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October 2008

Overview of Bush Administration Efforts to Block Consumer Remedies Through the Federal Preemption Doctrine

Preemption is the notion that federal law or regulation supersedes state law or regulation. This memo provides a brief overview of preemption with regard to state common-law duties and damages claims.

Federal regulation has long had a role in products liability cases, but its role traditionally was not the immunity that manufacturers seek to make of if today. Rather, traditional state tort law, and the current law in most states, allows a manufacturer who is alleged to have sold a defective product, to use compliance with federal standards or regulations as non-dispositive evidence that the product was not defective or that the manufacturer acted non-negligently. In this way, traditional tort law principles recognize that federal approval and compliance with federal requirements have a role to play, and a potentially very powerful role, in product liability cases. A typical jury instruction might say, for example, that “FDA approval, though not dispositive, may be considered to show whether a product is safe or not safe.” Sometimes the approval evidence is given even greater weight, as in this pattern jury instruction from Kansas: “If a product was at the time of manufacture in compliance with administrative regulatory safety standards relating to design or performance, the product is not defective by reason of design or performance, unless the plaintiff proves that a reasonably prudent manufacturer could and would have taken additional precautions to design the product so as to be reasonably safe for the ordinary consumer”

Over the past 20 years or so, manufacturers have argued with increasing success that regulatory approval or compliance is not only a defense on the merits—not only evidence that the product was not defective or that the label was adequate—but a defense to being sued in the first place. Beginning about 6 years ago, federal regulatory agencies began making the same argument—that federal approval or compliance with federal standards *preempts* state-law damages claims as a threshold matter, acting as a get-out-of-jail-free card that bars product liability suits. This preemption argument is unrelated to whether a product has caused injury—in fact, it can be assumed that the product did. The argument is not about whether the company or the consumer was at fault—it applies even if the company acted purposefully or negligently. The argument does not care about the nature of the injury or the extent of damages. The argument for preemption is that, because the product is subject to federal regulation, the company cannot be held liable, no matter the facts of the case.

This term, the U.S. Supreme Court will hear a case addressing whether FDA approval preempts damages claims brought by a patient against a drug manufacturer. That question, however, is a fairly recent development. It was raised only rarely prior to 2002, and did not



become popular until 2006. But in the 1990s, preemption became the favored defense of medical device, pesticide, and automobile companies. The common thread was an express preemption provision in the consumer protection statutes that establish federal regulation of cigarette labels, medical devices, pesticides, and motor vehicles. The question in these cases was whether damages claims were preempted by statutory language explicitly stating that certain state “requirements” are preempted, or terminology somehow similar to “requirements.” In the end, the plaintiffs did not fare too badly in the express preemption cases. With regard to vehicles and motor boats, the Supreme Court held that the relevant statutes do not expressly preempt damages claims; with regard to pesticides and medical devices, the Supreme Court held that some but not all damages claims are expressly preempted. (Each Chamber of Congress has a bill pending that would overturn the Supreme Court decision that held that the medical device laws preempt damages claims brought by patients injured by FDA-approved devices.)

After a decade of watching litigation over the scope of express preemption provisions, which generally ended more favorably to plaintiffs than to defendants, and having failed to push any bills through Congress to eliminate product liability suits, manufacturers and the Bush Administration started pressing an implied preemption theory. In the context of product liability law, the implied preemption doctrine asks whether the obligations imposed by manufacturers of federally regulated products are inconsistent with or “frustrate the purposes of” duties imposed by state common law. Soon after President Bush took office, drug companies, with the FDA’s support, began to push an implied preemption theory to avoid liability for injuries caused by their products. Then, beginning in mid-2005, federal regulatory agencies (including the National Highway Traffic Safety Administration, the Consumer Product Safety Commission, and the Federal Railroad Administration) began routinely to insert language into the commentary that accompanies the issuance of proposed and final rules, stating that their rules would preempt damages claims. The agencies seemed to be taking their cue from the Supreme Court’s 2000 decision in *Geier v. American Honda Motor Co.*, in which the Court found implied preemption of product liability claims based on the Court’s understanding of the purposes for the substantive choices that NHTSA made in formulating a particular regulation, as gleaned from the Federal Register commentary accompanying the proposed and final rule. Misunderstanding *Geier*, the agencies are **not** now seeking deference to their regulatory choices, but to their views on preemption.

