

Agency Preemption and the *Shimer* Analysis: Unmasking Strategic Characterization By Agencies and Giving Effect to the Presumption Against Preemption

Abstract

Significant federalism concerns are raised when state products liability actions are preempted by federal regulatory schemes. For example, the FDA has recently taken the position that its approval of the labels on prescription drugs preempts civil tort claims grounded in a manufacturer's failure to warn. Using the FDA's recent stance on the issue of preemption, this Article demonstrates that federal agencies can engage in "strategic characterization" by pointing to Congress as the source of preemption, rather than the agency itself. In doing so, agencies avoid political and judicial scrutiny of agency action. This Article proposes that courts use a more realistic, totality of the circumstances approach when deciding whether Congress or an agency is the source of preemption. Further, the Article demonstrates that properly identifying a case as one of preemption by the agency can result in a type of "hard-look" review of the agency's decision to preempt. Use of a hard-look review can serve as a proxy - in cases of agency preemption - for the "presumption against preemption" which is used in all other categories of preemption analysis.

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Agency Preemption and the *Shimer* Analysis: Unmasking Strategic Characterization By Agencies and Giving Effect to the Presumption Against Preemption

A key federalism issue addressed and debated over the last few decades has involved the question of preemption of state common law products liability actions by federal regulatory schemes designed to protect the health and safety of the public.¹ The stakes are high because proponents on both sides of the issue can point to important interests. On one hand, preemption of state law actions would leave injured persons without an effective remedy. For example, in *Colacicco v. Apotex, Inc.*,² the complaint alleged that, despite ample peer-reviewed scientific literature linking Paxil and its generic equivalent to an increased risk of suicidality, the manufacturers of those drugs had failed to warn of the risk.³ The drug manufacturers argued that FDA's prescription drug labeling scheme preempted the plaintiff's tort law claim for failure to warn. The federal district court agreed, and granted the defendants' motion to dismiss.⁴ Similarly, in *Desiano v. Warner-Lambert & Co.*,⁵ the federal district court dismissed a plaintiff's

¹Most recently, the Supreme Court addressed the issue in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), which involved preemption by the pesticide registration program implemented by the Environmental Protection Agency (EPA). Other important cases resolved by the Court have involved the federal program for approval of medical devices implemented by the Food and Drug Administration (FDA), see, e.g., *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (both involving preemption due to the FDA process for approval of medical devices that are substantially similar to devices already on the market; and the motor vehicle safety program implemented by the Department of Transportation (DOT). See *Grier v. American Honda Motor Company, Inc.*, 529 U.S. 861 (2000) (involving preemption by the 1984 version of the regulation pertaining to passive restraint systems).

²432 F. Supp. 2d 514 (E.D. Penn. 2006).

³*Id.* at 519. The decedent's physician had prescribed both Paxil, manufactured by GlaxoSmithKline, and its generic equivalent manufactured by Apotex. *Id.* The plaintiff alleged that the scientific link surfaced in the mid-1990s. *Id.* The plaintiff committed suicide in October of 2003, after only twenty days of ingesting the drugs. *Id.* Although the drug labels at issue had been approved by the FDA, the FDA in 2005 issued a public health advisory warning of the potential for antidepressant medications to cause suicidal thoughts and behavior in adults. *Id.* n. 4 (citing FDA Public Health Advisory, *Suicidality in Adults Being Treated with Antidepressant Medications*, June 30, 2005, available at [the FDA website]).

⁴*Id.* at 532. As explained, *infra*, the district court's decision was grounded almost entirely on its view that it was required to "defer" to the FDA's position. See *infra* notes – to – and accompanying text.

⁵See 467 F.3d 85, 88-89 (2d Cir. 2006), cert. granted, 128 S.Ct. 31 (2007) (discussing the district court's decision). The Second Circuit reversed the district's courts decision, and the Supreme Court has granted cert in this case. Notably, however, the context of the preemption issue in *Desiano* is different from the typical failure to warn case in which the issue of preemption arises. In *Desiano*, the state of Michigan had enacted tort reform legislation that insulated drug manufacturers from products liability claims if the

action arising from injuries allegedly caused by the diabetes drug Rezulin, on the basis of preemption by the FDA's drug labeling regulations. Notably, the effect of the decision in Desiano went further than in Apotex because Desiano's claims included not just a failure to warn claim, but also claims grounded in breach of warranties, negligence, defective design, and defective manufacturing. Thus, the impact of preemption on an injured person's right to redress can be fatal.

On the other hand, federal agencies often view civil actions grounded in state law as inappropriately interfering with a regulatory scheme established by federal law. The issue is starkly illustrated by the FDA's recent shift in position on the question whether the FDA approval process for prescription drugs preempts civil actions against drug manufacturers in which plaintiffs are asserting claims grounded in negligent failure to warn. For years, the FDA had expressly opined that FDA decisions allowing marketing of prescription drugs did not insulate drug manufacturers from state law liability.⁶ However, beginning in the year 2000, the former chief counsel for the FDA affirmatively involved the FDA in several civil suits filed by plaintiffs injured by such drugs and, in the lawsuits, the FDA asserted a seemingly new view that its labeling decisions preempted the state law claims at issue.⁷ Then, in 2006, the FDA more

drug had been approved by the FDA. However, the legislation contained an exception *and thus allowed products liability actions*, if the defendant had – before the event that caused the injury – “intentionally [withheld] from or [misrepresented] to [the FDA] information concerning the drug that is required to be submitted under the [FDCA] and the drug would not have been approved . . . if the information were accurately submitted.” *Id.* (quoting M.C.L. § 2946(5)(a)). Because invocation of the exception raises issues of fraud on the FDA, the Court's decision in *Buckman Co. V. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), arguably is controlling precedent. Because the Court could limit its discussion to the issue of preemption of a state exception that raises issues of “fraud on the FDA,” the extent to which the Supreme Court's decision will address the issues raised in this Article is unclear.

⁶For example, in the explanation accompanying the publication of the 1979 content and format rules, the FDA reiterated its view that the label requirements for prescription drugs were not intended to impact civil liability but, rather, were intended only “to provide physicians with a clear and concise statement of the data and information necessary for the safe and effective use of the drug.” See FDA Notice of Final Rule, Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37434, 37435 (June 26, 1979). For a more detailed discussion, see *infra* notes – to – and accompanying text.

⁷See, e.g., Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, New York Times, July 25, 2004, § 1, at – (reporting the administration's position that “consumers cannot recover damages for [injuries caused by prescription drugs and medical devices] if the products have been approved by the [FDA]”; and citing Justice Department briefs in which the administration acknowledged that this position reflects a “change in governmental policy”). During the fourteen months immediately following Troy's

formally asserted its “matured” view in the Federal Register announcement of a Final Rule amending certain aspects of FDA regulation of the content and format of prescription drug labeling.⁸ According to the FDA, its duty of ensuring that drugs are safe and effective includes considerations relating to risk management; and that the labels on approved prescription drugs communicate to health practitioners the agency’s “formal, authoritative conclusions” as to what constitutes the right balance of risk and benefit information.⁹ Further, in contrast to its prior view that it was not problematic if products liability laws might cause manufacturers to make conservative labeling decisions, the FDA has now asserted that state law civil actions cause “defensive labeling” and undermine the purpose of labeling on prescription drugs.¹⁰ The FDA has broadly asserted that products liability actions threaten FDA’s statutory role as *the* expert responsible for evaluating and regulating drugs, and that state laws that frustrate FDA’s objectives are preempted – i.e., the FDA has asserted, in essence, field preemption.¹¹

For injured plaintiffs and their attorneys, the question is: “Can they do that?” Stated more

appointment as FDA’s Chief Counsel, he held at least fifty meetings with representatives of FDA-regulated industries. In December 2003, Troy acknowledged that the FDA was “deeply immersed in tort reform issues.” And key Bush personnel noted that “FDA’s litigation strategy embodies ‘good health policy and good tort reform.’” Affidavit of Jessica R. Dart, March 1, 2004 at <http://www.house.gov/hinchey/issues/fda2.pdf> . Get cites from Karin.

See also *Motus v. Pfizer*, 127 F. Supp 2d 1085 (C.D. Cal. 2000) (involving the drug Zoloft and the risk of suicidal behavior). The experience with Zoloft highlights the problematic nature of the FDA’s “matured view.” The FDA in 1991 approved Zoloft as safe for use in treating depression in adults. The labeling approved by the FDA noted the risk of suicide inherent in depression, and identified “suicide attempt” as a an “infrequent occurrence;” but expressly noted that identified reactions were “not necessarily caused” by the drug. Over the following twelve years (through 2003), the FDA approved Zoloft as safe for an additional six uses, including use for certain pediatric conditions. Anecdotal reports of some association between antidepressants such as Zoloft and suicide began surfacing in the early 1990s, but data from clinical trials did not seem to bear out a causal link. However, in September 2004, the FDA acknowledged that a new analysis of clinical trials, some of which allegedly had been kept secret for years by drug companies, showed a consistent link between antidepressants such as Zoloft and suicidal behavior in children and teenagers. An FDA advisory committee recommended “black box warnings” on the information provided to physicians, and an attached patient guide for the drug’s packaging. Concerns are surfacing now about a similar association in adult patients, and thus the need for additional warnings.

⁸See FDA Notice of Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-3997 (January 24, 2006).

⁹Id at 3934.

¹⁰Id. at 3935.

¹¹Id. at 3936. See *infra* notes – to – and accompanying text for a discussion of a type of field preemption

precisely, the issue is whether, and if so how, this new assertion by the agency will affect a court's analysis and resolution of the issue of preemption. Questions of preemption are complicated in and of themselves.¹² Indeed, the complexity of the preemption issue is evidenced by the continuous stream of cases involving preemption that make their way to the Supreme Court.¹³ That complexity is compounded when the preemption arises from federal agency action and when the agency has asserted its view of the preemption issue. The complexity increases due to issues relating to judicial deference to the agency. For example, judicial review of action by administrative agencies often involves deference; and the degree and mode of deference varies depending on the type of agency action and the basis of a particular challenge to the agency action. The most familiar forms of administrative law deference are Chevron deference and Skidmore deference.¹⁴

arising from the "stands as an obstacle" branch of conflict preemption.

¹²For example, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), involved preemption due to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under FIFRA, all pesticides sold in interstate commerce must be "registered;" and registration of the pesticide depends on compliance with FIFRA's requirements, as well as a determination by the EPA its label complies with FIFRA's prohibition on misbranding. The plaintiffs in *Bates*, farmers who sustained significant damages due to a new pesticide manufactured by Dow Agrosciences, alleged that Dow should have known that the new pesticide would damage peanut crops in soils with high pH levels, and thus should have disclosed that information to farmers. The Supreme Court held that many of the plaintiffs' claims were not preempted because they fell outside of the law's targeted by FIFRA's express preemption clause. The Court held that the duties imposed by claims for negligent design, testing and marketing, and for breach of express warranty on the label did not constitute "requirements for labeling" since liability on the claims would not "require" manufacturers to label their packages in any particular way. *Id.* at 444-446. Similarly, the claims for breach of warranty and fraud grounded in oral statements about the pesticide did not impose duties as to "labeling" since FIFRA defines labeling as including "written, printed or graphic matter." *Id.* However, the Court recognized that, if any of the plaintiffs' claims were grounded in a failure to warn or fraud because of statements in the pesticide labeling, the claims would be preempted (*Id.* at 446) -- unless any duty thereby imposed could be characterized as "equivalent to a requirement under FIFRA." *Id.* at 453.

¹³"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." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230-32 (1947) (citing cases).

¹⁴Chevron deference is triggered when the agency has engaged in statutory interpretation, and promulgated a notice and comment rule which gives effect to the agency's interpretation. See *Chevron v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Skidmore deference is triggered when the agency's view as to statutory interpretation is issued in a "less formal" format, e.g., agency guidance documents or advisory opinions. See *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). See also *United States v. Mead Corporation*, 533 U.S. 218 (2001) (clarifying that Skidmore deference survived Chevron, and applying it to a decentralized adjudicatory decision by the U.S. Customs Service). In *Colacicco v.*

However, in the area of preemption arising from agency action, yet another type of deference exists – arising from a distinct line of cases and involving a distinct analysis which this Article will refer to as the Shimer analysis.¹⁵ The degree of deference involved if the Shimer analysis is invoked is viewed by some as greater than if Shimer is not triggered.¹⁶ The Shimer analysis historically has been called into play in cases involving preemption arising from decisions *by the agency* to preempt – as opposed to preemption arising from *congressional* intent: that is, in cases involving what some refer to as “regulatory preemption,” and what this Article will refer to “agency preemption.” Notably, under recent Supreme Court precedent, the Shimer analysis is triggered only if the agency has made *express* statements indicating that *the agency has determined* that preemption is appropriate.¹⁷ That is, the Court has adopted a significantly restricted view of what constitutes agency preemption.

In the many recent discussions of preemption of state products liability actions by federal regulatory schemes, important issues relating to the use of the Shimer analysis have been overlooked: issues such as when the Shimer analysis should be called into play and, when it is triggered, whether the Shimer analysis provides adequate safeguards to protect the important state and consumer interests at stake.¹⁸ It is these issues which this Article addresses. These

Apotex, 432 F. Supp. 2d 514 (E.D. Penn. 2005), the district court based its decision that the plaintiff’s state law claims were preempted almost entirely on the need to defer to the FDA’s interpretation of congressional intent as to the issue of implied preemption. .

¹⁵The analysis was first used in *United States v. Shimer*, 367 U.S. 374 (1961). See *infra* notes – to – and accompanying text.

¹⁶See Jack W. Campbell, *Regulatory Preemption in the Garcia/Chevron Era*, 59 U. Pitt. L. Rev. 805, 820 (1998) (noting that a “genealogical” analysis “suggests that the Court has erroneously incorporated the highly deferential analysis of regulatory conflict cases into regulatory preemption scenarios”).

¹⁷See *infra* notes – to – and accompanying text. If such statements by the agency do not exist, the preemption is treated as arising from Congressional intent to preempt; and traditional preemption doctrines are triggered, albeit modified by considerations of agency deference (e.g., *Chevron*, or *Skidmore*, or some other form of deference).

¹⁸Indeed, in the recent cases involving FDA preemption, neither the litigants nor the courts have considered whether the Shimer analysis should apply. See, e.g., *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), cert. granted, 128 S.Ct. 31 (2007) . See also *Zyprex Products Liability Litigation*, 489 F. Supp. 2d 230 (E.D. N.Y. 2007); *Levine v. Wyeth*, – A.2d – (S. Ct. Vt 2006) (2006 WL 3041078); *Perry v. Novartis Pharma. Corp.*, 456 F. Supp. 2d 678 (E.D. Penn. 2006); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Penn. 2006); *Peters v. Astrazeneca, LP*, 417 F.Supp. 2d 1051 (W.D. Wis 2006); *McNellis v. Pfizer, Inc.*, 2006 WL 2819046 (D.N.J.); *Akermann v. Wyeth Pharmaceuticals*, 2006 WL 2591078 (E.D. Tex.); *Laisure-Radke v. Par Pharmaceutical, Inc.*, 2006 WL 901657 (W.D. Wash.);

issues are important for two key reasons. First, limiting agency preemption to circumstances where the agency has expressly determined that preemption is appropriate sidesteps accountability for such preemption decisions. Using the FDA’s recent activity as an example, the FDA has carefully characterized the preemption as a matter of congressional intent; and has deliberately avoided making explicit statements that it is the FDA that has decided that preemption is appropriate.¹⁹ Yet, scrutiny of the FDA’s assertions reveals a case of “strategic characterization.” Objectively, the preemption is more appropriately viewed as agency preemption.²⁰ This Article therefore asserts that courts should be able to “call a spade a spade” and identify preemption as “agency preemption” notwithstanding the spin used by the agency.

At the same time, unmasking strategic characterization of preemption decisions will not ensure accountability for the preemption decision if the scope of judicial review lacks sufficient rigor. Thus, a second important issue is whether the Shimer analysis allows courts to adequately safeguard state and consumer interests. In cases where preemption arises from agency regulations – but where it is nonetheless appropriate to view the preemption as stemming from congressional intent – the Court has long recognized a “presumption against preemption.”²¹ Yet in cases of preemption by the agency – in cases where the Court has applied the Shimer analysis – the Court has not used or discussed a presumption against preemption. Indeed, the language used by the Court could easily be taken as creating a presumption *in favor of preemption*.²² Yet, in at least in some circumstances of agency preemption, greater judicial scrutiny would seem to be warranted. That is, a decision by a federal agency to preempt broad swaths of state law may warrant greater scrutiny than a similar decision made by Congress. This Article therefore also demonstrates that – notwithstanding its deferential language – the Shimer line of cases actually establishes a type of “hard-look” judicial review of agency decisions to preempt.

Carwright v. Pfizer, Inc., 369 F. Supp. 2d 876 (E.D. Tex. 2005); Witzak v. Pfizer, Inc., 377 F. Supp. 2d 726 (D. Minn. 2005); Needleman v. Pfizer Inc., 2004 WL 177397 (N.D. Tex).

¹⁹See *infra* notes – to – and accompanying text.

²⁰See *infra* notes – to – and accompanying text.

²¹See *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (citing *Napier v. Atlantic Coast Line R. Co.*, 272 U.S. 605, 611 (1926); *Allen-Bradley Local v. Wisconsin Employment Relations Board*, 315 U.S. 740, 749 (1942)).

²²See *infra* notes – to – and accompanying text (explaining the key language from the Shimer analysis).

I. Preemption Analysis – Considerations Stemming From the Multitude of Types of Federal Agency Activity

Whether and how a federal agency's assertion of preemption will affect judicial analysis and resolution of the preemption issue, depends on the source of preemption, the type or category of preemption, and the context of any agency pronouncement of the agency's view of the preemption issue. The issues addressed in this Article stem from the source of preemption. In the area of preemption of state products liability actions by federal regulatory schemes, the source of preemption will be statutes enacted by Congress, or regulations promulgated by, or other actions of, federal agencies. More specifically, then, this Article focuses on issues arising when the source of preemption is not the statute (and thus not Congress), but, rather, is agency action.

In an analysis of preemption arising from agency action, a threshold task is to identify the particular agency action which is the source of the preemption. For example, the FDA's official pronouncement of its matured view of the preemption issue was asserted in the "preamble" or "statement of basis and purpose" accompanying new rules and regulations. What then is the actual agency action that is the source of the preemption: the preamble, the rules, the individual labeling decisions (which are adjudications)? The issues that arise are whether each of these forms of agency action can "preempt" state law; and, even if so, can they result in the type of *field* preemption asserted by the FDA?²³

A. Brief Refresher of Preemption Arising From Congressional Statutes

Preemption doctrine applicable to federal agency activity generally follows the principles formulated in the context of preemption by Congress. It is thus appropriate to discuss, very briefly, the basic parameters of congressional preemption of state laws. Congress' power to preempt flows from the dual operation of the general powers delegated to Congress through the Constitution, and of the Supremacy Clause.²⁴ The Supremacy Clause of the Constitution

²³See *infra* notes - to - and accompanying text (explaining why it is appropriate to view the FDA's assertions as field preemption).

²⁴Professor Gardbaum has explained that the widely held assumption that Congress' power of preemption

provides that the Constitution and all laws made under its authority shall be the “supreme Law of the Land.”²⁵ The supremacy of federal law means that valid federal law overrides otherwise valid state law in cases of conflict between the two. However, the concept of preemption is broader and goes beyond the constitutional question.²⁶ Congress has the complete authority to define the allocation of federal and state regulatory power over those matters within the domains of its delegated powers. Thus, when Congress has used its delegated powers and enacted legislation, state laws can be preempted -- even in the absence of a real conflict and thus without reference to the Supremacy Clause. But, in all cases, preemption by Congress is through properly enacted statutes.

In analyzing the question of preemption by Congress, the Supreme Court has traditionally emphasized three categories of preemption.²⁷ Congress can expressly define the extent to which federal statutes preempt state law, thereby giving rise to “express preemption;”²⁸ or, in the absence of explicit statutory language, state law will be found impliedly preempted where it regulates conduct in a field that Congress intended the federal government to occupy exclusively,²⁹ or conflicts with federal law.³⁰ In turn, two variants of conflict preemption exist. The Court has found preemption where it is impossible to comply with both state and federal law, or where state law “stands as an obstacle to the accomplishment and execution of the full

derives from the Supremacy Clause is not entirely accurate because the Supremacy Clause does not grant powers but, rather, operates as a dispute resolution mechanism. See also Stephen Gardbaum, *Rethinking Constitutional Federalism*, 74 *Tex. L. Rev.* 795, 803-07 (1996).

