ''Memorandum For The Heads Of Executive Departments And Agencies'' stating the following: ''The purpose of this memorandum is to state the general policy of my Administration that preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption.''[5] Notably, the May 20 memorandum asked ''[h]eads of departments and agencies [to] review regulations issued within the past 10 years that contain statements in regulatory preambles or codified provisions intended by the department or agency to preempt State law, in order to decide whether such statements or provisions are justified under applicable legal principles governing preemption.''

These recent actions by the Supreme Court and the current administration will likely decrease the effectiveness of using the preemption doctrine to avoid any divergence between regulatory obligations and common law tort liabilities. At the same time, the policy justifications in favor of judicial deference to agency determinations strongly support continued use of some other method to allow courts to prevent plaintiffs from seek-

[1] *See* Restatement (Second) of Torts § 288C (1965) (''Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions.'').

[2] *Wyeth v. Levine*, —- U.S. —-, 129 S.Ct. 1187, 1208 (2009) (''Pre-emption must turn on whether state law conflicts with the text of the relevant federal statute or with the federal regulations authorized by that text.'') (J. Thomas, concurring).

[3] *See Wyeth v. Levine*, —- U.S. —-, 129 S.Ct. 1187 (2009) (holding that federal law does not preempt a state-law tort claim asserting that an FDA-approved label for a drug did not contain an adequate warning); *Altria Group, Inc. v. Good*, —- U.S. —-, 129 S.Ct. 538 (2008) (holding that the Federal Cigarette Labeling and Advertising Act does not preempt a state-law action alleging that Philip Morris deceptively advertised ''light'' cigarettes).

[4] *See Levine*, 129 S.Ct. at 1200 (referring to a ''preamble to a 2006 FDA regulation governing the content and format of prescription drug labels [in which] the FDA declared that the FDCA establishes 'both a ''floor'' and a ''ceiling,'' ' so that 'FDA approval of labeling . . . preempts conflicting or contrary State law' '').

[5] Available at http://www.whitehouse.gov/the_press_office/presidential-memorandum-regarding-preemption.

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ing to impose liability for conduct that was fully in compliance with regulatory standards that take into account the same risk of injury that is at issue in the litigation.

II. Regulatory Compliance Defense Allows Courts to Decide Compliance With Statutory and Regulatory Standards of Conduct Is Reasonable Per Se

The concept that complying with prescribed standards of conduct may be a defense to common law tort liability is not new. Rather, it is rooted in basic tort jurisprudence, with examples of its application found in decisions from courts around the country.

A version of the regulatory compliance defense is found in the Restatement of Torts, although it appears to be overshadowed by the more often cited principle that compliance with regulations is only evidence of due care, but is not conclusive. Comment (a) to Section 288C of the Restatement repeats the traditional rule that a court may find that regulatory compliance is insufficient to show due care where special circumstances require additional precautions: ''Where a statute, ordinance or regulation is found to define a standard of conduct for the purposes of negligence actions, . . . the standard defined is normally a minimum standard, applicable to the ordinary situations contemplated by the legislation. This legislative or administrative minimum does not prevent a finding that a reasonable man would have taken additional precautions where the situation is such as to call for them.''

However, comment (a) also states that: ''Where there are no such special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted by the triers of fact, or by the court as a matter of law, as sufficient for the occasion; but if for any reason a reasonable man would take additional precautions, the provision does not preclude a finding that the actor should do so.''

Thus, it seems that the ''rule'' and the ''exception'' have been reversed in our thinking about these issues. When correctly analyzed, the general rule is that evidence of regulatory compliance may establish, as a matter of law, that a defendant acted with reasonable due care; and the exception arises if there are special circumstances that require a different result.

Applied to the typical case, unless special circumstances exist concerning dangerous situations or risks that were not contemplated by the agency when it issued the applicable regulations, then proof of regulatory compliance should be conclusive as to whether a defendant was negligent. Absent such facts, if the agency considered the same risks or injuries at issue in the litigation when they drafted the regulations, then it is reasonable for a court to defer to the agency's expertise in crafting the standard of care expected of those covered by the regulations. For example, safety regulations imposed by federal or state agencies strike a balance between preventing avoidable injuries, while not imposing on the employer exorbitant costs to avoid unlikely injuries. If, after weighing all of the evidence and issues, an agency decided that a particular piece of safety equipment or procedure is too expensive to justify the risk at issue, then there is no societal benefit to second-guessing that decision through *ad hoc* tort litigation.