For example, in January 2006, in a preamble to a new regulation about drug labeling, the FDA advocated for broad preemption of failure-to-warn claims with regard to any FDA-approved drug. Unfortunately, the FDA’s position has broadened even since that time. In a recent FDA’s amicus brief filed in the U.S. Supreme Court, the Bush Administration describes a theory of preemption so broad as to bar most any labeling claim, if not any claim at all. (That case, *Wyeth v. Levine*, presents the issue whether FDA approval preempts a labeling claim. That case will be heard by the Court in November.) The Administration’s pro-active approach to the topic of preemption illustrates the its increasing efforts over the past 7 years to use to the regulatory agencies to effect tort reform, which companies and their advocates in Congress have had so little success achieving in Congress.

It is important to note that the Federal Register commentary in which the agencies assert preemptive authority is not been a part of the regulation and does not have the force of law. And



damages claims are not preempted just because an agency says in a Federal Register notice that it thinks that claims are preempted. Nonetheless, courts very often defer to the agencies' views on the question whether a claim for damages "conflicts with" federal regulation. Indeed, it is indisputable that the manufacturers' preemption arguments would have far less success in the courts if they were not supported by the agencies. The debate about whether to hold companies liable for injuries caused by their products really is one that belongs in Congress—the branch of government structured to be sensitive to state interests. But through the statements about preemption that are thrown into Federal Register notices, unelected officials at the regulatory agencies and the Office of Management and Budget are side-stepping the legislative branch by offering unsolicited statements intended to influence judges presiding over tort suits. In fact, the agencies have only that authority delegated to them by Congress. The recent agency preemption efforts do not represent applications of the laws Congress passed; rather, they are efforts to make law, unconstrained by the political process.

Most recently, NHTSA has issued two new final rules (one on seating position and the other on school bus seat belts) that state in the standards themselves (not just in the preambles to the standards) that they preempt tort law. This action suggests that, in its final months, the Administration will take an even more aggressive approach to trying to oust consumer remedies. Although whether the standards in fact preempt tort law will still be a decision for the courts, courts may accord greater deference to a standard than they would to a preamble. In addition, it will be harder for the next Administration to distance itself from the preemption language, because it will have to go through notice-and-comment rulemaking to amend the rule (to omit the preemption language), whereas an agency could disavow its prior commentary without going through rulemaking.

This transformation of federal compliance from evidence relevant to a merits defense to the basis for a legal preemption defense is bad for consumers for a number of reasons. First, and most obviously, it cuts consumers off from even the possibility of recovering any compensation for injury caused by regulated products. It leaves no room for consideration of what a reasonable manufacturer would have done in a particular situation. It leaves no room for factual distinctions between individual cases. It sweeps away traditional common-law approaches to assessing fault and liability.

More broadly, preemption ignores the reality that technology is constantly advancing. For example, by 2008, it might be feasible to design a product or to revise a product to provide a level of safety greater than the level provided by a 1990 safety standard or a 1995 federal approval. Yet if compliance with the relatively old standard or the fact of approval preempts damages claims, then the injured consumer can never show that the design (or indeed the standard) was outdated or that a reasonable manufacturer would have known that the approved warning was inadequate. Or suppose that the FDA approved a drug and its labeling in 2003, but that the manufacturer received adverse event reports in 2004 showing that the product was causing an unanticipated adverse reaction or that physicians were misunderstanding something stated on the label. The manufacturer does not raise the issue with the FDA—it neither seeks to change its label unilaterally nor asks the FDA for approval of a new label. Eventually, the information will get out; eventually, the label will be revised or the drug withdrawn from the market. The question remains, though, what about the injured patients? Who bears the cost of



the injuries? Historically, that question has been for a jury to decide. But the preemption doctrine bars judicial consideration of the facts, based on the notion that this question must be answered as a matter of law and in favor of the defendant.