²⁵U.S. Const., art. VI, cl. 2.

²⁶Laurence Tribe has explained that the validity of state regulation is assessed in constitutional terms only when Congress has not chosen to act. For example, when state regulation is challenged as being in violation of the dormant commerce clause. See Laurence H. Tribe, *American Constitutional Law* § 6-25, at 479 (2d ed.) (1988).

²⁷See, e.g., *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218 (1947); *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990). See also Robert B. Leflar & Robert S. Alder, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 *Tenn. L. Rev.* 691, 694 (1997) (noting that courts addressing a preemption issue recite, “like a mantra, a formulaic incantation of black-letter law.”).

²⁸*English*, 496 U.S. at 79. (citing *Shaw v. Delta Air Lines, Inc.* 463 U.S. 85, 95-98 (1983)).

²⁹*Id.* at 79 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

³⁰*Id.* Field and conflict preemption doctrines constitute the implied preemption doctrines because they emerged as a means of addressing the question of the division of state and federal authority when Congress had not explicitly spoken.

purposes and objectives of Congress.³¹

Yet, the Court has acknowledged that the categories of preemption are not rigidly distinct. Most notably, the terms field preemption and “stands as an obstacle” conflict preemption often become interchangeable. For example, in *Gade v. National Solid Wastes Management Ass’n*,³² a federal regulation requiring a minimum of forty hours of instruction and three days of field experience for employees working with hazardous materials was upheld as preempting a state regulation which required a greater amount of training. Although compliance with the state rule would not hinder the primary substantive federal objective of promoting worker safety, a plurality of the Court found evidence that Congress intended to subject employers to only one set of regulations. Because state standards stood as an obstacle to uniform federal regulation, preemption was found appropriate.³³ The Court in *Gade* noted: “Although we have chosen to use the term ‘conflict’ pre-emption, we could as easily have stated that the promulgation of a federal safety and health standard ‘pre-empts the field’ for any nonapproved state law regulating the same safety and health issue.”³⁴

Preemption is fundamentally a question of congressional intent,³⁵ and thus preemption analysis is largely a matter of statutory interpretation,³⁶ with all that that implies in terms of looking to the text of statute, as well as to the structure and purpose of the statute as a whole and to its object and policy.³⁷ At the same time, preemption is fundamentally a matter of federalism.³⁸ That is, preemption raises “important questions concerning the way in which the

³¹Id. (citing *Florida Lim & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963); *Hines v. Davidowitz*, 312 U.S. 52 (1941)).

³²505 U.S. 88 (1992).

³³Id. at 103-04 (holding that OSHA’s worker safety regulations impliedly preempted state safety regulations because, even though not impossible for an employer to comply with both, Congress intended to establish a system of uniform federal occupational health and safety standards).

³⁴Id. at 104 n.2 (citing *English v. General Elec. Co.*, 496 U.S. 72, 79-80, n.5 (1990)).

³⁵*English*, 496 U.S. 78-79.

³⁶See generally Karen A. Jordan, *The Shifting Preemption Paradigm: Conceptual and Interpretive Issues*, 51 *Vand. L. Rev.* 1149 (1998).

³⁷See *Gade*, 505 U.S. at 98 (citing *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987)).

³⁸As describe by Justice Stevens in *Geier*, federalism is “about respect for ‘the constitutional role of the States as sovereign entities.’” *Geier*, 529 U.S. 861, 887 (2000) (Stevens, J., dissenting) (citing *Alden v. Maine*, 527 U.S. 706 713 (1999)).

Federal government may exercise its undoubted power to oust state courts of their traditional jurisdiction over common-law tort actions.”³⁹ Because of the federalism concerns, the Court has repeatedly emphasized that, where Congress legislates in a field which the states have traditionally occupied, the preemption analysis proceeds upon “the assumption that the historic police powers of the States [are] not be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”⁴⁰ That is, the Court will not find that Congress impliedly preempted such state laws unless that intent is “clear and manifest.”⁴¹ This “presumption against preemption” is used by the Court even in cases of express preemption, as a guiding principle as the Court is interpreting the scope of the terms of an express preemption clause.⁴²

B. The Preemptive Capabilities of Particular Agency Activity

As applied to action by federal agencies, preemption becomes more complicated. Similar to Congress’ ability to preempt, the capacity of an agency to preempt state laws flows from the dual operation of the Supremacy Clause and the agency’s delegated authority -- i.e., the powers delegated to the agency by Congress. A key difference exists, however. Whereas Congress acts primarily through the enactment of statutes, agencies generally are empowered to engage in a number of different functions; and the issue at hand is whether all of the many forms of agency action can constitute a source of preemption of state law.

Broadly speaking, agency action can be divided into the two worlds of rulemaking and adjudication.⁴³ Most federal agencies are granted the authority to engage in at least some rulemaking: i.e., the formulation of general statements designed to prospectively implement or

³⁹Id.

⁴⁰See *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (citing *Napier v. Atlantic Coast Line R. Co.*, 272 U.S. 605, 611 (1926); *Allen-Bradley Local v. Wisconsin Employment Relations Board*, 315 U.S. 740, 749 (1942)).

⁴¹See *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990) (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (quoting *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

⁴²See, e.g., *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005).

⁴³“Investigation” is a third distinct type of agency activity; but one which is unlikely to give rise to preemption except in those cases where the subject of an investigatory action may face conflicting requests for information from state and federal authorities. See generally Alfred C. Aman, Jr. & William T. Mayton, *Administrative Law*, 740- 800 (West Group, 2d ed.)(2001) (discussing agency acquisition of information).

prescribe law or policy.⁴⁴ Thus, agencies often act in a quasi-legislative manner and promulgate substantive regulations, i.e, regulations that create legal rights or duties.⁴⁵ But, agencies also issue non-substantive rules. Non-substantive rules take the form of rules that do not create legal rights and duties, such as rules of interpretation, statements of policy, or rules of agency organization, procedure or practice.⁴⁶

Additionally, many federal agencies are empowered to conduct adjudications; and adjudications can take a multitude of different forms, spanning the spectrum from very informal to a very formal, trial-like proceedings. In an adjudication, the agency acts in a quasi-judicial manner and addresses specific issues presented by the particular case. Like judicial action by courts, agency adjudication involves fact-finding, the application of law to facts, and the issuance of an “order.” In contrast to a “rule,” the order resulting from an adjudication is a statement of the decision in the case which has a present effect and specific applicability to the parties to the proceeding.⁴⁷

The Supreme Court has answered in part the question whether all of the many forms of agency action can constitute the source of preemption of state law. The Court, in *City of New York v. Federal Communications Comm’n*, has noted that the “phrase ‘Laws of the United States’ [in the Supremacy Clause] encompasses both federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization;” and that, “[w]hen the Federal Government acts within the authority it possesses . . . , it is empowered to pre-empt state laws to the extent it is believed that such action is necessary to achieve its

⁴⁴See 5 U.S.C. § 551(4). The Administrative Procedure Act (APA) definition of “rule” is “an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency” See 5 U.S.C. § 551(4).

⁴⁵See, e.g, *American Hospital Ass’n v. Bowen*, 834 F.2d 1037 (D.C. Cir. 1987) (noting that the imposition of rights and duties is a distinguishing feature of substantive rules) .

⁴⁶See, e.g., *American Mining Congress v. Mine Safety & Health Administration*, 995 F.2d 1106 (D.C. Cir. 1993). See also 5 U.S.C. § 553(b)-(A) (provision exempting non-substantive rules from the APA’s informal notice and comment rulemaking requirements).

⁴⁷Compare 5 U.S.C. § 551(6) with 5 U.S.C. § 551(4). However, as is also the case with judicial action by courts, agencies can and do at times pronounce “rules” in the course of an adjudication; i.e., statements designed to implement or prescribe law or policy, which the agency intends to have, in addition to a present effect in the case, a prospective effect in other cases. See *infra* notes – to – and accompanying text.

purposes. The Supremacy Clause of the Constitution gives force to federal action of this kind”⁴⁸ Thus, preemption is triggered by action by the federal government, including agencies, when that action is in accord with delegated authority. But, the Court in *City of New York* was referring to properly promulgated “regulations.” The Court has not specifically held that other types of agency action can also preempt; nor discussed the potential scope of preemption of the varying types of agency actions.

The answer arguably lies in the text of the Supremacy Clause itself. Federal supremacy is triggered by “the Laws” of the United States. Notably, however, the extent to which agency action is considered “law” varies. Thus, the question becomes whether all forms of agency action constitute “law” within the meaning of the Supremacy Clause. Courts have not explicitly addressed this issue and scholars have generally failed to perceive the issue.⁴⁹ A review of case law, however, reveals that the types of agency action which have been found to have preemptive effect are those that have the “force of law.”⁵⁰

1. Rulemaking and the Force of Law

As noted, rulemaking by an agency can be divided into two categories: substantive and non-substantive rules. Substantive regulations are readily recognized, and indeed characterized, as having the “force of law.” The legal effect of substantive agency regulations is virtually identical to that of a statute passed by Congress.⁵¹ Substantive regulations create rights and

⁴⁸See *City of New York v. Federal Communications Comm’n*, 486 U.S. 57, 63 (1988).

⁴⁹See, e.g., Nina A. Mendelson, *Chevron and Preemption*, 102 Mich. L. Rev. 737 (2004); Amanda Frost, *Judicial Review of FDA Preemption Determinations*, 54 Food & Drug L.J. 367 (1999); Jack W. Campbell, *Regulatory Preemption in the Garcia/Chevron Era*, 59 U. Pitt. L. Rev. 805 (1998); Paul E. McGreal, *Some Rice With Your Chevron?: Presumption and Deference in Regulatory Preemption*, 45 Case Western Reserve L. Rev. 823, 828 (1995) (noting that the Supreme Court has stated that “administrative actions should receive the same preemptive effect as statutes,” but not exploring whether all agency action have the capacity to preempt).

⁵⁰The phrase “force of law” is a term of art in the arena of administrative law. An administrative regulation has the force of law when it is a substantive rule, rather than an “interpretative rule or a general statement of policy, or rule of agency organization, procedure, or practice. Beyond being substantive, a regulation “must be rooted in a grant of [quasi-legislative] power by the Congress and subject to limitations which that body imposes” to have the ‘force of law.’” See, e.g., *Pearce v. United States*, 261 F.3d 643, 648 (6th Cir. 2001) (citing *Chrysler Corp. v. Brown*, 441 U.S. 281, 301-302 (1979)).

⁵¹See Richard J. Pierce, Jr., Sidney A. Shapiro, & Paul R. Verkuil, *Administrative Law and Process* 307

duties, and are binding on both the agency and regulated entities.⁵² Accordingly, speaking of substantive rules, the Supreme Court has stated that “federal regulations have no less preemptive effect than federal statutes.”⁵³ Given the burgeoning administrative state, the Supreme Court has cautioned against finding implied field preemption from “comprehensive and detailed” regulatory schemes.⁵⁴ But, substantive regulations have readily been found to preempt conflicting state laws,⁵⁵ including state laws that stand as an obstacle to the goals or objectives intended by Congress or by the agency.⁵⁶

In addition to preemption arising from conflicts between federal rules regulating the conduct of regulated entities and state rules, the Court has explained that, as with statutes, agencies can through a federal regulation – referring to substantive regulations promulgated through the rulemaking process – render unenforceable even state laws that are otherwise *not* inconsistent with federal law.⁵⁷ Thus, an agency can, through a substantive regulation, expressly

(3d ed, Foundation Press, 1999).

⁵²See, e.g., *Chocolate Manufacturers Ass’n v. Block*, 755 F.2d 1098 (4th Cir. 1985) (discussing a USDA rule that prohibited the use of chocolate favored milk in the federally funded supplemental food program for women, infants, and children). See also *Pearce*, 261 F.3d at 648 (citing *Chrysler*, 441 U.S. at 301-302).

⁵³See *Fidelity Federal Savings and Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

⁵⁴See *Hillsborough County, Florida v. Automated Medical Laboratories*, 471 U.S. 707, 717 (1985) (explaining a hesitancy to infer field preemption from comprehensive regulations given that agencies normally “deal with problems in far more detail than does Congress). But see *United States v. Shimer*, 367 U.S. 374, 381 (1961) (finding field preemption due to a comprehensive regulatory scheme devised by the Veteran’s Administration: “We have no doubt that this regulatory scheme, complete as it is in every detail, was intended to provide the whole and exclusive source of protection of the interests of the Veterans’ Administration as guarantor . . .”).

⁵⁵See, e.g. *Fidelity Federal Savings and Loan Ass’n v. de la Cuesta*, 458 U.S. 141 (1982) (holding that an agency regulation which permitted Federal Savings and Loan Associations to use and enforce “due-on-sale” clauses preempted inconsistent California law which would have limited that right).

⁵⁶See e.g. *Geier v. American Honda Motor Company*, 529 U.S. 861 (2000) (holding that motor vehicle safety standard promulgated by the Department of Transportation impliedly preempted a state law products liability action due to interference with the agency’s objectives); *Jones v. Rath Packing Co.*, 430 U.S. 519 (1977) (holding that federal regulations governing weight labeling of flour products preempted a state law governing weight labeling, because although it was not impossible for national flour millers to comply with both, compliance with the state rules would hinder a key purpose underlying the federal regulatory scheme, namely consumer value comparisons).

⁵⁷See *City of New York v. Federal Communications Comm’n*, 486 U.S. 57, 63-64 (1988) [describe the AA at issue].

preempt state law-even in the absence of a real conflict.⁵⁸ Such agency action constitutes agency dictated field preemption.

At the other end of the “force-of-law” spectrum lie “non-substantive rules:” namely, interpretative rules and statements of policy. Although considered “rules” under the APA, interpretive rules and statements of agency policy ordinarily do not have the force of law:⁵⁹ they do not create rights and duties, nor do they have a binding effect in the same way as an agency’s substantive rules. Agencies often issue rules as non-substantive rules in order to avoid the APA’s requirement of notice and comment rule making. To qualify for the exemption from notice and comment, courts require that statements of policy are non-binding on the agency as well as regulated entities.⁶⁰ Further, although agencies are bound to their “interpretations” of a statute or a substantive regulation in the sense that they will generally adhere to them, regulated entities are free to ignore agency interpretations and statements of policy.⁶¹ Given this distinction, in contrast to substantive rules, non-substantive rules have not been found to trigger preemption.

However, interpretive rules certainly can have a significant impact on the preemption analysis. As discussed in more detail, *infra*, even when preemption arises due to conflict with a regulatory scheme, courts and the agency can characterize the preemption as arising from congressional intent.⁶² In that case, the traditional preemption doctrines are triggered. Because traditional preemption analysis purports to focus on statutory interpretation, the agency’s

⁵⁸See *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691,702-705 (1984) (detailing the FCC’s explicit statements declaring its intent to preempt the field of signal carriage regulation, and holding state law preempted because the state had “interfered with a regulatory area that the Commission ha[d] explicitly pre-empted”). See also *City of New York*, 486 U.S. at 65-66 (noting that, because the FCC had clearly expressed its intent to preempt state regulation, the preemption analysis did not turn on whether there was an actual conflict; and upholding the FCC’s preemption of attempts by state or local authorities to regulate, through franchise agreements, technical standards relating to facilities and equipment of cable systems).

⁵⁹In the context of addressing the deference a court should give to an agency’s interpretation of the statute it administers, the Court has characterized some “interpretive rules” as having the “force of law.” See *Chevron, Mead*. However, even interpretive rules with the force of law would not seem to carry preemptive force. As explained *infra*, where an agency promulgates a rule which interprets a statute as preempting certain state law, it is the statute (and the rule) that has the preemptive force.

⁶⁰See *Pearce*, 261 F.3d at 648 (citing *Chrysler*, 441 U.S. at 301-302).

⁶¹*Id.*.

interpretation of the statute becomes relevant. Indeed, following *Chevron*, courts may give substantial deference to the agency’s interpretation. For example, in *Colacicco v. Apotex, Inc.*,⁶³ the complaint alleged that manufacturers of the drugs taken by the decedent had failed to warn of an increased risk of suicidality, despite ample scientific evidence showing an association between the drugs and the risk.⁶⁴ The defendant manufacturers argued that FDA’s prescription drug labeling scheme preempted the plaintiff’s tort law claim for failure to warn, and bolstered their argument by pointing to the FDA’s pronouncements on the issue of preemption.⁶⁵ The district court resolved the issue largely on the basis of deference to the agency.⁶⁶ Although the plaintiff pointed out reasons why deference may not be warranted – such as the agency’s inconsistency on the issue – the district court held that the FDA regulatory scheme preempted the plaintiff’s claim, noting: “Given the overwhelming caselaw on the issue of deference, and specifically the Supreme Court’s holdings in *Geier* . . . that preemptive intent may properly be communicated in amicus briefs, preambles and interpretive statements, we find Plaintiff’s argument lacks merit.”⁶⁷ Whether the district court should have given the agency’s interpretation such substantial weight

⁶²See *infra* notes – to – , and accompanying text.

⁶³432 F. Supp. 2d 514 (E.D. Penn. 2006).

⁶⁴*Id.* at 519. The decedent’s physician had prescribed both Paxil, an SSRI manufactured by GlaxoSmithKline, and its generic equivalent manufactured by Apotex. *Id.* The plaintiff alleged that the scientific link surfaced in the mid-1990s. *Id.* The plaintiff committed suicide in October of 2003, after only twenty days of ingesting the drugs. *Id.* Although the drug labels at issue had been approved by the FDA, the FDA in 2005 issued a public health advisory warning of the potential for antidepressant medications to cause suicidal thoughts and behavior in adults. *Id.* n. 4 (citing FDA Public Health Advisory, *Suicidality in Adults Being Treated with Antidepressant Medications*, June 30, 2005, available at [the FDA website]).

⁶⁵*Id.* at 524 (pointing to the *amicus* briefs filed by the FDA in several cases, as well as to the 2006 Final Rule (Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-97 (Jan. 24, 2006)). The FDA had also filed an *amicus* brief to the district court in the *Apotex* case. *Id.* However, the facts of the *Apotex* case were distinguishable from many “failure to warn” cases because the FDA had specifically considered the issue of additional warnings, and found inadequate evidence of an association between adult use of SSRI and suicidality. *Id.*

⁶⁶See *Id.* at 528 (“Pursuant to the principles announced by the Court in *Chevron*, *Medtronic*, *Geier* and their progeny, . . . , it is therefore appropriate to afford deference to the FDA’s position based on the *Colacicco Amicus* alone.”).

⁶⁷*Id.* at 530 (also noting that “it is not the function of this Court, or for a jury empaneled to decide this case, to substitute its judgment for the FDA’s about these medical issues. Congress has given the FDA broad power, the President has appointed its executives, . . . and [the FDA] has rendered its judgment on these issues.”).

is beyond the scope of this Article.⁶⁸ The decision provides, however, an apt example of the concept that interpretive rules can have a significant impact on the preemption analysis arising from congressional intent.

2. Adjudications and the Force of Law

Because agency adjudications can take a multitude of different forms, spanning the spectrum from very informal, to a very formal, trial-like proceedings, agency action in the adjudicative context cannot be as readily categorized as action in the rulemaking context. Nonetheless, two types of adjudicative actions have been found to have the force of law. First, the actual decision or order resulting from an adjudication -- i.e., the agency action which represents application of the law to the facts⁶⁹ -- of course creates rights and duties which are binding on the agency and the parties to the proceeding.⁷⁰ An adjudicative “decision” thus has the “force of law” -- and thereby may have a preemptive effect. However, adjudicative decisions, by themselves, would seem to give rise only to implied conflict preemption. Agency decisions are drafted with findings and conclusions as to specific issues involved in the proceedings, and are directed to parties to the proceedings. Thus, agency decisions reflected in orders would seem to rarely if ever be drafted in a way that would give rise to express preemption of state laws or implied field preemption. Yet, an agency order could readily trigger implied conflict preemption if enforcement of a state law (including a judgment or order from a state court or administrative

⁶⁸The Supreme Court has not squarely addressed the issue of how to properly integrate deference to the agency and the presumption against preemption which courts must employ in cases of implied preemption of state law in the field of health and welfare. In contrast to the substantial deference accorded by the district court in the *Apotex* case, other courts have given greater weight to the presumption against preemption. See, e.g., *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 97 (2d Cir. 2007), cert. granted, . . . (“To the extent that the FDA’s statement might bear peripherally on the claims asserted in this case, it is not clear what, if any, deference would be owed to the FDA’s view.”). See also *Levine v. Wyeth*, – A.2d – (Vt. 2006) (2006 WL 3041078).