The New Jersey Supreme Court adopted this view in holding that compliance with highway safety regulations confers absolute immunity for claims of negligence:

> We believe that responsibility for the safety of motorists should rest with those who own, control, and maintain the thoroughfare. Although utility companies have a duty to foresee that motorists will leave the traveled portion of the highway, the governmental bodies and highway planners are best suited to determine how the utilities should fulfill that duty. Those public bodies are in the best position to provide and to enforce standards and regulations governing utilities. . . . A uniform standard of care imposing the responsibility for highway safety on the public bodies is the proper solution. When a public utility has located its poles or structures within public rights-of-way in accordance with the location and design authorized by the public body, the utility, in the absence of countermanding directions from the public body, should have no further duty to protect the motoring public.[6]

In deciding this case, the New Jersey Supreme Court relied upon the fact that the common law rule of liability despite regulatory compliance was based on a time where safety regulations were far fewer and less comprehensive, noting that: ''One need only travel on a roadway as well designed as the Garden State Parkway to note the continuing improvements in reflectors, exit signs, acceleration-deceleration lanes, and the many other features of highway safety made by a State agency for the protection of the motoring public.''[7] Given the expense, expertise and comprehensiveness of safety regulations issued by federal, state and local agencies, it makes little sense to allow courts to impose isolated and *ad hoc* duties on top of a well-considered safety regimen.

The Connecticut Supreme Court similarly found that compliance with statutory requirements should constitute reasonable conduct as a matter of law.[8] In a case against a school bus driver where one of his passengers was hit by a car after leaving the bus, the court held that a negligence claim need not be presented to the jury where the evidence showed that the bus driver had ''complied with all of the statutory requirements for the safe discharge of his passengers.''[9] The court held that, ''[a]lthough it is true that compliance with a statute does not necessarily preclude a finding of negligence, where the facts are similar to those contemplated by the statute and no special or unusual circumstances or dangers are present, a defendant satisfies his duty of care by complying with the statute.''[10]

The limited case law in this area recognizes that federal, state and local agencies are often in a better position to consider the potential risks and benefits of the challenged activity. For example, in *Jefferson County School Dist. R-1 v. Gilbert by Gilbert*,[11] the Colorado Supreme Court addressed whether a ''city was negligent in designing, constructing, and maintaining [an] intersection'' in which a pedestrian was hit by an auto-

[6] *Contey v. New Jersey Bell Telephone Co.*, 136 N.J. 582, 590-591, 643 A.2d 1005, 1009-1010 (N.J. 1994).
[7] *Id.* at 590-591, 643 A.2d at 1010.
[8] *Josephson v. Meyers*, 180 Conn. 302, 307-308, 429 A.2d 877, 880-881 (Conn. 1980).
[9] *Id.* at 307, 429 A.2d at 880.
[10] *Id.* at 307-308, 429 A.2d at 880-881.
[11] 725 P.2d 774 (Colo. 1986).

mobile.[12] The trial court granted summary judgment in favor of the city relying on an affidavit by a professional engineer, ''stating that the intersection and all the crosswalks were designed and maintained in accordance with 'nationally recognized engineering standards.' ''[13] The Colorado Supreme Court affirmed, holding that the city's affidavit was sufficient to satisfy ''exactly those standards which define the scope of the city's duty to provide safe traffic control under [state and federal regulations].''[14] The court held, ''Because perfect safety is not realistically attainable, local governments are required to achieve only a reasonable level of safety in conformance with [statutory and agency safety regulations].''[15]

This concept was also adopted by the California Supreme Court in *Ramirez v. Plough, Inc.*[16] In *Ramirez*, the court held that a drug manufacturer was not negligent for failing to include foreign-language warnings on the product labeling for a prescription drug.[17] The court found that ''there is some room in tort law for a defense of statutory compliance[,]'' and accepted the defendant's argument ''that the standard of care for packaging and labeling nonprescription drugs, and in particular the necessity or propriety of foreign-language label and package warnings, has been appropriately fixed by the dense layer of state and federal statutes and regulations that control virtually all aspects of the marketing of its products.''[18] In holding that the relevant agency regulations should dictate the appropriate standard of care for this issue, the court noted that ''[d]efining the circumstances under which warnings or other information should be provided in a language other than English is a task for which legislative and administrative bodies are particularly well-suited.''[19] The court concluded that ''the prudent course is to adopt for tort purposes the existing legislative and administrative standard of care on this issue.''[20] The court further noted, ''we are conscious that our decision here may prompt review of this issue by the California Legislature. That is as it should be, for further study might persuade the Legislature, the FDA, or any other concerned agency to revise the controlling statutes or regulations for nonprescription drugs.''[21]

In at least one instance, a state legislature has gone to the next step and codified the regulatory compliance defense. Michigan adopted the standard of care set by the FDA, conferring absolute immunity to drug manufacturers against claims that a drug is defective or unreasonably dangerous if the drug and its labeling were approved by the FDA.[22] This absolute immunity does not apply if the defendant intentionally withheld or misrepresented information to the FDA or engaged in bribery, which is consistent with the ''special circumstances'' exception.[23] The Michigan legislature found that, because there are significant policy advantages in favor of deferring to agency safety determinations, it is within the state's best interest to adopt and apply a stronger regulatory compliance defense. Courts can and should reach the same conclusion even without such a statutory pronouncement.