In addition, by deciding up front that industry cannot be held accountable to consumers, preemption eliminates an important motivation for companies to revise labeling in a timely manner, to improve products as soon as a defect is identified, and to remove from the market older products that do not provide the safety that newer the ones offer. The consequences of this retrograde attitude can be disastrous, as in the case of rollover and roof crush, where 10,500 people are killed annually in part due to a woefully out-of-date safety standard.

Finally, preemption is not only used in an effort to block product liability cases. Preemption is also asserted with regard to consumer protection laws such as state unfair and deceptive trade practices acts and state consumer protection laws in the banking context, such as state usury laws and lending disclosure laws.



November 2008

Key Fuel Economy Issues

NHTSA must issue the maximum feasible fuel economy standards required by the Energy Policy and Conservation Act (EPCA). The fuel economy standards proposed by NHTSA (and due to be finalized Nov. 17 for model years 2011-2015) do not meet the maximum feasible criteria envisioned by EPCA. The agency used an industry-biased economic model to set standards, which has undercut the standards to be less than the maximum feasible level.

EPA must reverse its decision on California's petition for a waiver under the Clean Air Act to set greenhouse gas emissions standards for motor vehicles. The decision to deny California's petition has been fraught with controversy. The California standards would require that the combined fleet of passenger cars and light trucks achieve 43 miles per gallon in 2020, over the Congressionally-mandated minimum of 35 miles per gallon by 2020. The States should not be blocked from requiring a greater level of fuel economy if NHTSA cannot do so.

NHTSA must remove the language regarding fuel economy standards' preemption of greenhouse gas standards set by the States. The decision in *Green Mountain Chrysler v. Crombie* resolved the issue of whether greenhouse gas emissions standards were preempted under EPCA. While decision in the appeal of this case to the Second Circuit Court of Appeals is still pending, currently, the standards have been found not to be preempted. NHTSA should not attempt to block the States from enforcing greenhouse gas emissions standards if the EPA reverses its decision on the waiver.

NHTSA must assess and reevaluate the method it uses to set fuel economy standards. The Energy Independence and Security Act (EISA) requires NHTSA to set attribute-based fuel economy standards "in the form of a mathematical function," effectively adopting the agency's cost-benefit model for fuel economy (often referred to as the "Volpe model"). The Volpe model fails to set standards at the "maximum feasible" level, because it excludes technologies that it deems too expensive or not ready to deploy, based on cost estimates supplied by the industry.

Also problematic about this scheme is that it relies on economic assumptions, which are subject to change including the price of oil, social cost of carbon, the rebound effect, and other externalities. The purpose of fuel economy standards is to encourage reduced oil consumption independent of the price of oil. The experience of sustained low gas prices from the mid-1980s to the early 2000s show the need for consistent, long-term energy policy that continues to stress efficiency and transition to advanced vehicles independent of the price of oil in any given month or year.

Transportation fuels should be assessed based on lifecycle greenhouse gas emissions. The best way to address carbon content of fuels is to establish lifecycle greenhouse gas emissions profiles for all transportation fuels – gasoline, diesel, tar sands, ethanol, and electricity. These values should change based on the specifics of how a fuel is manufactured, or what the source of



electricity is. This information should be made publicly available, and a means of comparing the relative greenhouse gas impact of fuels should be used.

NHTSA should contemplate potential safety issues related to changing vehicle fleet. NHTSA should start researching potential safety hazards unique to advanced vehicles, so that it can anticipate auto safety issues in the future.