⁶⁹The APA requires that all adjudicatory “decisions” to include a statement of findings and conclusions, and the reasons therefore; and the appropriate “order, sanction, relief, or denial thereof.” See 5 U.S.C. § 557(c)(3)(A) & (B). For more detailed information regarding the effects of agency orders, findings, and conclusions on the rights of the parties, see 2 Admin. L. & Prac. § 5.68, *The Internal Processes: Adjudication: The Decision* (available in WL, ADMLP § 5.68).

⁷⁰See cite case.

tribunal) would create an impermissible conflict for a party subject to the order.⁷¹

Of course, an adjudicative decision could have a broader preemptive scope if that is what Congress or the agency intends. However, in such a case, it is not the adjudicative decision itself which creates the broader preemption; but, rather, the source of broader preemption would be the statutory scheme or regulatory scheme which expressly or impliedly establishes that the decision will have a broader preemptive effect. In such cases, a *dual source* of preemption exists: a statutory or regulatory rule which dictates or establishes the *possibility* of preemption and the scope of preemption; and the agency order or decision which triggers *actual* preemption. As discussed *infra*, the FDA's assertion of preemption exhibits this type of dual source.

In addition, a second type of agency action which sometimes occurs as part of an adjudication could also trigger preemption of state law. In some adjudications the agency must formulate a necessary "rule of decision;" and, the agency often intends that such rules will also operate prospectively. For example, in *Securities and Exchange Commission v. Chenery Corp.*,⁷² the Supreme Court upheld the authority of the SEC to formulate, during an adjudication, a new rule or standard of conduct governing issues before it in the adjudication – even though the agency could also have promulgated such a rule through a rulemaking proceeding.⁷³ Such rules may be applied in future cases in virtually the same manner as a rule promulgated through a rulemaking proceeding.⁷⁴ Such rules, if they implement or prescribe law or policy, are, in essence, substantive rules akin to substantive rules made through rulemaking.⁷⁵ Thus, such rules have the force of law and could expressly or impliedly preempt state law to the same extent as a

⁷¹Indeed, this is, in part, the alleged basis for the FDA's assertion of preemption in the 2006 Final Rule. See *infra* notes – to – and accompanying text.

⁷²332 U.S. 194 (1947).

⁷³*Id.* at 201-203. The Court noted a variety of reasons why an agency may legitimately prefer to develop some rules in adjudications, and explained that "the choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency. *Id.* at 202-03 (citing *Columbia Broadcasting System v. United States*, 316 U.S. 407 (1942)). The Court also explained that the "retroactive effect" of such a rule "was not necessarily fatal to its validity." *Id.* at 203. See also *National Labor Relations Board v. Bell Aerospace Company*, 416 U.S. 267 (1974).

⁷⁴See *Retail Wholesale and Department Store Union, AFL-CIO v. National Labor Relations Board*, 466 F.2d 380 (D.C. Cir. 1972) (analyzing the extent to which a rule developed in a prior adjudication may be applied in second and subsequent cases).

⁷⁵In *Chenery*, the rule formulated by the SEC prohibited certain shareholder trading practices by management of a company during the company's reorganization. See *Chenery*, 332 U.S. at 197-201.

rule promulgated through rule making.⁷⁶

In sum then, substantive rules, whether formulated in rulemaking or adjudication, can be a source of all types of preemption. Adjudicatory decisions, on the other hand, will ordinarily trigger only implied conflict preemption; but can trigger broader preemption if so intended by Congress or the agency. In contrast, statements of policy and interpretive rules ordinarily would not, in and of themselves, trigger preemption. However, an agency's interpretative rule -- set forth formally in a regulation or informally in the form of policy guidance or statements of policy -- will often play an important role in the preemption analysis, by virtue of the deference a court may accord to the agency's view. The discussion, *infra*, reveals that several of these aspects of preemption arising from agency activity come into play when analyzing the FDA's recent assertion of preemption.

II. The Role of Agency Intent in the Preemption Analysis

A crucial aspect of the preemption analysis when preemption arises from agency rules or adjudicative decisions is the proper identification of the source of the *intent* to preempt. Federal agencies can act only pursuant to directives by Congress. Because every agency action must constitute a valid exercise of delegated power, agency action must conform with congressional intent. However, in effectuating congressional intent, agencies often act with a distinct agency intent; i.e., agencies sometimes have goals and objectives underlying agency action which are distinct from, although in alignment with, congressional objectives. In the context of preemption of state products liability actions by federal agency activity, the possibility of distinct agency intent is relevant in two ways. In some cases, agency objectives have been the trigger for implied conflict preemption; i.e., preemption arising because a state law "stands as an obstacle" to federal objectives reflected the agency's regulatory scheme. In these cases, courts and the agency have treated the preemption as arising from *congressional* intent. In other cases, the

⁷⁶Cf. *Louisiana Public Service Comm'n v. Federal Communications Comm'n*, 476 U.S. 355 (1986) (addressing preemptive effect of a new rule of depreciation formulated in a rule making proceeding, but issued in an agency order (see *In the Matter of Amendment of Part 31 (Uniform System of Accounts for Class A and Class B Telephone Companies)* so as to permit depreciable property to be placed in groups comprised of unites with expected equal life for depreciation under the straight-line method, 83 F.C.C. 2d 267 (Nov. 6, 1980)).

agency may have asserted that the preemption was grounded not in congressional intent to preempt, but in the *agency's* intent to preempt. The distinction is important because the Supreme Court analyzes the issue of preemption differently depending on the source of the intent to preempt, and characterizing the matter as one of congressional intent may allow agencies to avoid accountability for far-reaching preemption decisions.

A. Frustration of *Agency* Objectives as a Trigger for Characterizing Preemption as Arising From Congressional Intent

In *Geier v. American Honda Motor Company*,⁷⁷ the Supreme Court extended the traditional implied preemption doctrines – namely, that variant of implied preemption which arises when a state law “stands as an obstacle” to federal objectives – to protect not just congressional objectives, but *agency* objectives. At issue in *Geier* was the preemptive effect of a motor vehicle safety standard, known as FMVSS 208, promulgated pursuant to the National Traffic and Motor Vehicle Safety Act (NTMVSA) to address the need for passive restraint systems in passenger vehicles. After a long and tortuous history,⁷⁸ the Department of Transportation eventually promulgated in 1984 a standard that established a gradual phase-in of passive restraints, beginning in 1987.⁷⁹ The standard also allowed manufacturers, in meeting the required standard, to choose among different restraint mechanisms (e.g., airbags, automatic belts, or other passive restraint technologies).⁸⁰ The plaintiff in *Geier* had filed a common law products liability action against Honda, alleging that Honda had a duty to design and install, in its 1987 Accord models, a passive restraint system that included an airbag.⁸¹ The issue was whether agency action–FMVSS 208– preempted the lawsuit.

⁷⁷See *Geier, v. American Honda Motor Company*, 529 U.S. 861 (2000).

⁷⁸The promulgation of a safety standard requiring passive restraint systems began in 1967, and went through numerous revocations, re-issuances and revisions before resulting in promulgation in 1984 of the standard at issue in the case. The Court details the history of FMVSS 208. See 529 U.S. at 875-77.

⁷⁹For example, the standard required that manufacturers in 1987 equip only a minimum of 10% of their new passenger cars with passive restraint systems. *Id.* (citing 49 Fed. Reg. 28962 (1984)). The phase-in authorized by the standard set minimum percentage requirements for the installation of passive restraint systems, which increased in annual stages of 10, 25, 40 and 100%. See *Geier*, 529 U.S. at 903-04 (Stevens, J., dissenting).

⁸⁰*Id.* at 878-79.

⁸¹*Id.* at 865.

Congress enacted the NTMVSA to “reduce traffic accidents and deaths and injuries to persons resulting from traffic accidents;”⁸² and directed the Secretary of Transportation to issue motor vehicle safety standards that “shall be practicable [and] shall meet the need for motor vehicle safety”⁸³ Further, the NTMVSA defines the term “safety standard” as a “minimum standard for motor vehicle performance, or motor vehicle equipment performance.”⁸⁴ As pointed out by the dissent in Geier, the standard at issue, FMVSS 208, was intended to address “[o]ccupant crash protection;” and its purpose was to “reduce the number of deaths of vehicle occupants, and the severity of injuries, by specifying vehicle crashworthiness requirements.”⁸⁵ Thus, the plaintiffs had a strong argument that their common law liability claim would *not* stand as an obstacle to the purposes and objectives of the federal regulatory scheme – as established by Congress. A state law imposing a higher standard of care as to passive restraint systems would reduce deaths and injuries resulting from traffic accidents and promote occupant crash protection. Further, such a state law would not frustrate the purpose of a federal law establishing “minimum” standards; especially when the record revealed that the Secretary favored a more rapid increase in the use of airbags.⁸⁶

Nonetheless, the majority of the Court found tension between the plaintiff’s tort action and the *specific objectives determined by the agency to be important*. The administrative record revealed that DOT considered a number of factors in deciding on the 1984 regulation: safety concerns (perceived or real) associated with airbags, the need for data on comparative effectiveness, the industry’s need for time to overcome the high production costs associated with airbags and any safety problems, the potential for development of alternative, cheaper and safer passive restraint systems, and the need to build public confidence.⁸⁷ Thus, the DOT opted for a regulation that allowed a phase-in period, and use of a variety of restraint systems during the

⁸²Id. at 888-89 (Stevens, J., dissenting) (citing 15 U.S.C. § 1381).

⁸³Id. at 889 (citing 15 U.S.C. § 1392(a)).

⁸⁴Id. (citing 15 U.S.C. § 1391(2)).

⁸⁵Id. (citing 49 C.F.R. § 571.208, S2 (1998)).

⁸⁶See Geier, 529 U.S. at 903-04 (Stevens, J., dissenting) (explaining that the administrative record and history showed that politics and public acceptance were key reasons for the phase-in period and the variety of restraint systems allowed).

⁸⁷Id. at 878-79.

phase-in period.⁸⁸ The Court held that FMVSS 208 preempted the plaintiff’s tort action because it frustrated those specific objectives devised by the agency,⁸⁹ thereby extending the concept of implied preemption due to “frustration with federal purpose” to state laws hindering a purpose or objective devised by the agency.⁹⁰

Importantly, the majority in *Grier* treated the preemption as arising from *congressional* intent. That is, although on one hand the source of the preemption was the regulation – FMVSS 208 – preemption was ultimately grounded in ordinary implied conflict preemption.⁹¹ The majority noted that “Congress [likely would] have wanted ordinary pre-emption principles to apply where an actual conflict with a federal objective is at stake.”⁹² This characterization by the Court channeled the analysis of the preemption issue to the traditional implied preemption analysis, with its focus on congressional intent; and thus away from an analysis with a focus on the appropriateness of the agency activity.

⁸⁸During the *Geier* litigation, the DOT informed the Court that FMVSS 208 “embodi[ed] the Secretary’s policy judgment that safety would best be promoted if manufacturers installed alternative protection systems in their fleets rather than one particular system in every car.” *Id.* at 881 (citing Brief for United States as Amicus Curiae 25; 49 Fed. Reg. 28997 (1984)).

⁸⁹Although Congress defined the term “safety standard” as a “minimum standard” for motor vehicle performance, *Id.* (citing 15 U.S.C. § 1391(2)), the majority did not view FMVSS 208 as setting only a minimum airbag standard. Rather, the majority saw FMVSS 208 as a “deliberate” decision by the DOT to allow a range of choices in order to bring about a mix of different devices over time. *Id.* at 874-75. The majority also concluded that *Geier*’s tort action would impose a duty which, “by its terms would have required manufacturers of all similar cars to install airbags rather than other passive restraint systems It thereby would have presented an obstacle to the variety and mix of devices that the federal regulation sought.”

⁹⁰It could be argued, however, that the case does not really represent such an extension since the DOT grounded its “phase-in” and “variety” objectives in Congress’ purpose of occupant safety. That is, during the *Geier* litigation, the DOT informed the Court that FMVSS 208 “embodi[ed] the Secretary’s policy judgment” of how “*safety would best be promoted.*” *Id.* at 881 (citing Brief for United States as Amicus Curiae 25; 49 Fed. Reg. 28997 (1984)) (emphasis added). This view of the case is valid despite the fact that, in deciding on the final form of the regulation, the agency considered factors other than safety. As explained by the majority, the administrative record showed that the agency made a deliberate decision to allow the “phase-in” and “variety” because, in its view, FMVSS 208 would then “lower costs, overcome technical safety problems, encourage technology development, and win widespread consumer acceptance-*all of which would promote FMVSS 208’s safety objectives.*” *Id.* at 875 (citing 49 Fed. Reg. 28962 (1984)) (emphasis added). Thus, although preemption was inferred due to hindrance to the objectives of variety and mix that were devised by the agency; those objectives were viewed by the agency as being integral to Congress’ objective in promoting safety.

⁹¹See *infra* notes – to – for a more in-depth discussion of the approach used by the Court in *Geier*.

⁹²*Geier*, 529 U.S. at 871.

B. Agency Intent to Preempt

Cases exist, however, in which the agency has asserted that the preemption was grounded not in congressional intent to preempt, but in the *agency's* intent to preempt. That is, even if Congress was silent as to the preemption issue, the agency may decide that, in order to effectively carry-out its mandated mission, preemption is necessary. For example, *Capital Cities Cable, Inc. v. Crisp*,⁹³ involved the FCC's decision that, in order to effectuate Congress' mandate to foster and promote "a rapid, efficient, nation-wide and world-wide wire and radio communications service," federal preemption of state and local regulation was necessary and proper.⁹⁴ After notice and comment on the issue, and consideration of arguments on both sides, the FCC announced: "we now find that there is a necessity to rationalize, interrelate, and bring into uniformity the myriad standards now being developed by numerous jurisdictions. We, therefore, are pre-empting the field of technical standards"⁹⁵

In cases where the preemption is grounded in the agency's expressed intent to preempt, the Supreme Court has used a distinct analysis in deciding whether to uphold the agency's decision; i.e., an analysis that frames the inquiry with different issues than the analysis used when the preemption is grounded in congressional intent to preempt. If preemption arising from agency regulation is viewed as being grounded in congressional intent to preempt – as in the *Geier* decision – the Court has applied the traditional doctrines of express and implied preemption. In most of the recent cases addressing preemption of state products liability actions by federal regulatory schemes -- *Geier*, *Medtronic*, *Bates* - the Court has analyzed the issue from the perspective of the traditional preemption doctrines.⁹⁶ In explaining the distinct analysis, a

⁹³467 U.S. 691 (1984). *United States v. Shimer*, 367 U.S. 374 (1961), is generally identified as the first case in which the Supreme Court recognized "agency or regulatory" preemption. See Jack W. Campbell, *Regulatory Preemption in the Garcia/Chevron Era*, 59 U. Pitt. L. Rev. 805 (1998); Paul E. McGreal, *Some Rice With Your Chevron?: Presumption and Deference in Regulatory Preemption*, 45 Case Western Reserve L. Rev. 823, 828 (1995)

⁹⁴*Crisp*, 467 U.S. at 707. See also 49 F.C.C.2d 470 (1974) (1974 WL 28430 at *7-10).

⁹⁵See *In the Matter of Amendment of Part 76 of the Commission's Rules and Regulations Relative to the Advisability of Federal Preemption of Cable Television Technical Standards or the Imposition of a Moratorium on Nonfederal Standards*, 49 F.C.C.2d 470 (October 22, 1974) (1974 WL 28430 at * 9).

⁹⁶See *Geier*, 529 U.S. 861 (2000); *Bates*, 544 U.S. 431 (2005); *Medtronic*, 518 U.S. 470 (1996).

district court recently noted:

There are two related but analytically distinct frameworks that may be applied in determining whether the [agency] regulations validly preempt state law. While Congressional intent is critical to both methods of analysis, the focus of each is somewhat different, depending on whether the agency has issued a regulation interpreting existing law (i.e., the statute) or has determined to issue a pre-emptive regulation pursuant to its delegated authority.⁹⁷

The underlying reason for the distinct frameworks is that, if the agency has expressed its intent to preempt, the case becomes one of express rather than implied preemption. That is, the question for the court is not whether it is proper to infer congressional intent to preempt. Rather, the question is whether the agency's decision should be upheld. Accordingly, the issue presented is not a matter of statutory interpretation; but, instead, is a matter of judicial review of an agency's policy decision.

The distinct analysis was first used by the Supreme Court in *United States v. Shimer*.⁹⁸ In *Shimer*, the Court established what has become known as a two-pronged inquiry for review of an agency decision to preempt. The *Shimer* analysis requires a court to first assess whether the agency acted within the scope of its authority; and, if so, the question is becomes whether the decision to preempt is reasonable. As the Court explained in *Crisp*:

“If [the agency] choice represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned.”⁹⁹

Although the *Shimer* analysis has been characterized by some as establishing a highly deferential scope of judicial review,¹⁰⁰ the analysis in reality opens the door for rigorous scrutiny. Precisely

⁹⁷See *National City Bank of Indiana v. Turnbaugh*, 367 F. Supp.2d 805, 814 (D. Maryland 2005) (parenthetical added).

⁹⁸367 U.S. 374 (1961).

⁹⁹*Crisp*, 467 U.S. at 699. See also *City of New York v. Federal Communications Comm'n*, 486 U.S. 57, 64 (1988); *Fidelity Federal Savings and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 154 (1982).

¹⁰⁰See *Campbell*, supra note – , at 820 (noting that a “genealogical” analysis “suggests that the Court has erroneously incorporated the highly deferential analysis of regulatory conflict cases into regulatory preemption scenarios.”). However, this Article demonstrates that, notwithstanding its deferential language, the *Shimer* line of cases actually establishes a type of “hard-look” judicial review of agency decisions to preempt. See *infra* notes – to – and accompanying text.

because the analysis shifts to one of judicial review of an agency's policy decision, Shimer provides a means for holding agencies accountable.

It is the existence of this distinct and purportedly deferential mode of analysis – and the restrictive manner in which the Supreme Court has used the analysis – that raises the issues addressed in this Article: issues bearing on the question of whether and how an agency's assertion of preemption will affect judicial analysis of the preemption issue. The first issue relates to the question of which analytical mode is appropriate in any given case: i.e., should the case be treated as one of preemption by Congress, triggering the traditional implied preemption analysis; or as preemption by the agency, thereby triggering the Shimer analysis. The second issue relates to how to conduct the Shimer analysis to ensure adequate protection of the important state and consumer interests at stake.

III. Agency Preemption, Or Strategic Characterization as Congressional Intent?

As noted, the rationale underlying the distinct mode of analysis in cases of agency intent to preempt is that, if the agency has expressed its intent to preempt, the case is one of express rather than implied preemption. However, especially today, an agency may be reluctant *to appear* to be asserting preemption. Both political parties are cognizant of strong states rights sentiments.¹⁰¹ Thus, regardless of which party holds executive office, an administrative agency – as an arm of the executive – may prefer to engage in “strategic characterization” by pointing to Congress as the body preempting state law, especially when the state law at issue is protective of and provides remedies for injured consumers. When agencies avoid overt acts of preemption the actual source of the *intent* to preemption becomes blurred. Yet, getting it right is important. Characterizing the matter as one of congressional intent channels the analysis to the traditional preemption doctrines – as modified by considerations of Chevron or Skidmore deference¹⁰² – as opposed to the Shimer analysis, and, as a consequence, allows agencies and courts to by-pass holding the agency accountability for what are often sweeping preemption decisions. Given the agencies' predilection to point to Congress, the issue is whether an agency's overt acts and

¹⁰¹Find authority to cite.

¹⁰²See, e.g., *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Penn.2006)(discussed in the introduction). See also *Zyprexa Products Liability Litigation*, 489 F. Supp.2d 230 (E.D.N.Y. 2007)

pronouncements should control the question of which analysis should be used to resolve the preemption issue.