III. Regulatory Compliance Defense Is Well-Justified

There are several policy justifications in favor of concluding that parties who comply with comprehensive regulatory standards should be found, as a matter of law, to have acted with due care.

First, agencies typically have greater expertise than a judge or jury in considering the issues that are needed to determine whether a party failed to take all reasonable precautions. Millions of dollars and countless hours are devoted by our agencies to research and understand the technical and economic factors that go into safety determinations. Agencies have access to experts in the field, and through public comment, they can draw upon expertise and viewpoints from a wide variety of groups to ensure that all interests are accounted for in the decision-making process, after full deliberation and consideration of all issues raised. That process stands in stark contrast to the way such issues are resolved through the adversarial process of litigation and trial, where one or more experts on each side present their perspectives, and a judge or jury is asked to decide the issue based on that limited information and in the context of that individual case.

Second, relying on agency determinations is significantly more efficient and reliable than allowing these issues to be litigated. Safety determinations by federal and state agencies involve a balancing of risk against benefit, such that the adopted regulation is intended to be an optimal standard of care when all issues are considered. If this optimal standard has been developed after considerable research and investigation, then it is inefficient and unnecessary for a judge or jury to second guess and redo this exercise on a case-by-case basis.

Third, deference to agency determinations allows for uniformity among the various jurisdictions. Allowing the standard of care to be decided in litigation allows for a different standard to exist in every state and potentially in every individual case. For companies that distribute products nationwide or have national operations, the multitude of standards is both unworkable and unpredictable.

Fourth, overdeterrence can result from tort litigation that imposes liability for actions already in compliance with agency regulations. If an agency has created an optimal standard, taking into account both the risk of injury and the benefit to be generated by the activity, any court imposing a more restrictive standard than the agency regulation can result in overdeterrence and the possible loss of socially useful products or activities.[24] By imposing additional or uncertain restrictions beyond

[12] *Id.* at 775.
[13] *Id.*
[14] *Id.* at 778.
[15] *Id.* at 779.
[16] 6 Cal.4th 539 (1993).
[17] *Id.* at 556.
[18] *Id.* at 548.
[19] *Id.* at 550.
[20] *Id.* at 553.
[21] *Id.*
[22] Mich. Comp. Laws § 600.2946(5) (2010).
[23] *Id.*, § 600.2946(5)(a) & (b).

[24] *See, e.g.*, *Ramirez*, 6 Cal.4th at 553 (''The burden of including warnings in so many different languages would be onerous, would add to the costs and environmental burdens of the packaging, and at some point might prove ineffective or even counterproductive if the warning inserts became so large and cumbersome that a user could not easily find the warning in his or her own language.'').

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the agency standard, courts impose an unnecessary burden on inherently risky but socially necessary and beneficial activities.

For these reasons, the regulatory compliance defense allows for the advancement of several policies that lead to a more efficient and effective set of safety and business regulations. Notice and certainty is all the business community can reasonable expect when it comes to the level of due care expected from them. Likewise, if weaknesses or omissions become evident in a particular set of regulations, then the answer should be to revise the applicable regulations, with open and vigorous debate over the right answer. But going around the process and asking judges and juries to address the problem on an *ad hoc* basis hardly seems like the prudent solution.

IV. Conclusion

The Obama administration has announced that it supports a narrower application of the doctrine of federal preemption. However, whether or not there is an intent to preempt common law does not address whether a governmental agency has properly determined what is reasonable conduct. If one accepts the premise that our agencies enact reasonable requirements, then it is axiomatic that the regulated community should not be held to a different standard of conduct in courtrooms around this country. And if we doubt the soundness or completeness of our agencies' decisions, then the question remains whether allowing judges and juries to provide a back-stop makes the problem better or worse—are such *ad hoc* decisions better than requiring agencies to revisit their decisions and require a different standard of conduct? The regulatory compliance defense provides a means by which a court can answer this question, and thereby decide to turn the issue back to the agency and the public to resolve as a general matter, rather than allowing the decision to be made on a particular day, in the context of the acts of a particular defendant, and in the context of a particular case.

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