A. The Supreme Court Has Implicitly Endorsed “Strategic Characterization”

The Supreme Court has not expressly addressed the issue of strategic characterization of the intent to preempt. However, a majority of the Court implicitly answered the question in the Geier case.¹⁰³ In Geier, the Court treated the case as involving implied conflict preemption grounded in congressional intent to preempt – rather than preemption grounded in agency intent to preempt – presumably for the sole reason that the agency did not *express* its intent to preempt. As discussed, Geier involved preemption arising due to the DOT’s promulgation of FMVSS 208: the passive restraint safety standard which prescribed a phase-in period, and allowed car manufacturers to use a variety of restraint systems during the phase-in period. The state law preempted was a common law products liability action against Honda.

The federal statute in Geier contained an express preemption clause and a savings clause.¹⁰⁴ Importantly, the majority construed the preemption clause as *not* preempting common law tort actions when the DOT established a standard consistent with Congress’ definition of safety standard – i.e., a minimal standard. “We have found no convincing indication that Congress wanted to pre-empt, not only state statutes and regulations, but also common law tort action, *in such circumstances.*”¹⁰⁵ Further, the majority found that the express preemption and savings clauses did not provide evidence of congressional intent to foreclose operation of “ordinary pre-emption principles.”¹⁰⁶ However, the majority limited its focus to ordinary

¹⁰³Geier, 529 U.S. 861 (2000).

¹⁰⁴The preemption clause in the National Traffic and Motor Vehicle Safety Act provides as follows: “Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State . . . shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle . . . , any safety standard applicable to the same aspect of performance of such vehicle . . . which is not identical to the Federal standard.” Id. at 867 (quoting 15 U.S.C. § 1392(d)). The savings clause provides that “[c]ompliance with’ a federal safety standard ‘does not exempt any person from any liability under common law.’” Id. at 868 (quoting 15 U.S.C. § 1397(k)).

¹⁰⁵Id. at 868 (emphasis added).

¹⁰⁶Id. at 869. The majority noted that “Congress [likely would] have wanted ordinary pre-emption principles to apply where an actual conflict with a federal objective is at stake.” The majority noted that *not* interpreting the statute as allowing implied conflict preemption would “permit th[e] law to defeat its

preemption principles relating to preemption *by Congress*. Although the Court noted that the text of the savings clause did not suggest “an intent to save state tort actions that conflict with federal *regulations*,”¹⁰⁷ the majority spoke in terms of the preemptive effect of the “statute.”¹⁰⁸ The majority referred to the appropriateness of preemption of state common law tort actions that “would upset the careful regulatory scheme established by federal law,”¹⁰⁹ and recognized that the federal law at issue was established by the DOT as a safety standard.¹¹⁰ Nonetheless, the majority simply did not seem to recognize or consider that the preemption could be attributed *to the agency*.

The only apparent reason for not viewing the case as one of agency preemption is that the agency had not, at the time of promulgating the regulation, expressed any view as to the issue of preemption. Because the agency had not overtly acted in a manner consistent with an agency’s decision to exercise preemption, the Court seemed to assume that the case could not be one of agency preemption. Moreover, the Court did not seem to notice the logical implications of the circumstances. The majority noted that the express preemption clause and the savings clause “reflect a neutral policy, not a specially favorable or unfavorable policy, toward the application of ordinary conflict preemption principles.”¹¹¹ That is, the preemption clause reflected a desire for uniformity as to “standards” – which could include state tort suits; but that the savings clause reflected recognition of the desirability of occasional non-uniformity when appropriate to provide necessary compensation to victims.¹¹² Further, the Court expressly noted that non-uniformity –

own objectives, or . . . to ‘destroy itself’”; and further stated: “We do not claim that Congress lacks the constitutional power to write a statute that mandates such a complex type of state/federal relationship. But there is no reason to believe that Congress has done so here.” *Id.* at 871-72.

¹⁰⁷*Id.* at 869 (emphasis added).

¹⁰⁸For example, the Court stated that “when this Court previously considered the pre-emptive effect of the *statute’s* language, it appeared to leave open the question of how, or the extent to which, the savings clause saves state-law tort actions that conflict with federal regulations” *Id.* at 869 (emphasis added). See also the quoted language in foot note 107 (“we do not claim that Congress lacks the constitutional power to write a *statute* that mandates such a complex type of state/federal relationship”).

¹⁰⁹*Id.* at 870.

¹¹⁰*Id.* at 869 (“when this Court previously considered the pre-emptive effect of the statute’s language, it appeared to leave open the question of how, or the extent to which, the savings clause saves state-law tort actions that conflict with *federal regulations promulgated under the Act.*” *Id.* at 869 (emphasis added).

¹¹¹*Id.* at 870-71.

¹¹²*Id.* at 871.

and thus *no* preemption – would be appropriate when a state tort suit would establish liability for failing to provide greater protection than that established by a “minimum” standard set by DOT;¹¹³ and expressly recognized that the preemption at issue was triggered by a DOT regulation that deviated from the type of minimum standard that Congress expressly empowered the DOT to promulgate. Stated another way, the Court expressly recognized that state tort suits would not be preempted by minimum safety standards; but only by standards such as FMVSS 208, which the DOT later construed not as a minimum standard, but as setting a “floor and ceiling” as to installation of airbags. These circumstances logically would point towards the appropriateness of viewing the case as one of agency preemption. Yet, without explanation, the Court went on to attribute preemptive intent to Congress - and not the agency.¹¹⁴

By failing to acknowledge the agency’s affirmative actions as the source of the preemptive intent – when the circumstances so readily pointed to the agency – the Court in *Geier* implicitly restricted *Shimer*’s agency preemption analysis to cases where the agency has expressed, in some manner, its intent to preempt. As a result, the Court implicitly endorsed “strategic characterization.” Tying judicial review of the agency’s decision to express statements by the agency invites strategic characterization of the preemption issue. Scrutiny of the recent FDA assertions aptly illustrates this tendency. The FDA has carefully characterized the preemption as a matter of congressional intent, and has deliberately avoided making explicit statements that it is the FDA that has decided that preemption is appropriate. Yet scrutiny of the FDA’s assertions readily shows that, objectively, the preemption is more appropriately viewed as

¹¹³Id. at 871. See also Id. at 868 (discussing Congress’ intent that state law would not be preempted when the safety standard established a minimum standard) .

¹¹⁴It is not clear whether the dissenting Justices recognized the case as involving agency preemption. The dissent noted: “regulations ‘intended to pre-empt state law’ that are promulgated by an agency acting non-arbitrarily and within its congressionally delegated authority may . . . have preemptive force.” Id. at 899 (quoting *Fidelity Fed. Sav. & Loan Assn v. De la Cuesta*, 458 U.S. 141, 153-54 (1982)). However, the dissenting opinion never clearly asserts that the case is or should be treated as one of agency preemption. That may be because the dissent believes that the agency did not have authority to promulgate FMVSS 208, as interpreted by the agency and the majority. See Id. (noting that the saving clause denies the DOT the authority to preempt common-law remedies). See also 887-88 (noting that, as to the “preemptive rule” devised by the majority’s decision, “[i]t is . . . quite clear to me that Congress neither enacted any such rule nor authorized the Secretary of Transportation to do so.”). Nonetheless, the dissenting opinion engaged in an extensive analysis of implied preemption, pointing out flaws in the arguments that state common law tort remedies would frustrate congressional or agency purposes. Id. at 900-906 (concluding that Honda had not overcome the presumption against preemption).

agency preemption. Courts should be able to “call a spade a spade” – by identifying preemption as “agency preemption” notwithstanding the spin used by the agency.

B. The FDA’s Spin on the Preemption Issue: A Case of Strategic Characterization

As noted, the FDA for years had expressly opined that FDA decisions allowing marketing of prescription drugs did not insulate drug manufacturers from state law liability in actions in which plaintiffs asserted claims grounded in negligent failure to warn. In 2000, however, the FDA began asserting in various contexts, the opposite view: that FDA decisions did trigger preemption which would insulate drug manufacturers.¹¹⁵ Analysis of the FDA’s “official” announcement readily reveals a case of strategic characterization of the issue.

1. The Context of the FDA’s Official Pronouncement

In 2006, the FDA formally asserted its “matured” view of the issue of preemption of state actions arising from deficiencies in prescription drug labeling. The FDA placed its official statement of its shift in position about the preemptive effect of drug approval decisions in the Federal Register as part of the Final Rule establishing new labeling requirements, and revising others.¹¹⁶ The new regulations did not simply “amend” prior labeling requirements, but, rather, created several new requirements and whole new sections of labeling information.¹¹⁷

Specifically, the new regulations set forth in the Final Rule require newly approved prescription drugs to include in their labeling “introductory highlights” and a “table of contents,” in addition to the “full prescribing information” previously required.¹¹⁸ In contrast to the rules

¹¹⁵Include info from Karin’s version.

¹¹⁶See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-3997 (January 24, 2006).

¹¹⁷In addition to the new requirements set forth in the following paragraphs, the new rules address ordering and organization of previously required labeling information, *Id.* at 3923 (Section I.C.); revise the definition of “adverse reaction,” *Id.* at 3923 (Section I.C.), and the information to be included in the “contraindications” section, *Id.* at 3927 (Section II); and require patient labeling to accompany the FDA approved labeling, which is crafted for use by the health care professionals who prescribe the drugs. *Id.* at 3928 (Section II).

¹¹⁸The “Highlights” section would include: product names and other required information, boxed warnings, recent major changes, indications and usage, dosage and administration, dosage forms and strengths, contraindications, warnings and precautions, adverse reactions, drug interactions, use in

for other aspects of labeling, the new regulations require that applicants obtain prior approval of any labeling changes to the “highlights” portion of the label.¹¹⁹ The agency explained that its efforts in improving the content and format of prescription drug labeling were a component of the agency’s “broad effort to improve the communication to health care practitioners of information necessary for the safe and effective use of prescription drugs.”¹²⁰

Key statements relating to the FDA’s shift in position on the preemption issue are found in the agency’s response to comments received in the rulemaking process.¹²¹ In its “Notice of Proposed Rulemaking” proceeding the January 2006 Final Rule, the FDA did not expressly raise the issue of preemption.¹²² However, the FDA asked for comments on the product liability implications of the proposed revisions. In the explanation of the Final Rule, the FDA expressly discussed the issue of preemption in the context of comments received.

The comments received focused on liability implications arising from the proposal for a “highlights” section in labeling materials. Some manufacturers expressed concerns that a highlights section would make them more vulnerable to products liability claims by virtue of the

specific populations. See Id. 3924, Table 1.

¹¹⁹Id. at 3925 (except for identified minor changes).

¹²⁰Id. at 3928 (section IV). Indeed, the FDA announced in the Final Rule the availability of four guidance document on content and format, which were “intended to assist manufacturers and FDA reviewers in developing clear, concise, and accessible prescription drug labeling.” Id. at 3928-3929 (the documents are entitled: (1) “Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements”; (2) “Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Contents and Format”; (3) “Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Contents and Format”; (4) “Clinical Studies Section of Labeling for Prescription Drug and Biological Products—Contents and Format”).

¹²¹The FDA’s specific statements relating to its shift in position on the preemption issue are found in two places in the Final Rule. In part VI, in which the FDA explained and responded to “comments” received in the rule making process. Specifically, section D of part VI. See Id. at 3933 (“Comments on Product Liability Implications of the Proposed Rule”). And in part X, in which the FDA addressed “federalism” concerns associated with the new regulations. See Id. at 3967 (“Executive Order 13132: Federalism”).

¹²²The APA requires an agency to follow certain procedures before promulgation and enforcement of a substantive regulation. The agency must publish a Notice of Proposed Rulemaking, which informs interested parties of the nature of, and the subjects and issues involved in, the rulemaking; and must allow adequate time for comments on the rulemaking. Additionally, the agency must, contemporaneously with publication of the Final Rule, provide an explanation of the agency’s findings and its rationale for the Rule, including explanations of the agency’s response to comments received. This contemporaneous explanation and discussion is referred to as the “Preamble” to a Final Rule.

fact that some information sufficiently important to be included on the label would nonetheless be excluded from the highlights section.¹²³ In response to this concern, the FDA noted that the new regulations included use of a prominent “highlights limitation statement,” which would help ensure that labeling would be considered in its entirety.¹²⁴ Other manufacturers expressed the concern that, in light of the revised standards, labels following the old format might be characterized by plaintiffs as “inferior to labeling in the new format,” and requested that the agency expressly state that FDA approval of labeling, in either format, preempts conflicting or contrary state law.¹²⁵ The FDA responded to this concern by devoting several pages to the issue of preemption.

2. The Content of FDA’s Assertions: “Congress Intended Our Labeling Decisions to Preempt the Field of Risk Disclosure”

The FDA’s explanation emphasized the role of the FDA and the purpose served by prescription drug labeling generally. According to the FDA, Congress charged the agency with the responsibility of ensuring (i) that drugs are safe and effective, and (ii) that drug labeling “informs users of the risks and benefits of the product and is truthful and not misleading.”¹²⁶ The FDA emphasized that approval decisions are based on comprehensive scientific evaluation of a product’s risks and benefits and, as well, on practical public health considerations -- such as the nature of the disease or condition for which the product’s use is directed, and the need for risk management to maintain an appropriate “benefit-risk balance.”¹²⁷ The FDA explained its view that (i) labeling reflects “the agency’s formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively;” and (ii) labeling is the FDA’s “principle tool for educating health care professionals . . . to help ensure safe and effective use.”¹²⁸

Regarding post-approval changes to labels, the FDA first asserted that it “continuously

¹²³Id. at 3933 (Section IV. D., comment 12).

¹²⁴Id.

¹²⁵Id. (comment 13).

¹²⁶Id. at 3934.

¹²⁷Id.

works to evaluate the latest scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate.”¹²⁹ The FDA noted that, technically, sponsors can add risk information to the label without prior approval, but emphasized that FDA reviews all changes or modifications and has authority to later deny approval and to initiate enforcement proceedings if a change renders a label false or misleading.¹³⁰ Thus, the FDA asserted that, “in practice, manufacturers typically consult with FDA prior to adding risk information to labeling.”¹³¹

The FDA then made a number of assertions relating to how state law actions could frustrate or interfere with the FDA's responsibilities under the statute. First, the FDA asserted that, since the date of the publication of the proposed rule (in which the FDA was silent as to preemption), FDA had learned of products liability suits which “have directly threatened the agency's ability to regulate manufacturer dissemination of risk information . . . in accordance with the act.”¹³² Second, the agency asserted that courts in products liability actions would “rely on and propagate interpretations of the [A]ct and FDA regulations that conflict with the agency's own interpretations and [thus] frustrate the agency's implementation of its statutory mandate.”¹³³ The agency asserted that courts had wrongly interpreted FDA regulations as giving manufacturers “latitude” to strengthen warning labels without first obtaining permission from the FDA since, “in fact, the determination whether labeling revisions are necessary is, in the end,

¹²⁸Id.

¹²⁹Id.

¹³⁰Id. [check whether FDA has ever pursued a change that provided extra warnings; case re: tobacco patch – where FDA had expressly considered and “banned” the warning ??].

¹³¹Id.

¹³²The FDA highlighted one case, in which the lower court had allowed a state action to proceed against a drug manufacturer, and which involved an alleged failure to warn of a specific risk which the FDA had considered and disallowed on the label. *Id.* (citing *Dowhal v. Smithkline Beecham Consumer Healthcare*, 2002 Cal. App. LEXIS 4384 (Cal. Ct. App.2002), rev'd 2004, Cal. LEXIS 3040 (Cal. April 15, 2004). Notably, the FDA did not point out that the appellate court had reversed the trial court decision for the reason that, given the FDA's specific disapproval of a label bearing the risk, it was indeed inappropriate on those facts to hold the manufacturer liable. The other cases cited by the FDA in which the courts had permitted claims to proceed did not involve similar facts; but, instead, involved the more typical cases in which the manufacturer had simply failed to seek approval of a label bearing the particular risk at issue. See *Id.*

¹³³Id.

squarely and solely FDA's under the act."¹³⁴ Yet, in the next sentence, the FDA more accurately noted that "in practice manufacturers typically consult with FDA" – for practical reasons rather than being mandated by the statute or regulations.¹³⁵ The agency also asserted that courts had wrongly interpreted the statute by characterizing the FDA labeling requirements as representing a "minimum safety standard."¹³⁶ According to the FDA, "[i]n fact, FDA interprets the act to establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability . . . if the additional statement is unsubstantiated or otherwise false and misleading."¹³⁷

At this point the FDA asserted certain other propositions purportedly supporting preemption of state laws that might cause manufacturers to disclose additional risks – risks other than those specifically approved for disclosure by the FDA. First, the FDA asserted that, given the comprehensiveness of FDA regulation under the statute, additional disclosures of risk "are not necessarily more protective of patients" and could lead to defensive labeling.¹³⁸ Second, the FDA asserted that state law actions would allow the FDA's statutorily prescribed, centralized and expert determinations to be usurped by individualized re-evaluation by lay judges and juries.¹³⁹

In closing the discussion, the agency made mixed statements; but, in the end, expressed a very broad view of preemption. The FDA first stated:

FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated. . . . [or], if it purports to preclude a firm from including in labeling or advertising a statement that is included in prescription drug labeling.¹⁴⁰

¹³⁴Id.

¹³⁵Id.

¹³⁶Id.

¹³⁷Id. at 3934-3935.

¹³⁸The FDA explained that additional disclosure could "disrupt the careful and truthful representation of benefits and risks" Id. at 3935. Thus, according to the FDA, "exaggeration of risk could discourage appropriate use of a beneficial drug." Id. Similarly, the FDA asserted that liability concerns were prompting manufacturers to engage in defensive labeling by including speculative risks, which would negatively impact a physician's appreciation of more significant risks: over-warning thus "potentially discourag[es] safe and effective use of approved products or encourag[es] inappropriate use" – thereby undermining the objective of the act. Id.

¹³⁹Id.

¹⁴⁰Id. at 3935. This statement targets only civil actions posing *conflicting* state laws.

This statement suggests a view limited to conflict preemption.¹⁴¹

However, the FDA also set forth a list of state law actions (or claims) that, in its view, would be preempted.¹⁴² Notably, although the list includes some claims that would readily present a conflict (e.g., a plaintiff's claim that the manufacturer failed to include a statement the substance of which FDA has prohibited),¹⁴³ the list includes other claims that seem to implicate a very broad view of preemption. For example, the FDA list includes "claims that a sponsor

¹⁴¹Some courts have construed the FDA's position as being limited to a narrow type of conflict preemption. See, e.g., *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 97 (2006), cert. granted, 128 S.Ct. 31 (2007) (noting that the FDA "apparently confined its view that state claims undermine federal law to circumstances 'when [state laws] purport to compel a firm to include in labeling or advertising a statement that [the] FDA has considered and found scientifically unsubstantiated.'). See also *Zyprexa Products Liability Litigation*, 489 F.Supp.2d 230, 270-72 & 277 (E.D.N.Y. 2007) (viewing the FDA's view broadly in one part of the opinion, and narrowly in a later part of the opinion).

¹⁴²The Notice explains that the FDA believes that "at least the following claims would be preempted" by its regulation of prescription drug labeling:

- (1) Claims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling;
- (2) claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug's sponsor has used Highlights consistently with FDA draft guidance regarding the "brief summary" in direct-to-consumer advertising ("Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements," 69 FR 6308 (February 2004)) (see comment 112);
- (3) claims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule, including § 201.57(c)(5) (requiring that contraindications reflect "[k]nown hazards and not theoretical possibilities") and (c)(7);
- (4) claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn);
- (5) claims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising; and
- (6) claims that a drug's sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug's label (unless FDA has made a finding that the sponsor withheld material information relating to the statement). Preemption would include not only claims against manufacturers as described above, but also against health care practitioners for claims related to dissemination of risk information to patients beyond what is included in the labeling.

Id. at 3936.

breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule¹⁴⁴ That is, a failure to warn claim such as in the cases involving Zoloft and Paxil.¹⁴⁵ Cases where – at the time of the plaintiff’s ingestion – the evidence may have suggested a statistically significant association between the drug and the risk, but where the evidence had not yet convinced the FDA to *require* a specific warning on the label. Thus, the FDA views the approval decision as shielding a prescription drug manufacturer from being held to any state tort standard relating to warnings on drug labels – even if that standard arguably *promotes* patient safety by requiring disclosure of risks that the FDA did not require, but also did not prohibit. Accordingly, FDA is not asserting merely conflict preempt; but, rather, the FDA’s view is consistent with field preemption.

3. Analysis Reveals the Illusory Nature of the FDA’s Assertions in the 2006 Rule

As noted in Part I, a sound preemption analysis requires identification of the particular agency action which is the source of the purported preemption. Scrutiny of the FDA’s assertions reveals a “dual source” of preemption.¹⁴⁶ First, the specific agency action which is the source or trigger of actual preemption is the FDA’s “approval decision” which allows a drug manufacturer to market its drug. The approval decision is an adjudicative decision. An adjudicative decision has the force of law and thus preemptive power, but, as noted, generally gives rise only to conflict preemption.¹⁴⁷ Yet, the FDA is asserting, in essence, a variant of field preemption. Although cast largely in terms of conflict preemption due to frustration with federal objectives,

¹⁴³Id. at 3936 (example number 5). See note (immed prior note).

¹⁴⁴Id. (examples 3 and 4). See note (immed prior note).

¹⁴⁵See, e.g., *Colacicco v. Apotex, Inc.*, 432 F. Supp 2d 514 (E.D. Penn. 2006) (involving the drug Paxil); *NcNellis v. Pfizer, Inc.*, 2006 WL 2819046 (involving the drug Zoloft). See also *Perry v. Novartis Pharma. Corp.*, 456 F. Supp. 2d 678 (E.D. Penn. 2006) (involving the drug Elidel).

¹⁴⁶See *supra* notes – to – and accompanying text. Although an agency’s adjudicatory decision ordinarily could give rise only to conflict preemption, a broader preemptive effect would be possible if so intended by the agency or Congress. In such a case, however, the broader preemptive effect would necessarily be established via a statute or an agency rule. In such a case, it is appropriate to state that “a *dual source* of preemption exists: a statutory or regulatory rule which dictates or establishes the *possibility* of preemption and the scope of preemption; and the agency order or decision which triggers *actual* preemption.” *Id.*

¹⁴⁷See *supra* notes – to – and accompanying text.

the FDA’s many supporting reasons collapse into the central idea that the approval decision sets the “floor and ceiling” for disclosure of risk information. Field preemption ordinarily cannot arise from an adjudicatory decision unless another source exists which supports a broader scope of preemption.

That other source is the statute. Throughout the 2006 Rule, the FDA consistently pointed to potential conflicts with the *statute* as being the key reason for the preemption.¹⁴⁸ The agency is, therefore, asserting that, although triggered by specific approval decisions, preemption is due to congressional intent: i.e., that Congress intended this type of adjudicatory determination to preempt the field of risk disclosure in prescription drug labeling.

Closer analysis reveals the illusory nature of the FDA’s assertions. It is true that the rationale for preemption crafted by the FDA hinges to some degree on the overall statutory responsibilities as outlined by Congress. For example, the FDA’s explanation stresses to some extent Congress’ charge to the agency to ensure (i) that drugs are safe and effective, and (ii) that drug labeling “informs users of the risks and benefits of the product and is truthful and not misleading.”¹⁴⁹ However, the FDA’s reasoning much more predominantly hinges on conflict with FDA functions, activities, and objectives that have evolved over time.

For example, in explaining that labeling reflects “the agency’s formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively,” the FDA emphasized a relatively contemporary view of efficacy. The FDA noted that the agency evaluates a product’s risks and benefits in light of “practical public health considerations -- such

¹⁴⁸For example, the FDA stated: (1) Products liability suits “have directly threatened the agency’s ability to regulate manufacturer dissemination of risk information . . . in accordance with *the act*.” Id. at 3934. (2) Judicial “interpretations of *the act* and FDA regulations that conflict with the agency’s own interpretations and [thus] frustrate the agency’s implementation of its *statutory* mandate.” Id. at 3934. (3) Courts have wrongly interpreted the *statute* by characterizing the FDA labeling requirements as representing a “minimum safety standard.” According to the FDA, “[i]n fact, FDA interprets *the act* to establish both a ‘floor’ and a ‘ceiling’” Id. at 3934-3935. (4) Given the comprehensiveness of *FDA regulation under the statute*, additional disclosures of risk “are not necessarily more protective of patients” since they can “disrupt the careful and truthful representation of benefits and risks” Id. at 3935. (5) Over-warning thus “potentially discourag[es] safe and effective use of approved products or encourag[es] inappropriate use” – thereby undermining “the objectives of *the act*.” Id. at 3935. (6) State actions allow the FDA’s *statutorily* prescribed, centralized and expert determinations to be usurped by individualized re-evaluation by lay judges and juries. Id. at 3935.

¹⁴⁹Id. at 3934.

as the nature of the disease or condition for which the product's use is directed, and the need for risk management to maintain an appropriate 'benefit-risk balance.'"¹⁵⁰ Yet, the objective of risk management generally, and the specific methodology of achieving the right "benefit-risk balance" and the "optimal use" of particular drugs are of relatively recent development.¹⁵¹ Historically, the term "safety" was understood as protecting consumers from "adulterated, poisonous and deleterious drugs," and "effectiveness" referred primarily to an assessment of a manufacturer's claims as to the "curative purpose" of a drug.¹⁵²

Similarly, the FDA emphasized that labeling is the FDA's "principle tool for educating health care professionals . . . to help ensure safe and effective use,"¹⁵³ again referring to the contemporary view of efficacy. Yet, the FDA has historically emphasized that prescription drug labels must convey to the practitioner all facts that are "material" – facts that are necessary to help the practitioner know how to use the drug prudently.¹⁵⁴ For example, in the preamble to the 1979 Final Rule - in response to comments as to the burden placed on physicians to interpret the labeling information given that the regulations "inhibit information about effectiveness," yet "require" information about potential hazards even without proof of a "causal relationship" – the FDA stressed that a label would be misleading if it "fails to reveal facts that are . . . material with

¹⁵⁰Id. at 3934 (or, Id. at 3922 (Section IV. D., comment 13))???

¹⁵¹See, e.g., Task Force on Risk Management, *Managing the Risks from Medical Product Use: Creating a Risk Management Framework*, available at <http://www.fda.gov/oc/tfrm/riskmanagement.pdf> (last visited December 7, 2007).

¹⁵²See *Kar-Ru Chemical Co. v. United States*, 264 F. 921, 923 (9th Cir. 1920) (quoting 62d Cong., 2d Sess., 48 Congressional Record, part 11, p. 11322) (statement of Mr. Sherley, explaining the 1912 Sherley Amendments and the emphasis on agency control over claims as to the "curative or therapeutic properties of drugs"). See also http://www.fda.gov/fdac/features/2006/106_cder.html (accessed October 2007) ("Before the 1962 amendments to the Federal Food, Drug, and Cosmetic Act, controlled trials were still developing, and many marketed drugs were ineffective for their labeled uses. Now, the standard for evidence is the well-controlled study, and the FDA's implementation of the 1962 amendments contributed greatly to that.") (statement of Steven Galson, M.D., who served as director of the FDA's Center for Drug Evaluation and Research (CDER) from July 2005 - -----).

¹⁵³Id. at 3934

¹⁵⁴See 44 Fed. Reg. 37434, at 37436. The FDA stated: "[W]hen a manufacturer prescribes, recommends, or suggests an intended use for a drug in its labeling, the labeling must also include any necessary statements on selection or monitoring of patients, duration of treatment, and other subjects, or risk misbranding the drug . . . [despite the fact] that the manufacturer may make conservative medical judgments in preparing labeling for its drugs to protect itself from civil liability . . ." Id.

respect to consequences that may result from use of the drug”¹⁵⁵

Moreover, a key FDA assertion is grounded in agency “practice.” The FDA conceded that the statute “technically allows” a drug manufacturer – without prior FDA approval – to add risk information to a label. Yet, the FDA emphasized that “in practice” prior consultation occurs.¹⁵⁶ The FDA specifically relied on this “practice” to support its assertion that, because of “conflicting” or “erroneous” judicial interpretations, state law actions could frustrate the agency’s implementation of its “statutory mandate.”¹⁵⁷ Yet, because the statute clearly allows changes that strengthen warnings, the real conflict is with objectives and activities developed by the agency – and developed to serve agency concerns.

Thus, if a conflict arguably now exists between state common law failure to warn claims and FDA labeling decisions, that conflict arose as a consequence of FDA functions, activities and objectives that evolved over time. As such, the FDA’s assertion that it is *Congress* that intended to preempt state failure to warn claims becomes illusory.

4. Other Evidence Highlights the Illusory Nature of the FDA’s Characterization

The history of both the FDA’s view and the judicial view of the preemption issue provides additional strong evidence that preemption of state failure to warn claims should be attributed to agency intent, and not congressional intent. In the 1979 Final Rule, the FDA clearly expressed its view that labeling decisions – at that time – were not considered as establishing both a “floor” and a “ceiling.” The FDA in 1979 frankly acknowledged that the information on labels would reflect less than current medical and scientific knowledge, noting that advances in medical knowledge inevitably precede formal submission of proposed new labeling by the manufacturer and approval by the FDA.¹⁵⁸ Further, the FDA recognized that the labeling requirements would, in essence, require manufacturers to make “medical judgments”– and that those judgments would be conservative “for their own protection.”¹⁵⁹ The FDA did not view as

¹⁵⁵Id. at p. 37436.

¹⁵⁶Cite 2006 Rule, at 3934.

¹⁵⁷Id. at 3934.

¹⁵⁸1979 Rule at p. 37435.

¹⁵⁹Id. at 37436.

objectionable the potential for “defensive labeling” as a means of protecting manufacturers from civil liability. Rather, the FDA noted: “that is the not unexpected outcome of our drug labeling laws and civil liability system.”¹⁶⁰ Moreover, the FDA expressly addressed the notion that “interaction” or “consultation” between the FDA and the manufacturer as to the final labeling decision might be used in civil litigation. In response, the FDA stressed: “It is not the intent of FDA to influence the civil tort liability of the manufacturer or of the physician. Rather, it is the agency’s intent to ensure that a complete and accurate explanation of the drug is provided to the medical community.”¹⁶¹

Similarly, the majority of courts have historically adopted the view that FDA approval of labeling does not warrant preemption of state law. Those courts typically cited two main reasons for the view that the federal FDA premarket approval scheme does not warrant conflict preemption of state products liability actions. First, the courts generally found that the FDA’s labeling decisions in the premarket approval process impose only “minimum standards” – that is, standards that are “open to supplementation.” Courts grounded this finding in congressional intent as well as *the scheme devised by the FDA through its regulations*. As stated by the Eighth Circuit, “FDA approval is not a shield to immunity FDA regulations are generally minimum standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area.”¹⁶² The courts cited to FDA regulations which allow a drug manufacturer to strengthen warnings in a timely manner, when new risk information surfaces. As explained by one district court,

The regulations contemplate that information may arise before and after application approval that, in the mind of the manufacturer, calls into question the current safety of the drug with respect to any or all indications and calls for a strengthened warning. Even after approval, additional or more forceful warnings may, in the drug manufacturer’s judgment, be added to labeling without prior FDA approval and on the drug manufacturers [sic] own initiative.¹⁶³

¹⁶⁰Id.

¹⁶¹Id. at 37437.

¹⁶²Hill v. Searle Laboratories, a Div. Of Searle Pharmaceuticals, Inc., 884 F.2d 1064, 1068 (8th Cir. 1989). See also Wells v. Ortho Pharmaceutical Corp., 788 F.2d 741, 746 (11th Cir.) (“An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes.”), cert. denied, 479 U.S. 950 (1986). See also Caraker v. Sandoz Pharmaceuticals Corp., 172 F. Supp. 2d 1018, 1033 at n. 11 (S.D. Ill. 2001) (collecting cases).

¹⁶³See Caraker v. Sandoz Pharmaceuticals Corp., 172 F. Supp. 2d 1018, 1033-34 (S.D. Ill. 2001) (citing

Further, the courts pointed to the history of FDA regulation relating to additional warnings.

Until 1965, the FDA . . . prohibited companies from adding warnings or other information without prior approval which allow. See 25 Fed. Reg. 12, 592, 12595 (1960). These regulations were amended in 1965, allowing labeling changes related to safety to be “placed into effect at the earliest time,” the goal of which was for drug manufacturers “to prompt adoption of such changes.”¹⁶⁴

The FDA adhered to the same view.¹⁶⁵ The courts *and the FDA* thus rejected the argument that state products liability actions would make it impossible for a drug maker to comply with both federal law.

Second, the courts also rejected the argument that state tort actions are impliedly preempted because they would frustrate the objectives underlying federal law. Courts have viewed drug safety as being the primary objective underlying the FDCA and the FDA regulations,¹⁶⁶ and have found that drug safety “is more enhanced than frustrated by state law.”¹⁶⁷ The Fifth Circuit has explained that, because the FDA regulations specifically permit – without the need to first obtain FDA approval – a manufacturer to add a warning to a previously approved label as soon as it becomes aware of the appropriateness of a warning, “federal law neither made it practically (nor legally) impossible, nor would it have posed an obstacle to accomplishing the objectives of the FDCA.”¹⁶⁸

The early express view of the FDA and the judicial understanding of the lack of

21 C.F.R. § 314.70) (citing also *Osborn v. Anchor Labs*, 825 F.2d 908, 912 & n. 4 (5th Cir 1987) (relying on parallel provisions for warnings on animal drugs), cert. denied, 485 U.S. 1009 (1988); *In re Tetracycline Cases*, 747 F. Supp. 543, 549-50 (W.D. Mo. 1989) (noting that a warning could be added in advance of FDA approval, and that other means existed, for the dissemination of warning information, which would not conflict with federal labeling requirements)).

¹⁶⁴See *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F. Supp. 2d 1018, 1034-35 (S.D. Ill. 2001) (quoting 30 Fed. Reg. 993 (1965)).

¹⁶⁵Cite.

¹⁶⁶See, e.g., *Abott v. American Cyanamid Co.*, 844 F.2d 1108, 1113 (4th Cir. 1998) (“The overall goal of the [Public Health Service Act] and the FDCA is the safety of drugs and biological products.”).

¹⁶⁷*Id.*

¹⁶⁸See *Osburn v. Anchor Laboratories, Inc.*, 825 F.2d 908, 912-13 (5th Cir. 1987) (interpreting the virtually identical FDA regulatory scheme for veterinary drugs (see 21 C.F.R. § 314.70(c)(6)(iii)(A)). This “minimum standards” approach also accommodates other rationales used by courts, namely that state law supplements FDA regulation by creating a compensatory mechanism not available under federal law. [insert re: reluctant to infer preemption when victims are left without a remedy].

preemptive effect of the FDA’s labeling decisions readily support the view that the source of the preemption that is now being asserted by the FDA is not really Congress and the statute, but, rather, is the ever-broadening scope of FDA labeling regulations. If the FDA’s current view of preemption is correct, it is because FDA’s views and practices have evolved over time. *The field occupied by FDA regulations has grown and the scope of the labeling decision has become more comprehensive.* Rather than representing a decision about the minimum risk information that a manufacturer must present, *the FDA now intends* the decision to control the totality of the risk information provided. Given this set of circumstances, it is misleading to characterize the preemption as arising from congressional intent. Rather, the FDA has simply engaged in strategic characterization.

C. The Court Should Reject the Implicit Endorsement of a Restricted View of Agency Preemption

Rather than promoting strategic characterization of the source of the intent to preempt, courts should be able to label preemption as “agency preemption” when scrutiny of the facts and circumstances show that preemption has arisen because of an evolution in agency regulation and activity – an evolution wherein it is the agency’s regulatory occupation of the field which has created the potential for conflicts with state law. The Court in *Geier* made a mis-step; but ample pre-*Geier* precedent would support a less-restrictive approach to identifying cases of agency preemption.

1. The Mis-Step in *Geier*

The situation presented in *Geier* readily fit the mold of “agency preemption.” Congress’ purpose in enacting the National Traffic Motor Vehicle Safety Act was to “reduce traffic accidents and deaths and injuries to persons resulting from traffic accidents.”¹⁶⁹ As one means of attaining that purpose, Congress directed the Secretary of Transportation to issue motor vehicle “safety standards,” and specifically defined the term “safety standard” as a “minimum standard for motor vehicle performance or motor vehicle equipment performance.”¹⁷⁰ The purpose of

¹⁶⁹See *Geier*, 529 U.S. 861, 889 (2000) (Stevens, J., dissenting).

¹⁷⁰*Id.*

FMVSS 208 was to reduce the number of deaths and the severity of injuries by specifying equipment requirements for active and passive restraint systems.¹⁷¹ However, rather than promulgating a traditional “safety standard,” DOT made a determination that a “phase-in” standard was appropriate.¹⁷² The administrative record revealed that DOT carefully considered options;¹⁷³ and deliberately opted for a regulation that allowed a phase-in period, and use of a variety of restraint systems during the phase-in period.¹⁷⁴ The Court held that FMVSS 208 preempted the plaintiff’s tort action because it frustrated the specific objectives devised by the agency.¹⁷⁵

As noted, the majority found that plaintiff’s tort suit preempted under the guise of *congressional* intent as found via the concept of implied preemption due to “frustration with federal purpose.”¹⁷⁶ Yet, because the text of the statute clearly suggested that Congress envisioned safety standards that would constitute minimal standards, the natural and appropriate way to view the phase-in program would have been to view it as setting “minimum percentage requirements.”¹⁷⁷ Indeed, it was a real stretch to hold that Congress impliedly intended to preempt a state tort suit such as that asserted by the plaintiff against Honda. Because DOT made a deliberate decision to promulgate standards for passive restraint systems at variance with the statutory definition of standard, the more natural characterization of the circumstances is that

¹⁷¹Id.

¹⁷²FMVSS 208 required manufacturers in 1984 to equip a minimum of ten percent of their new passenger cars with a passive restraint system; the requirement increased to 25 % in 1988, 40% in 1989. Id. at 890.

¹⁷³Id. at 878-79 (explaining that DOT considered a number of factors in deciding on the 1984 regulation: safety concerns (perceived or real) associated with airbags, the need for data on comparative effectiveness, the industry’s need for time to overcome the high production costs associated with airbags and any safety problems, the potential for development of alternative, cheaper and safer passive restraint systems, and the need to build public confidence).

¹⁷⁴The DOT informed the Court that FMVSS 208 “embodi[ed] the Secretary’s policy judgment that safety would best be promoted if manufacturers installed alternative protection systems in their fleets rather than one particular system in every car.” Id. at 881 (citing Brief for United States as Amicus Curiae 25; 49 Fed. Reg. 28997 (1984)).

¹⁷⁵The majority concluded that Geier’s tort action would impose a duty which, “by its terms would have required manufacturers of all similar cars to install airbags rather than other passive restraint systems It thereby would have presented an obstacle to the variety and mix of devices that the federal regulation sought.” Id. at 881.

¹⁷⁶See supra notes – to – and accompanying text.

¹⁷⁷Id. at 903-04 (Stevens, J., dissenting).

DOT made a decision to set a standard that would preempt state tort suits.¹⁷⁸ As such, the case should have been treated as one of “agency preemption.”

Thus, the majority in *Geier* missed the mark – and opened the door to strategic characterization such as that demonstrated by the FDA’s recent activity. The Court found that the express preemption and savings clauses did not provide evidence of congressional intent to foreclose operation of “ordinary pre-emption principles;”¹⁷⁹ but, ordinary preemption principles recognize that *an agency* may use its authority to preempt state law. By rejecting a totality of the circumstances approach in identifying the source of preemptive intent, the Court in *Geier* restricted *Shimer*’s agency preemption analysis to cases where the agency has expressed, in some manner, its intent to preempt – and thus also implicitly endorsed “strategic characterization.”

2. Key Pre-Geier Precedent Would Support a Less Restrictive “Totality of the Circumstances” Approach to Agency Preemption

The pre-*Geier* precedent from which the agency preemption analysis evolved would support a broader view of “agency preemption.” The more recent of the *Shimer* line of cases involved express statements by the agencies involved; i.e., the agency had expressly considered and decided the preemption issue. Importantly, however, the Court in those cases did not announce a principle that an agency *must* make express statements to trigger the *Shimer* analysis.

¹⁷⁸As explained *supra*:

The majority noted that the express preemption clause and the savings clause “reflect a neutral policy, not a specially favorable or unfavorable policy, toward the application of ordinary conflict preemption principles.” That is, the preemption clause reflected a desire for uniformity as to “standards” – which could include state tort suits; but that the savings clause reflected recognition of the desirability of occasional non-uniformity when appropriate to provide necessary compensation to victims. Further, the Court expressly noted that non-uniformity – and thus *no* preemption – would be appropriate when a state tort suit would establish liability for failing to provide greater protection than that established by a “minimum” standard set by DOT; and expressly recognized that the preemption at issue was triggered by a DOT regulation that deviated from the type of minimum standard that Congress expressly empowered the DOT to promulgate. Stated another way, the Court expressly recognized that state tort suits would not be preempted by minimum safety standards; but only by standards such as FMVSS 208, which the DOT later construed not as a minimum standard, but as setting a “floor and ceiling” as to installation of airbags. These circumstances logically would point towards the appropriateness of viewing the case as one of agency preemption.

See *supra* at notes – to – and accompanying text.

¹⁷⁹*Id.* at 869.

Moreover, in the earlier of the Shimer cases, the Court approached the matter as involving agency preemption notwithstanding the absence of express statements by the agency regarding preemption.

The most recent cases pre-Geier involved FCC decisions that agency regulations preempted state law. In *Capital Cities Cable, Inc. v. Crisp*,¹⁸⁰ decided in 1984, the Court upheld the FCC's 1974 decision to preempt state law. In 1974, the FCC had decided to preempt the field of state cable television regulation after notice and comment specifically addressing the preemption issue. The Court clearly framed the issue as one of judicial review of an agency's explicit decision to preempt state law, and reiterated the limited scope of judicial review if the federal regulatory scheme which preemption protects is within the scope of the agency's delegated authority.¹⁸¹ In *City of New York v. FCC*,¹⁸² decided in 1988, the Court similarly upheld the agency's express determination that preemption was appropriate. The FCC regulations at issue in *City of New York* established technical standards governing signal quality; and, in the explanation accompanying publication of the final rule, the FCC reiterated its view that its *prior* preemption policy was still warranted.¹⁸³ The Court in *City of New York* expressly explained that "in the proper circumstances," an agency may determine that its authority in a particular area is exclusive and thus preempts state efforts to regulate in that area.¹⁸⁴ The Court affirmed again that, when the agency has decided that preemption is warranted, the inquiry is two-fold: identifying the proper bounds of the agency's authority to preempt, and assessing whether the decision to preempt represents a reasonable accommodation of conflicting policies committed to the agency's care by the statute.¹⁸⁵ As noted, although these FCC cases involved express determinations by the agency that preemption was warranted, Court did not announce a principle that an agency must make express statements to trigger the Shimer analysis.

More importantly, earlier agency preemption cases did not involve express decisions to preempt. The case generally cited as the origin of the distinct agency preemption analysis is

¹⁸⁰467 U.S. 691 (1984).

¹⁸¹*Id.* at 699.

¹⁸²486 U.S. 57 (1988).

¹⁸³*Id.* at 61-62 (citing 50 Fed. Reg. 52462, 52464-52465).

¹⁸⁴*Id.* at 64.

United States v. Shimer,¹⁸⁶ decided in 1961. At issue in Shimer were regulations of the Veterans' Administration which governed the VA's obligations as guarantor on a secured debt. More specifically, regulations required application of "credits accruing" to reduce the amount payable on a claim, and specified, in detail, the method of determining the "credits."¹⁸⁷ The VA regulations were designed to protect the VA against the risk of "having to make good its guaranty simply because the mortgaged property is sold for an inadequate price at a judicial sale."¹⁸⁸ The state law at issue was designed to serve the same purpose, but used a judicial determination as the basis for determining the "credits accruing" rather than the method specified in the VA regulations.¹⁸⁹ A key issue in the case was whether, in cases where the VA administrator had failed to use the federal scheme to protect itself, the state law protections should apply.

Notably, the Court in Shimer did not point to any express statement of intent to preempt on the part of the VA. Indeed, none existed. Rather, the Court examined the regulatory scheme and, noting its completeness and attention to every detail, stated: "We have no doubt that this regulatory scheme . . . was intended to provide the whole and exclusive source of protection of the interests of the Veterans' Administration as guarantor"¹⁹⁰ The Court thus "inferred" the agency's intent to preempt, in a manner similar to a traditional implied field preemption analysis. The Court in Shimer then explained that the proper scope of review was very deferential: "where Congress has committed to the head of a department certain duties requiring the exercise of judgment and discretion, his action thereon, whether it involve questions of law or fact, will not be reviewed by the courts unless he has exceeded his authority or this court should be of opinion that his action was clearly wrong."¹⁹¹

In Fidelity Federal Savings and Loan Assn v. de la Cuesta,¹⁹² the Court similarly applied the regulatory preemption analysis despite the absence of an express statement of agency intent to

¹⁸⁵Id.

¹⁸⁶367 U.S. 374 (1961).

¹⁸⁷Id at 376-381.

¹⁸⁸Cf. Id at 379.

¹⁸⁹Id at 379 & 380-81.

¹⁹⁰Id at 381.

¹⁹¹Id at 381-82 (quoting Bates & Guild Co. v. Payne, 194 U.S. 106, 108-109 (19--)).

¹⁹²458 U.S. 141 (1982).

preempt. In *de la Cuesta*, the Court reviewed the use of preemptive authority by the Federal Home Loan Bank Board. The case involved a 1976 Board regulation which clarified that federal savings and loan associations had the power to include in its contracts a “due-on-sale” clause and, if included in contracts, provided that exercise of the option was governed exclusively by the terms of the loan contract.¹⁹³ At issue was preemption of California common law which deemed an unnecessary exercise of a due-on-sale clause as a violation of the state’s prohibition of unreasonable restraints on alienation.¹⁹⁴ The Court in *de la Cuesta* found that the “Board’s intent to pre-empt . . . [was] unambiguous.”¹⁹⁵ Notably, in this case too, the Board’s intent was not in the form of an outright statement that the regulation “preempted” state law. However, more textual evidence existed than in *Shimer*. The evidence consisted of (1) the text of the regulation which so plainly affirmed the power of federal savings and loans to use “due-on-sale” clause, and (2) a statement in the preamble accompanying the 1976 final publication of the regulation, in which the Board explained its intent that the due-on-sales practices of federal savings and loans would be governed “exclusively by Federal law.”¹⁹⁶

Both *Shimer* and *de la Cuesta* support a less restrictive view of when a case involves agency preemption. In both, the Court plainly distinguished between preemption arising due to congressional intent and preemption arising due to the agency’s decision; and the Court looked to the totality of the circumstances in assessing the type of preemption at hand. In both, the Court treated the matter as agency preemption despite the absence of an express statement of preemptive intent by the agency. Precedent thus readily supports a broader conception of agency preemption.

Rather than restricting agency preemption to cases involving an express exercise of an agency’s authority to preemption, courts should be able to look to the surrounding circumstances and call a “spade a spade.” Courts should be able to characterize preemption as “agency

¹⁹³See *id.* at 144-147.

¹⁹⁴*Id.* at 148-49 (citing *Wellenkamp v. Bank of America*, 21 Cal. 3d 943 (1978); Cal. Civ. Code Ann. § 711)).

¹⁹⁵*Id.* at 154.

¹⁹⁶*Id.* at 146-47 (quoting 12 C.F.R. § 545.8-3(f) (1982); 41 Fed. Reg. 18286, 18287 (1976)). The Court also cited a 1981 Board statement in the Federal Register which reiterated the Board’s policy of broadly authorizing, subject only to express limitations imposed by the Board, enforcement of “due-on-sale” clauses by federal savings and loans.

preemption” whenever the “intent to preempt” reasonably can be attributed to the agency as opposed to Congress. When can intent to preempt reasonably be attributed to the agency as opposed to Congress? As in *Shimer*, it could be circumstances where the “regulatory scheme” – or, the “agency activity” – that warrants preemption is a comprehensive scheme put in place by the agency, especially when the regulations go well beyond any specific directives detailed by Congress.¹⁹⁷ All regulatory schemes must, of course, be put in place pursuant to the charge given to the agency by Congress. However, if the predominant trigger for preemption is federal law devised by the agency – agency regulations which creates rights and duties (i.e., regulations with the force of law) – it would be appropriate to view the matter as one of agency preemption. Or, as in *Geier*, when the text of the statute lacks indicators of an intent to preempt and the federal law which triggers preemption is deliberate agency action that deviates from the norm envisioned by Congress, a more realistic assessment of the circumstances is that *it is the agency* which intended to preempt state law.

Under a less restrictive view, the “matured” view of the FDA should be deemed agency preemption, and not as preemption arising due to congressional intent. As illustrated, it is the more comprehensive FDA activity which has given rise to the FDA’s arguments for preemption. The agency’s rationale hinges on conflict with FDA functions, activities, and objectives that have evolved over time: for example, the recent risk management activity of the FDA, and the practice of consultation with manufacturers prior to any addition of risk information to the label.¹⁹⁸ In such cases, casting the matter as one of implied preemption arising from congressional intent is purely fictitious, unnecessary, and undesirable.

Allowing courts to treat such cases as agency preemption would open the door to appropriate scrutiny of preemption arising from the activities of federal agencies. Greater scrutiny would result in part due to the elimination of misleading strategic characterization; but also due to the invocation of judicial review which would focus on the appropriateness of the agency action triggering preemption. That is, treating such cases as agency preemption would

¹⁹⁷For example, many agency regulations merely “parrot” the statutory directives devised by Congress. See, e.g., [recent controlled substances Supreme Court case where the majority distinguished “regulations that merely parrot the statute”]. In that type of case, any preemption arising from the comprehensive regulatory scheme could reasonably be attributed to congressional intent.

¹⁹⁸See *supra* notes – to – and accompanying text.

trigger the analysis from the Shimer line of cases and, appropriately understood, the Shimer analysis opens the door for a more appropriate judicial assessment of an agency's decision to preempt state law.

IV. Invigorating the Agency Preemption Analysis

Unmasking strategic characterization of preemption decisions will not ensure accountability for the preemption decision if the scope of judicial review lacks sufficient rigor. The question thus becomes whether the Shimer analysis provides an adequate safeguard for the important federalism issues at stake when agency action preempts state laws. Importantly, in cases where preemption arises from agency regulations – but where it is nonetheless appropriate to view the preemption as stemming from congressional intent – the Court has long recognized a “presumption against preemption.”¹⁹⁹ Such a presumption has not been applied in cases of preemption by the agency. Rather, the two-fold inquiry seems to cut in the opposite direction. A court first assesses whether the agency acted within the scope of its authority and, if so, the question is becomes whether the decision to preempt is reasonable. The standard language is that, “if the agency choice represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned.”²⁰⁰ This language – if not carefully applied – could result not just in deferential review, but, in fact, could lead courts to view the analysis as creating a *presumption in favor of preemption*.²⁰¹ Yet, in at least in some circumstances of agency preemption, greater judicial scrutiny would seem to be warranted. On specific instance would be when an agency decides that its regulatory activity warrants preemption of broad swaths of state law – especially state

¹⁹⁹However, such cases turn on congressional intent and agencies have some recognized expertise in understanding congressional intent underlying the statutes they administer. An important issue is thus how to properly integrate or balance the presumption against preemption with the notion of deference to an agency's view of congressional intent. The Court has not squarely addressed this issue.

²⁰⁰Crisp, 467 U.S. at 699. See also *City of New York v. Federal Communications Comm'n*, 486 U.S. 57, 64 (1988); *Fidelity Federal Savings and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 154 (1982).

²⁰¹See Campbell, *supra* note – , at 820 (noting that a “genealogical” analysis “suggests that the Court has erroneously incorporated the highly deferential analysis of regulatory conflict cases into regulatory preemption scenarios.”).

common law civil actions which exist to provide remedies for injured consumers. The agency preemption analysis must therefore provide an appropriate level of judicial scrutiny for the type of agency decision at issue.

A. Precedent Supports a Rigorous Inquiry into the Agency’s Authority to Preempt

Although the language used by the Supreme Court in its agency preemption cases sounds very deferential, careful scrutiny of the Court’s *application* of the Shimer analysis reveals decidedly *undefereential* scrutiny into an agency’s authority and its decision making process – scrutiny which comes into play in both prongs of the Shimer analysis. Beginning with the Shimer decision itself,²⁰² the Supreme Court has repeatedly conducted a thorough and meaningful review in cases of agency preemption.

1. Shimer: Establishing a “Hard Look” Type of Review

The preemption in Shimer arose from regulations of the Veterans’ Administration which governed the VA’s obligations as guarantor on secured loans provided to veterans. The regulatory scheme existed to encourage creditors to provide generous financing to veterans. Under the scheme, if a veteran defaulted on a loan, the mortgagee could demand a guaranty payment from the VA if any amount of the mortgagee’s claim remained unpaid after foreclosure and sale of the property.²⁰³ The specific regulations at issue pertained to the VA’s risk of having to make good its guaranty “simply because the mortgaged property is sold for an inadequate price at a judicial sale.”²⁰⁴ The regulations allowed the Administrator to “specify in advance of [the foreclosure sale,] the minimum amount which shall be credited to the indebtedness . . . on account of the value of the security to be sold.”²⁰⁵ If the Administrator did not specify a

²⁰²367 U.S. 374 (1961).

²⁰³The VA regulations established a procedure for calculating the maximum amount of the guaranty owed by the VA; required application of “credits accruing” to reduce the amount payable on a claim; and specified the method of determining the “credits.” Id at 376-381.

²⁰⁴Cf. Id at 379. In the case, the mortgagee, Excelsior, notified the VA of the default and then obtained a Pennsylvania judgment foreclosing the mortgage. At that time, the mortgage secured a debt in excess of \$13,000. Excelsior purchased the property at a sheriff’s sale for \$250; triggering the VA’s obligation to pay a guarantee in the amount of \$4,000. Id. at 376.

²⁰⁵Id. The VA regulations required, at a minimum, a credit in the amount of the price for which the

minimum credit amount, the mortgagee was required to credit only the net proceeds of the sale.²⁰⁶

The state law in the case came into play because the VA administrator – as to Shimer’s default – *had failed to specify* a minimum amount to be credited to the outstanding debt. The VA had paid the entire guaranty amount of \$4000 and was seeking indemnity from Shimer.²⁰⁷ The lower court applied a surety law principle that would have precluded the VA’s recovery from Shimer if the VA had been released from the obligation at the time the VA made the guaranty payment to the mortgagee; and looked to state law in deciding whether the VA had been released from its obligations.²⁰⁸ Specifically, the VA would have been released under the Pennsylvania Deficiency Judgment Act (PDJA). Under the PDJA, a “mortgagee who purchases property in execution proceedings” cannot recover a deficiency judgment “unless and until the mortgagee obtains a court determination of the fair market value of the mortgaged property and credits that amount to the unsatisfied liability.”²⁰⁹ In Shimer’s case, the mortgagee – which had purchased the property at the sheriff’s sale for \$250²¹⁰ – had failed to obtain the judicial valuation and thus, under the PDJA, the VA would *not* have been liable on its guaranty to the mortgagee and thus could not recover from Shimer.²¹¹

Before the Supreme Court, the VA argued that it was error to rely on state law in determining the VA’s obligations – because the state law was preempted by the federal VA regulatory scheme. Yet, the state law at issue was designed to serve the same purpose as the VA scheme – that of protecting a guarantor against the risk of the property being sold at an

foreclosed property sold. If the Administrator set a minimum amount, the mortgagee was required to reduce its claim against the VA (credit the claim) by the minimum amount. Alternatively, if the property was sold for less than the minimum, the regulations allowed the mortgagee to sell the property to the VA for the specified minimum amount. *Id.* at 379-80.

²⁰⁶*Id.* at 380.

²⁰⁷Section 506 of the statute allows the VA to become “subrogated to the rights of the holder of the obligation to the extent of the amount paid on the guaranty.” *Id.* at 378 n. 5.

²⁰⁸The parties agree with application of the surety law principle. *Id.* at 376-77. However, the VA argued that it was error to apply state law to determine whether the VA’s obligation had been release. *Id.* at 377.

²⁰⁹*Id.* at 377 (citing Purdon’s Pa. Stat., Tit. 12, §§ 2621.1-2621.11).

²¹⁰*Id.* at 376.

²¹¹*Id.* at 377 (noting that when the mortgagee fails to bring the requisite judicial valuation proceeding within six months after the foreclosure sale, “the debtor and guarantor are permanently discharged”).

inadequate price. The PDJA, however, used a *judicial* determination as the basis for determining the “credits” which should “accrue” as offsets of the guarantor’s liability, rather than the method specified in the VA regulations.²¹² The crux of the case was whether, in cases where the VA administrator had failed to use the federal scheme to protect itself, the state law protections should apply.

After inferring the requisite agency intent to preempt, the Court seemingly stressed the limited scope of judicial review by noting that, “where Congress has committed to the head of a department certain duties requiring the exercise of judgment and discretion, his action thereon, whether it involve questions of law or fact, will not be reviewed by the courts unless he has exceeded his authority or this court should be of the opinion that his action was clearly wrong.”²¹³ On its face, this language reflects a fairly basic administrative law principle: the principle of deferential review of acts committed to the discretion of the agency. Yet, the Court carefully reviewed the matter – questioning both the VA’s “authority to displace state law”²¹⁴ and the reasonableness of the decision to preempt.

The Court first pointed to language in the statute giving broad rulemaking authority to the Administrator; specifically, language authorizing the Administrator to “promulgate such rules and regulations not inconsistent with this title, . . . , as are necessary and proper for carrying out the provisions of this title.”²¹⁵ In this part of the opinion, the Court’s focus was not on “authority to preempt,” but, rather, was on the authority to promulgate the specific regulations at issue: regulations pertaining to “amounts of setoffs” and “procedures for determining the setoffs,” in relation to amounts due a mortgagee as a result of the VA providing a guaranty to help a veteran secure a loan. Because the regulations were so clearly consistent with “administering” the loan guaranty program, there was little need for further exploration of the agency’s “general authority” to promulgate the specific regulations at issue.²¹⁶

²¹²Id at 379 & 380-81.

²¹³Id at 381-82 (quoting *Bates & Guild Co. v. Payne*, 194 U.S. 106, 108-109 (19–)).

²¹⁴Cf. Id. at 381 (using language of the Court’s conclusion).

²¹⁵Id. n. 9. (quoting section 504 of the Act (codified at 38 U.S.C. §§212(a), 1804)).

²¹⁶That is, the Court merely “concluded” that “[w]e thing that [the Act] authorized the [VA] to displace state law by establishing these exclusive procedures”; and cited the general provision of rulemaking authority. Id.

Nonetheless, the analysis continued as the Court next scrutinized the regulations for consistency with congressional intent. In this part of the analysis, the focus shifted to a review of the decision to preempt. Scrutiny was warranted because the choice to preempt state laws that provided *greater* protection for the VA arguably seemed counterintuitive. The Court noted that Congress intended to help veterans obtain loans and “to obtain them with the least risk of loss upon foreclosure, to both veterans and the [VA]”; and that allowing operation of the PDJA would have furthered “at least the second of these purposes.”²¹⁷ However, the Court also found evidence that Congress “intended the guaranty provisions to operate as the substantial equivalent of a down payment in the same amount by the veteran on the purchase price, in order to induce prospective mortgagee-creditors to provide 100% financing for a veteran's home.”²¹⁸ As such, the Court viewed the agency decision to preempt state law protections as an accommodation of competing policies within the agency’s purview.

But that did not end the matter. The question remained as to whether the accommodation was reasonable. And here, too, the Court conducted a careful analysis. The Court explained:

We cannot say that a Pennsylvania lender would not prefer a down payment to a guaranteed loan in the same amount if the [PDJA] were applicable. Nor can we say that the Administrator has unreasonably sacrificed either the Government’s or the veteran’s protection in relying *exclusively* on the ‘upset price’ device in order to preserve the interchangeability of a guaranty with a down payment. The Veterans’ Administration can and does protect itself from a sale at an inadequate price by specifying the minimum credit which the mortgagee must subtract from the unpaid debt. In protecting itself it also places its own financial resources behind the debtor-veteran who may be forced to reimburse the Administration only if the Administrator considers that the property has been sold at a fair price, and who retains all the benefits of state law as against the mortgagee.²¹⁹

Only after fleshing out the rationale did the Court uphold the decision to preempt, noting that the decision arguably reflected a “more effective reconciliation of [Congress’] twofold ends than

²¹⁷Id. at 383.

²¹⁸Id. n. 10 (citing See, e.g., H.R.Rep. No. 1418, 78th Cong., 2d Sess., pp. 3, 9; Hearings before Subcommittee of the Senate Committee on Finance on H.R. 3749, 79th Cong., 1st Sess., pp. 31-33 (General Omar Bradley)). The Court determined that these regulations guaranteed a mortgagee-creditor a recovery in the form of either the full amount of the guaranty or the sale of the mortgaged property to the United States. “In contrast, a mortgagee whose federal guaranty was subject to the law of a State... would be subjected both to an additional cost and to an additional risk, neither of which is present when there is an equivalent down payment.” Id. at 384.

²¹⁹Shimer, 367 U.S. at 385 (emphasis added).

might be accomplished by a complete or partial adoption of the law of a State such as Pennsylvania.”²²⁰

Thus, although stressing at the outset the deferential nature of the review, the Court nonetheless conducted a solid, meaningful review of the agency’s authority. Indeed, it is fair to characterize the Court’s analysis in *Shimer* as a type of “hard-look” review of the agency decision to preempt. A hard-look type of review has been recognized as appropriate as to certain types of agency decisions, such as challenges to the merits of an agency’s policy decision made in a rulemaking proceeding.²²¹ For example, in *Motor Vehicle Manufacturers Assoc. v. State Farm Mutual Automobile Ins. Co.*,²²² the Court explained and applied the hard-look review in resolving a challenge to the DOT’s policy decision to rescind requirements for passive restraint systems.²²³ Although agreeing with the agency that the proper scope of review was narrow, and would not allow a court to substitute its judgment for that of the agency, the Court nonetheless emphasized the need for rigorous judicial review.

[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’ In reviewing that explanation, we must ‘consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up the deficiencies: ‘We may not supply a reasoned basis for the agency’s action that the agency itself has not given.’ We will, however, ‘uphold a decision of less than ideal clarity if the agency’s path may be reasonably discerned.’”²²⁴

²²⁰*Id.* at 385.

²²¹For example, the courts use “hard look” review for agency decisions to deny a petition for rulemaking (see *Northern Spotted Owl v. Hodel*, 716 F. Supp 479 (W.D. Wash. 1988)); as well as when challenges are raised as to the merits of an agency’s policy decisions in the rulemaking context. See *Motor Vehicle Manufacturers Assoc. v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29 (1983).

²²²463 U.S. 29 (1983).

²²³The challenge was to the “substance” or the “merits” of the policy decision; as opposed to a challenge to the procedures used by the DOT in promulgating the rule of rescission.

²²⁴463 U.S. at 43 (citations omitted).

Although technically within the ambit of the “arbitrary and capricious” standard of review,²²⁵ a hard-look review requires a court to search for the rationale and reasoning underlying the agency’s decision. The premise underlying hard-look review is that requiring the agency to satisfactorily explain the data used, the findings made, and the connection between the findings and the policy decision, etc., will result in better decisions.²²⁶ At the same time, the mode of review allows a type of substantive check on the agency’s policy decision. What seems rational to the agency may not seem rational to a reviewing court.²²⁷

Although twenty-some years prior to the State Farm decision, the Court’s analysis in *Shimer* was similar. The Court’s inquiry included a two-fold review, including both (i) an assessment of the scope of the agency’s general rulemaking authority and (ii) an assessment of whether the decision to preempt could be reconciled with congressional intent. As to the second assessment, the Court conducted a searching inquiry into the agency’s reasons for disregarding state law; and affirmatively ensured consistency with goals legitimately attributed to Congress. The Court upheld the decision as “reasonable” only after ensuring that – and explaining how – the decision to forgo state law protections operated to benefit both the VA and veterans. It is therefore reasonable to characterize *Shimer* as establishing a type of hard-look review for agency decisions to preempt state law: a review that allows a court to scrutinize both the procedural and the substantive aspects of an agency decision to preempt state law.

2. Continuing the “Hard Look” Review Post-*Shimer*

A series of cases decided by the Court in the 1980s provide further illustration of a

²²⁵Under the Administrative Procedure Act (APA), many agency decisions cannot be set aside by a reviewing court unless found to be “arbitrary and capricious.” See 5 U.S.C. § 706(2)(a). In applying the arbitrary and capricious standard of review, a court accords some deference to the agency’s decision.

²²⁶In light of the APA – which explicitly details the procedures that federal agencies must use as they engage in various agency action – courts are restricted in their ability to impose additional “procedures.” See *Vermont Yankee Nuclear Power Corp v. Natural Resources Defense Council, Inc.*, 435 U.S. 519 (1978). Thus, courts have instead required proof that the agency has adequately engaged in the procedures set forth in the APA. For example, the APA requires agency’s to “incorporate in the rules adopted a concise general statement of [the agency’s] basis and purpose” See 5 U.S.C. § 553(). In hard look review, courts are requiring “adequate” explanation of the “basis and purpose” underlying new rules.

²²⁷At the same, if the decision is rational and well-explained, a reviewing court cannot set aside the agency decision just because the court concludes that another decision would be more rational.

rigorous hard-look type of review by the Court when applying Shimer’s agency preemption analysis. In *Fidelity Federal Savings and Loan Assn v. de la Cuesta*,²²⁸ the Court reviewed the use of preemptive authority by the Federal Home Loan Bank Board (the Board). The case involved a 1976 Board regulation which clarified that federal savings and loan associations had the power to include in its contracts a “due-on-sale” clause and, if included in contracts, provided that exercise of the option was governed exclusively by the terms of the loan contract.²²⁹ At issue was preemption of California common law which deemed an unnecessary exercise of a due-on-sale clause as a violation of the state’s prohibition of unreasonable restraints on alienation.²³⁰ After confirming that the case involved preemption grounded in *agency* intent, the Court noted the appropriateness of using the Shimer analysis.

In restating the basic principles, the Court in *de la Cuesta* used the now familiar two-pronged formula: a court should first assess whether the agency acted within the scope of its authority; and, if so, the question becomes whether the agency choice was reasonable. However, here more clearly than in *Shimer*, the Court described the analysis in terms sounding more in-line with a searching inquiry:²³¹ if the choice “represents a reasonable accommodation of conflicting policies that were committed to the agency’s care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned.”²³² The Court in *de la Cuesta* also clarified – in a manner consistent with the premise that an agency can decide to preempt state law – that the preemptive force of an agency regulation will not depend on express congressional authorization to displace state law. At the same time, however, the Court emphasized (1) that the agency could do so only if acting within the scope of its authority as to the particular regulation or regulatory scheme triggering

²²⁸458 U.S. 141 (1982).

²²⁹See *id.* at 144-147.

²³⁰*Id.* at 148-49 (citing *Wellenkamp v. Bank of America*, 21 Cal. 3d 943 (1978); Cal. Civ. Code Ann. § 711)).

²³¹In *Shimer* that Court had stated: “where Congress has committed to the head of a department certain duties requiring the exercise of judgment and discretion, his action thereon, whether it involve questions of law or fact, will not be reviewed by the courts unless he has exceeded his authority or this court should be of the opinion that his action was clearly wrong.” See *Shimer*, 367 U.S. at 381-82.

²³²*Id.* at 154 (1982). See also *Crisp*, 467 U.S. at 699; *City of New York v. Federal Communications Comm’n*, 486 U.S. 57, 64 (1988).

preemption; and (2) that no deference would be due if the agency acted outside the scope of its authority.²³³

In applying the principles, the Court in *de la Cuesta* first conducted a meaningful inquiry into the authority of the Board in relation to the particular regulation at issue and the particular state law being displaced. The Court began with an analysis of the basic purpose and the text of the delegation of rulemaking authority. Congress created the Board in 1932 and vested it with authority to administer the Home Owner’s Loan Act (HOLA) of 1933. The Court noted that HOLA was intended “‘to provide emergency relief with respect to home mortgage indebtedness’ at a time when as many as half of all homes in the country were in default;”²³⁴ and at a time when “‘half the counties in the country . . . were without home-financing institutions.’”²³⁵ Congress directed the Board to create a system of Federal Savings and Loan Associations (FSLAs), and to ensure their vitality as permanent associations which would help people to finance homes in a cooperative manner.²³⁶ With that end in mind, section 5(a) of HOLA empowers the Board to promulgate rules and regulations “‘to provide for the organization, incorporation, examination, *operation*, and *regulation* of . . . [FSLAs] . . . giving primary consideration to the best practices of local mutual thrift and home-financing institutions in the United States.’”²³⁷ The Court noted that the text of section 5(a) expressed no limits on the Board authority to regulate “‘lending practices.’”²³⁸ However, the Court’s inquiry went deeper, with an eye on the particular regulation at issue. The regulation authorized FSLAs to put due-on-sale clauses into their loan instruments, and to enforce such clauses at their option. The Court noted that authority over the “operation”

²³³*de la Cuesta*, 458 U.S. at 154 (citing *Shimer*, 367 U.S. at 381-383).

²³⁴*Id.* at 159.

²³⁵*Id.* at 159-160.

²³⁶*Id.* at 160.

²³⁷*Id.* at 144-45 & at 160 (emphasis in text). The delegation of rulemaking authority provides as follows: In order to provide local mutual thrift institutions in which people may invest their funds and in order to provide for the financing of homes, the Board is authorized, under such rules and regulations as it may prescribe, to provide for the organization, incorporation, examination, operation, and regulation of associations to be known as “Federal Savings and Loan Associations” . . . and to issue charters therefor, giving primary consideration to the best practices of local thrift and home-financing institutions in the United States.” See *Id.* at 160 (quoting 12 U.S.C. § 1464(a)(1) (1976 ed., Supp. IV).

²³⁸*Id.* at 161.

of FSLAs “must empower the Board to issue regulations governing mortgage loan instruments, *for mortgages are a central part of any savings and loan ‘operation.’*”²³⁹

The Court in *de la Cuesta* then went further and considered other evidence bearing on congressional intent relating to regulations that might supercede state law.²⁴⁰ For example, section 5(a) included the directive to consider “best practices of local mutual thrift and home-financing institutions.”²⁴¹ Because these institutions were at that time all state-chartered, the Court concluded that Congress “plainly envisioned” that FSLAs would be governed by the *Board’s* determination of “best practices” – and not the determination of any particular State as to “best practices.”²⁴² The Court also pointed to several remarks in the legislative history to the effect that details as to the operation of FSLAs could be left to the Board’s discretion, thereby operating to establish a *uniform* system of savings and loan institutions “where there are not any now.”²⁴³ The Court noted that, although the Board’s power to exempt FSLAs from state law “may not be boundless,” further exploration of the limits of such power was unnecessary because, again, use of a due-on-sale” clause by FSLAs was so clearly within the scope of the type of regulations envisioned by Congress.²⁴⁴

As in *Shimer*, the Court continued its scrutiny in the second-prong of the analysis by carefully considering whether preemption of state law via the due-on-sale clause regulation was consistent with congressional purposes underlying HOLA. The Court first pointed to evidence in the legislative history of congressional concern with permanency and stability;²⁴⁵ and then carefully detailed not just the agency’s conclusions,²⁴⁶ but also the agency analysis upon which

²³⁹*Id.* at 161 (emphasis added).

²⁴⁰*Id.* at 162 (rejecting the contention that certain decisions made by Congress in HOLA about particular aspects of state law should be read as limiting any further preemption of state law).

²⁴¹See *supra* note 232 (quoting 12 U.S.C. § 1464(a)(1) (1976 ed., Supp. IV)).

²⁴²*Id.* at 161.

²⁴³*Id.* at 163-167.

²⁴⁴*Id.* at 167.

²⁴⁵*Id.* at 168 (quoting S. Rep. No. 91, 73d Cong., 1st Sess., 2 (1933); H.R. Rep. No. 55, 73d Cong., 1st Sess., 2 (1933)) (highlighting statements made during House hearings and in House and Senate Reports on HOLA).

²⁴⁶*Id.* (noting that the Board had concluded that elimination of due-on-sales clauses would have an adverse impact on the earning power and financial stability of FSLAs, impair their ability to sell loans in the secondary markets, reduce the amount of home-financing funds available to potential home buyers,

the conclusions were based.²⁴⁷ As in *Shimer*, the Court upheld the regulation only after affirmatively ensuring consistency with goals legitimately attributed to Congress.²⁴⁸

The Supreme Court has also applied the *Shimmer* analysis in a series of cases stemming from FCC decisions to preempt state law. These decisions similarly reveal a searching hard-look review of an agency's decision to preempt – even when the agency clearly has broad regulatory authority. In *Capital Cities Cable, Inc. v. Crisp*,²⁴⁹ the Court upheld the FCC's explicit decision, made in 1974 after notice and comment specifically addressed to the issue, to preempt the field of regulation of cable television signal carriage.²⁵⁰ The case raised significant federalism issues because the state law preempted was an Oklahoma ban on advertising of alcoholic beverages. As applied to the cable industry, the law required Oklahoma cable operators to delete alcoholic beverage commercials when retransmitting out-of-state signals to Oklahoma subscribers.²⁵¹ The decision shows careful scrutiny in both prongs of the analysis.

and generally cause a rise in home loan interest rates).

²⁴⁷The Court explained:

The Board's analysis proceeds as follows: It observes that the federal associations' practice of borrowing short and lending long – . . . [explanation omitted] . . . – combined with rising interest rates, has increased the cost of funds to these institutions and reduced their income. Exercising due-on-sales clauses enables savings and loans to alleviate this problem by replacing long-term, low-yield loans with loans at the prevailing interest rates and thereby to avoid increasing interest rates across the board. (Citation omitted) Moreover, the Board has determined that restrictions like the *Wellenkamp* doctrine lengthen the expected maturity date of a lender's mortgages, thus reducing their marketability in the secondary mortgage market. As a result, the Board fears, the financial stability of Federal associations in California will be eroded and the flow of home loan funds into California will be reduced."

Id. at 168-169.

²⁴⁸*Id.* at 169-170. The Court stated: "Admittedly, the wisdom of the Board's policy decision is not uncontroverted. But neither is it arbitrary or capricious. . . . [T]he Board reasonably exercised the authority, given it by Congress. . . . [T]he Board intended to pre-empt conflicting state restrictions. . . . Our inquiry ends there." *Id.* Notably, the Court in *de la Cuesta* also expressly examined whether, and found that, the state law at issue conflicted with the federal policy adopted by the Board. Thus, the Court could have resolved the case as a matter of implied preemption. The reason the Court did not treat it as implied preemption is clear: in this case, the agency expressly stated that the decision to displace state law was the decision of the Board, not Congress. It is the fact of "agency intent to preempt" which changed the focus of the analysis.

²⁴⁹467 U.S. 691 (1984).

²⁵⁰In *Crisp*, the Court clearly framed the issue as one of judicial review of an agency's explicit decision to preempt state law; and reiterated the limited scope of judicial review if the federal regulatory scheme which preemption protects is within the scope of the agency's delegated authority. *Id.* at 699

²⁵¹*Id.* at 694-95.

In the first prong, the Court again considered, but went beyond, the statutory rulemaking delegation. The Court noted that Congress had given the FCC “broad responsibilities to regulate all aspects of interstate communication by wire or radio,” and authority which extended to “all regulatory actions ‘necessary to ensure the achievement of [those] responsibilities.’”²⁵² Nonetheless, the Court also carefully scrutinized the particular federal regulation and state law at issue in light of historical circumstances; namely, the FCC’s decision to *allow state and local regulation of licensing* of cable systems, including delineation of franchise areas and construction of cable facilities.²⁵³ The state law at issue regulated the “carriage of signals” by cable operators. The Court thus traced a long history of FCC regulation of carriage of signals – and, specifically, of regulations bearing on the ability of cable operators to import out-of-state carriage signals.²⁵⁴ Only after this careful review did the Court conclude that the state law had reached beyond the authority reserved to local authorities by the FCC, and into the domain regulated by the FCC.²⁵⁵

In conducting the second prong of the analysis – the purportedly deferential review of the decision to preempt – the Court in *Crisp* followed the examples provided in *Shimer* and *de la Cuesta* and scrutinized for consistency with congressional objectives. The Court upheld the regulation only after ensuring consistency with a goal legitimately attributed to Congress.²⁵⁶ Specifically, the Court noted that it was not illogical to think that the “uniformity of standards” resulting from preemption would ensure cable systems “the breathing space necessary to expand vigorously and provide a diverse range of program offerings . . . in all parts of the country;” and,

²⁵²Id. at 700 (citing *United States v. Southwestern Cable Co.*, 392 U.S. 157, 177-178 (1968) (addressing the responsibilities granted to the FCC via § 2(a) of the Communications Act of 1934, 47 U.S.C. § 152(a)); *FCC v. Midwest Video Corp.*, 440 U.S. 689, 706(1979)).

²⁵³Id. at 702.

²⁵⁴In the 1960s, the FCC took a somewhat restrictive approach, out of concern for adverse impacts on local television broadcasting stations. Id. at 701-02. In the 1970s, although foregoing regulation over licensing matters, the FCC retained exclusive jurisdiction over operational aspects of cable communications – including signal carriage and technical standards. Id. at 702-03 (citing 36 F.C.C. 2d 143, 170-76 (1972)). In the 1980s, the FCC continued its regulation, albeit by lessening the carriage restrictions to allow greater importation of distant broadcast signals. Id. at 704.

²⁵⁵Id. at 704-05. The Court also found several ways in which the state law and its requirement of deleting signals for retransmission “conflicted” with specific federal regulations. Id. at 705-08.

²⁵⁶Id. at 708 (holding that the regulation was not arbitrary – although it may not enjoy universal support).

further, that the action was consistent with the FCC’s charter to “make available, so far as possible, to all the people of the United States a rapid, efficient, Nationwide and world-wide wire and radio communication service.”²⁵⁷

In *City of New York v. FCC*,²⁵⁸ the Court addressed another type of cable operation regulation by the FCC: technical standards established to ensure the quality of cable television signals. As in *Crisp*, the case was clearly one of express preemption by the agency.²⁵⁹ In light of *Crisp*, the only real issue for the Court was whether the 1984 Cable Act in any way vitiated the FCC’s authority to preempt state regulation of technical standards, including *more stringent standards* than those adopted by the FCC. Section 624(e) of the 1984 Act provided that “[t]he Commission may establish technical standards relating to the facilities and equipment of cable systems which a [state or local] franchising authority may require in the franchise.”²⁶⁰ The Commission eventually adopted technical standards, citing § 624(e), and took the position that its previously established preemption policy precluded local regulation of technical standards. Various cities challenged the FCC’s authority to preempt more stringent local technical standards.²⁶¹

The cities’ challenge was grounded in agency practice, as well as the text of § 624(e). The relevant agency practice flowed from a decision in 1974 *to allow* localities to maintain pre-existing technical standards. That is, although the FCC had decided in 1974 that national uniformity in technical standards was essential, the FCC also understood the importance of allowing the change to occur gradually – at least when many of the pre-existing standards

²⁵⁷Id. In *Crisp*, as in *de la Cuesta*, the Court also found that the preempted state law at issue “conflicted” with the federal regulatory scheme; both generally and with specific federal regulations. Thus, the scope of the “agency preemption” expressly upheld by the opinion was somewhat narrow.

²⁵⁸486 U.S. 57 (1988).

²⁵⁹In the explanation accompanying publication of the final rule, the FCC reiterated its view that its prior preemption policy was still warranted. Id. at 61-62 (citing 50 Fed. Reg. 52462, 52464-52465). The Court affirmed again that, when the agency has decided that preemption is warranted, its inquiry is two-fold: identifying the proper bounds of the agency’s authority to preempt; and, assessing whether the decision to preempt represents a reasonable accommodation of conflicting policies committed to the agency’s care by the statute. Id. at 64.

²⁶⁰Id. at 61 (quoting 47 U.S.C. § 544(e) (1982 ed., Supp. IV)).

²⁶¹Id. at 61-62.

adopted by cities and states could not be shown to adversely effect FCC goals.²⁶² The FCC thus extended “grandfather approval” to certain standards; and later established a “waiver” mechanism which specifically authorized certain localities to impose different or additional technical standards.²⁶³ The cities read §624(e) as reflecting Congress’ intent that cities and states would be able *to continue* using different technical standards.²⁶⁴

The Supreme Court disagreed. The Court explained that the 1984 Act was enacted “against a background of federal pre-emption,” specifically as to technical standards.²⁶⁵ In essence, the Court viewed the grandfather and waiver opportunities as *exceptions* to the general rule of preemption clearly established by the FCC. “For the preceding 10 years, the Commission had pre-empted such state and local standards”²⁶⁶ The Court also noted that *Crisp* – which had broadly upheld the FCC’s preemptive authority over very similar activity – was decided during the time that Congress was considering the 1984 Act.²⁶⁷ The Court thus read the text of § 624(e) as “mirroring” the state of regulatory law before the Cable Act was passed.

Nonetheless, the Court continued its evaluation by also carefully reviewing relevant legislative history.²⁶⁸ After careful – and extensive – consideration, the Court concluded that Congress had not manifested any intent to remove power from the FCC; or an intent to give authority to localities to supplement the technical standards set by the FCC – “a power which they generally had not been permitted to exercise for 10 years and which, according to the Commission’s consistent view, disserves the public interest.”²⁶⁹

Thus, despite the broad authority of the FCC, in both *Crisp* and *City of New York* the Court clearly engaged in significant review of the agency’s decision to preempt state law. Notably, the cases also readily reveal the Court’s willingness to look beyond textual evidence in

²⁶²Id. at 59-60, & n. 2.

²⁶³Id.

²⁶⁴Id. at 62 (explaining petitioners view that “franchising authorities would impose stricter technical standards than those specified by the Commission).

²⁶⁵Id. at 66.

²⁶⁶Id. at 66-67 (citing the broad grant of rulemaking authority in the FCC Act).

²⁶⁷Id. at 67.

²⁶⁸Id. at 67-68 (reviewing pertinent parts of the legislative history).

²⁶⁹Id. at 68-69.

assessing whether the agency’s decision to preempt was fully consistent with congressional intent. In both cases, the Court looked to legislative history and relevant circumstances – circumstances bearing on congressional purposes in enacting an agency program, as well as circumstances pertaining to relevant historical practice as to the interaction between state and federal law.

Moreover, the Court in *City of New York* expressly emphasized, in two ways, the importance of rigorous scrutiny in cases of agency preemption. First, the Court stressed the reasons underlying careful scrutiny of the scope of the agency’s authority:

We have identified at least two reasons why this part of the inquiry is crucial to our determination of the pre-emption issue. “First, an agency literally has no power to act, let alone pre-empt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it. Second, the best way of determining whether Congress intended the regulations of an administrative agency to displace state law is to examine the nature and scope of the authority granted by Congress to the agency.”²⁷⁰

Second, because upholding the FCC’s use of its broad authority in this case resulted not merely in preemption of conflicting state law, but in preemption of state standards that were *more stringent* than the federal standards, the Court was careful to state only that – “in the proper circumstances” – an agency may determine that its authority in a particular area is *exclusive* and thus preempts all state efforts to regulate in that area.²⁷¹ Both statements reflect the Court’s commitment to rigorous review of an agency’s authority when an agency acts to preempt state law. In sum, the Court’s post-Shimer agency preemption cases reflect a continuing commitment to a type of hard-look review for an agency decision to preempt state law.

3. Hard-Look Review Can Result in Rejection of an Agency’s Decision to Preempt

The Court has declined to uphold an agency decision to preempt in at least one post-Shimer case: *Louisiana Public Service Comm’n v FCC*,²⁷² a case involving preemption via FCC orders prescribing the methods which private phone companies could use to calculate

²⁷⁰Id. at 66.

²⁷¹Id. at 64.

²⁷²476 U.S. 355 (1986). The Court in *City of New York* contrasted the evidence of congressional intent in that case from the evidence of congressional intent in *Louisiana Public Service Comm’n*.

depreciation.²⁷³ A national association of state regulators petitioned the FCC for a declaration that the orders did not restrict the discretion of state commissioners to follow different depreciation practices when computing rates for intrastate telephone services.²⁷⁴ The FCC first agreed with the state regulators; but, upon reconsideration, the FCC reversed itself and decided that, because the Communications Act of 1934 expressly mandates the FCC to prescribe depreciation methods for carriers, and because the FCC had acted pursuant to that delegated authority, the Act itself operated automatically to preempt inconsistent state action.²⁷⁵ That is, the FCC determined that the text of the Act revealed that *Congress* intended that FCC mandates regarding depreciation calculation would preempt any state regulations that would require different means of depreciation calculation. In the alternative, the FCC found that state depreciation rate prescriptions that were inadequate to sustain a competitive market would frustrate the FCC’s policies and were thus preempted as a matter of federal supremacy.²⁷⁶

Despite the FCC’s emphasis on ordinary implied preemption principles,²⁷⁷ the FCC concluded by stating that, because of the interference with efficient operation of the communications marketplace, “we find that this Commission’s depreciation policies and rates . . . preempt inconsistent state depreciation policies and rates.”²⁷⁸ The FCC further stated: “[e]ven if Section 220(b) does not [expressly] preempt state commissions, we would act under our authority to preempt state actions that interfere with the accomplishment of federal policies and

²⁷³Id. at 360-61. The orders permitted use of the “equal-life” approach to grouping of property for purposes of depreciation (rather than requiring use of the “vintage year” approach), and replaced the “whole life” depreciation method with the “remaining life” method.

²⁷⁴Id. at 361 (the National Association of Regulatory Utility Commissioners).

²⁷⁵Id. at 362 (citing 92 F.C.C. 2d 864 (1983)). See also 92 F.C.C.2d 864, — (*3-*7) (1983). Section 220(b) provides that: “The Commission shall . . . prescribe for such carriers the classes of property for which depreciation charges may be properly included under operating expenses, and the percentages of depreciation which shall be charged with respect to each of such classes of property Such carriers shall not, after the Commission has prescribed the classes . . . charge to operating expenses any depreciation charges on classes of property other than those prescribed by the Commission” Id. at — (*4).

²⁷⁶92 F.C.C.2d 864, at — (*9-*12).

²⁷⁷See, e.g., Id. at — (*12) (“it is apparent to us that a substantial impact on federal policies could result if state commissions were allowed to diverge from Commission prescribed depreciation rates and practices. Accordingly, it is essential to preempt inconsistent state depreciation practices to avoid frustration of these vital national policies.”).

²⁷⁸Id. at — (*13).

objectives.”²⁷⁹ Thus, it is legitimate to view the case as involving, at least in some respects, agency intent to preempt.

In contrast to the other agency preemption cases, the Court in *Louisiana Public Service Comm’n* held that preemption was not proper. The key difference was that, as to the state laws at issue in this case (state prescribed means for depreciation calculation for purposes of setting rates for intrastate services), the text of the Act arguably provided evidence that Congress intended to *preserve* state authority. Section 152(b) of the Act provides that:

[N]othing in this chapter shall be construed to apply or to give the Commission jurisdiction with respect to (1) charges, classifications, practices, services, facilities, or regulations for or in connection with intrastate communication service by wire or radio of any carrier”²⁸⁰

The FCC argued that reading the terms of §152(b) *in pari materia*, along with the legislative history, made apparent that Congress was concerned with preserving state autonomy “over the rates charged by carriers for specific services, not over depreciation.”²⁸¹ Further, the FCC argued that construing §152(b) as controlling would have a severe impact on the *interstate* communications network – because “investment in plant [would] be recovered too slowly or not at all, with the result that new investment [would] be discouraged to the detriment of the entire network.”²⁸²

The Court disagreed with the both arguments. As to FCC’s textual argument, the Court noted that the words were “terms often used by accountants, regulators, courts, and commentators to denote depreciation treatment.”²⁸³ More importantly, the Court rejected the FCC’s policy argument – in part due to the FCC’s misunderstanding of the preemption inquiry.

²⁷⁹Id. at – (*13). See also Id. at – (*10) (“State depreciation rate prescriptions that do not adequately provide for capital recovery in the competitive environment . . . would frustrate the accomplishment of that policy and are preemptable by this Commission.”)

²⁸⁰*Louisiana Public Service Comm’n*, 476 U.S. at 365 (quoting section 152(b) of the Communications Act of 1934).

²⁸¹Id. at 371 (noting that “the words ‘charges,’ ‘classifications,’ ‘practices,’ and ‘regulations’ appear throughout the Act in contexts where it is clear that what is meant is charges which relate directly to carriers’ rate and service relationships with their customers, rather than depreciation or accounting charges”).

²⁸²Id. at 373.

²⁸³Id. at 372 (noting that terms of art should be interpreted by reference to the trade or industry to which they apply).

The Court stated:

While it is certainly true, and a basic underpinning of our federal system, that state regulation will be displaced to the extent that it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, . . . it is also true that a federal agency may pre-empt state law only when and if it is acting within the scope of its congressionally delegated authority.²⁸⁴

The Court was thus again emphasizing that, the area of agency preemption, the overarching focus is on agency authority rather than frustration with federal policy.²⁸⁵ The Court’s construction of §152(b) was therefore determinative. As interpreted, the text of the Act *limited* the FCC’s authority as to the specific orders at issue, at least as applied to intrastate service. The Court therefore declined to view FCC’s broad rulemaking authority – or the breadth of congressional objectives as to the national communications marketplace – as overriding Congress’ intent to limit the FCC’s authority as evidenced in §152(b).²⁸⁶

As in the other post-Shimer cases, then, the Court in Louisiana Public Service Comm’n carefully scrutinized the agency’s authority to preempt. Evidence of congressional intent inconsistent with preemption of state law controlled. In this case, Congress had expressly preserved a certain area of state law through a limit on the agency’s authority. Upon finding that Congress would not have sanctioned the agency activity in this case, the agency decision to preempt state law could not be upheld – even if the agency could articulate a reason that seemed to reconcile competing policies.

B. A Hard-Look Review Serves the Function of a Presumption Against Preemption

The preceding analysis reveals that it is a mistake to view the scope of judicial review under the Shimer line of cases as overly deferential to the agency’s view of the appropriateness of

²⁸⁴Id. at 374.

²⁸⁵For example, as the Court emphasized in *de la Cuesta*, any deferential review of agency preemption is triggered only if the agency had acted within the scope of its authority. *De la Cuesta* . . . at 154 (citing *Shimer*, 367 U.S. at 381-383).

²⁸⁶*Louisiana Public Serv. Comm’n*, 476 U.S. at 370 (noting the “disinclination” to favor the provision declaring a general statutory purpose, over a provision which defined the jurisdictional reach of the agency).

preemption. Although the oft quoted language used to describe the analysis could lead courts to view the analysis as creating a presumption in favor of preemption, that view is not supported when one takes into account the Court’s application of the Shimer analysis. In reality, the Shimer analysis holds the potential to appropriately invigorate judicial review in cases of regulatory preemption – in a manner akin to a presumption against preemption.

Careful analysis of the Shimer line of cases reveals a rigorous two-fold review of the agency’s authority. The Court accepts the “ordinary preemption principle” that federal agencies can decide to preempt state law. However, the Court has repeatedly emphasized that that principle applies only if the agency is acting within the scope of its authority as to the particular regulation or regulatory scheme triggering preemption. In the Shimer line of cases, the Court conducted a meaningful search for indicators of the agency authority – as part of both prongs of the Shimer analysis. The Court first assessed whether the particular regulation was within the agency’s general rulemaking authority;²⁸⁷ but then went further and assessed whether the decision to preempt could be reconciled with congressional intent. The Court in each case conducted an inquiry into Congress’ policy objectives in establishing the agency scheme, the agency’s reasons for the regulation(s) at issue, and the reasons for the decision to preempt.²⁸⁸ The Court upheld the agency’s decision to preempt only after ensuring that the regulatory scheme – along with the effect of any preemption – was consistent with goals legitimately attributed to Congress. The Court also carefully considered any indicators of Congress’ intent relating to preemption of the state law at issue: evidence in the text of the statute,²⁸⁹ in the legislative history,²⁹⁰ or in the history and context of pertinent congressional action.²⁹¹ Further, the Court carefully considered any pertinent history of the agency’s actions in relation to allowing operation of state law of the type arguably preempted.²⁹²

Notably, the hard-look review demonstrated in the Shimer line of cases has operated in a manner akin to the “presumption against preemption.” In cases involving preemption of state

²⁸⁷See supra notes – to – and accompanying text.

²⁸⁸See supra notes – to – and accompanying text.

²⁸⁹See supra notes – to – and accompanying text.

²⁹⁰See supra notes – to – and accompanying text.

²⁹¹See supra notes – to – and accompanying text.

law grounded in congressional intent, the Court has firmly established the importance of judicial caution due to important federalism concerns. That concern is made operative via the presumption against preemption. As the Court explained recently in *Bates*, “because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.”²⁹³ Thus, in areas of traditional state regulation, the Court assumes that federal law has not supplanted state law unless “Congress has made such intention ‘clear and manifest.’”²⁹⁴

A presumption is an evidentiary tool. Its function relates to the burdens of proof allocated to parties in a litigation. In the context of preemption grounded in congressional intent, the presumption operates by heightening the burden of producing evidence of congressional intent.²⁹⁵ In cases involving congressional intent to preempt, the Court has applied the presumption against preemption when considering all categories of preemption: express preemption,²⁹⁶ as well as both implied field and implied conflict preemption.²⁹⁷

There is no basis for not applying the presumption against preemption in cases of agency

²⁹²See *supra* notes – to – and accompanying text.

²⁹³See *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (quoting *Metronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

²⁹⁴*Id.* (quoting *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947))).

²⁹⁵That burden is allocated to the party asserting preemption. Certain statements of the Court have made this clear. For example, in *Bates* the defendant pesticide manufacturer was the party asserting that Congress, through FIFRA, had intended preemption of the plaintiff’s state law claims. Section 136v(b) of FIFRA provides that states “shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under [FIFRA].” See *Bates*, 544 U.S. 431, 436 (quoting 7 U.S.C. s 136v(b)). The Court found that this provision evinced congressional intent not to preempt a state law labeling requirement that was “equivalent to, and fully consistent with, FIFRA’s misbranding provisions.” *Id.* at 447. Dow, of course, had advanced an interpretation of the preemption provision that would preempt even “parallel” state requirements. Yet the Court noted that, because of the presumption against preemption, “[e]ven if Dow had offered us a plausible alternative reading of s 136v(b) – indeed, even if its alternative were just as plausible as our reading of the test – we would nonetheless have a duty to accept the reading that disfavors pre-emption.” *Id.* at 449.

²⁹⁶See *Bates*, 544 U.S. 431 (2005) (involving FIFRA’s express preemption provision); *Metronic*, 518 U.S. 470 (1996) (involving the express preemption provision of the MDA to the FDCA); *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) (involving ERISA’s express preemption provision).

²⁹⁷See *Hillsborough County, Florida v. Automated Medical Laboratories*, 471 U.S. 707 (1985) (addressing implied preemption under the FDCA).

preemption; and strong reasons supporting it. A distinct analysis for cases of agency preemption exists because, if the agency has expressed its intent to preempt, the case becomes one of express rather than implied preemption. Thus, rather than searching for congressional intent to preempt, the analysis becomes one of judicial review of an agency's policy decision.²⁹⁸ However, the Supreme Court has applied the presumption against preemption in cases of express preemption by Congress. In cases involving express preemption, Congress' intent to preempt some state law is clear. Nonetheless, the Court has used the presumption against preemption to ensure the proper *scope* of preemption;²⁹⁹ i.e., the presumption has provided a judicial tool to help protect against undue encroachment on state sovereignty. In cases of agency preemption, courts should have a similar tool. Moreover, courts can and should use hard-look review in cases of agency preemption not just to delimit the scope of preemption, but, as well, to heighten the burden of producing evidence as to the appropriateness of preemption at all.

Indeed, it could be argued that the need for such a tool is even greater in cases involving agency preemption. In *Geier*, the dissenting Justices explained that a key virtue of the presumption against preemption was the effect of placing the power of preemption "squarely in the hands of Congress, which is far more suited than the Judiciary to strike the appropriate state/federal balance."³⁰⁰ Further, the Justices noted that the requirement that Congress speak clearly ensures a structural safeguard: the legislative process, which would operate to "defend state interests from undue infringement."³⁰¹ Importantly, the Justices then noted:

While the presumption is important in assessing the pre-emptive reach of federal statutes, it becomes crucial when the pre-emptive effect of an administrative regulation is at issue. Unlike Congress, administrative agencies are clearly not designed to represent the interests of States, yet with relative ease they can promulgate comprehensive and detailed

²⁹⁸See supra notes – to – and accompanying text.

²⁹⁹See *Bates*, 544 U.S. 431 (2005) (involving FIFRA's express preemption provision); *Medtronic*, 581 U.S. 470 (1996) (involving the express preemption provision of the MDA to the FDCA); *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) (involving ERISA's express preemption provision).

In cases of implied preemption, the presumption takes on greater significance, bearing on both the issue of whether Congress intended any preemption and, if so, the issue of its scope.

³⁰⁰*Geier*, 529 U.S. 861, 907 (2000) (Stevens, J., dissenting).

³⁰¹*Id.* (citing *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528 (1985); other citations omitted). The dissent also emphasized the role the presumption played in tempering judicial use of implied conflict preemption based on frustration of purposes. *Id.*

regulations that have broad pre-emptive ramifications for state law.³⁰² A tool such as a presumption against preemption would thus seem especially crucial in cases grounded in agency intent to preempt.

Understanding that the Shimer-line of cases demonstrates use of a type of hard-look review therefore becomes crucial. In *Louisiana Public Service Comm'n*, the hard-look review enabled the Court to restrict the FCC's ability to preempt certain state law, despite FCC's generally broad rulemaking authority and despite having upheld other preemptive activity by the FCC.³⁰³ Like a presumption against preemption, Shimer's hard-look review can provide a tool to help protect against undue encroachment on state sovereignty by federal agencies.

Conclusion

Using the FDA's recent activity relating to the issue of preemption of state tort law remedies, this Article has demonstrated that federal agencies may engage in "strategic characterization" by pointing to Congress as the source of an "intent to preempt" state law. In doing so, they can avoid political and judicial scrutiny of agency action with significant federalism implications. Accordingly, this Article has proposed that courts be empowered to consider the totality of the evidence when deciding whether Congress or an agency is the source of the intent to preempt. The Supreme Court should move away from *Geier*'s implicit rejection of such an approach, and re-affirm a "totality of the circumstances" approach such as that used by the Court in the earlier of the Shimer line of cases. A totality of the circumstances approach not only would eliminate incentives to engage in misleading strategic characterization, but, as well, would open the door to appropriate scrutiny of the exercise of preemptive intent by federal agencies.

The appropriate scrutiny would arise, in part, from use of the analysis demonstrated by

³⁰²Id. at 908. The key point of the dissent was different than that being made in this part of the Article. The dissent asserted that the DOT regulation should not be given preemptive effect due to the failure of the agency to "declare" its intention "with some specificity." Id. at 908-910 (noting that requiring such "declarations" would "ensure that States [would] be able to have a dialog with agencies through the normal notice-and-comment procedures of the Administrative Procedure Act . . ."; and citing also Exec. Order No. 12612 § 4(e), 3 C.F.R. § 252, 255; Exec. Order No. 13132, § 4(e), 64 Fed. Reg. 43255, 43257 (1999)).

³⁰³See supra notes – to – and accompanying text.

the Court in the *Shimer* line of cases. Properly understood, the Court's agency preemption cases reveal use of a type of hard look review: a rigorous two-pronged analysis that can operate akin to the presumption against preemption employed in cases of preemption by Congress. The *Shimer* hard-look review entrusts courts to use whatever wide range of evidence may exist to ensure that the agency's assertion of preemption is appropriate. Courts must analyze, first, whether the particular agency activity which the agency is saying preempts state law, is clearly within the scope of the agency's authority; and, second, whether the decision to preempt reflects a rational, deliberative process and a reasonable reconciliation of policy objectives legitimately attributed to Congress. Courts should set aside an agency decision to preempt when the proponent of preemption is unable to clearly show that Congress would have sanctioned this particular disruption to the federal-state relations at issue.