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OPENING THE DOOR TO “HARD-LOOK” REVIEW OF AGENCY PREEMPTION

KAREN A. JORDAN *

Preemption of state tort actions by federal regulatory schemes, especially products liability actions, poses recurring federalism concerns. This Article revisits the problem, with a focus on the challenging issue of identifying whether a particular case of asserted preemption should be attributable to Congress or to the agency.1 The issue is important because characterizing a case as one of preemption by the agency can open the door to an appropriate level of scrutiny into the decision to preempt: a mode of review akin to the hard-look review used in other areas of judicial review of agency action. When trying to identify the source of the intent to preempt, courts should use a totality of the circumstances approach. A court should take into account any relevant evidence, but especially evidence relating to whether the precise agency activity giving rise to the preemption was devised or envisioned by Congress, or by the agency itself, through a regulatory scheme clearly going beyond specific directives detailed by Congress.

Using the FDA’s recent assertions of preemption arising from its market-approval decisions for prescription drugs, this Article illustrates how a totality of the circumstances analysis can lead to an appropriate characterization of the source of the intent to preempt. The analysis probes the evolution of federal drug regulation, contrasting the limited nature of Congress’s role with the ever-expanding nature of the agency’s role in the regulation of prescription drug labeling. Additionally, the analysis takes into account the frequently emphasized yet often discounted fact that the agency recently changed its view of the preemption issue. In the case of the

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1. The issues introduced and discussed briefly in this section of the Article have been addressed by the author in greater depth. See generally Karen A. Jordan, Agency Preemption and the Shimer Analysis: Unmasking Strategic Characterization by Agencies and Giving Effect to the Presumption Against Preemption, 2008 Wis. L. REV. 69 [hereinafter Jordan, The Shimer Analysis].
FDA's assertion of preemption, a totality of the circumstances analysis points strongly to the appropriateness of characterizing the agency as the source of preemption.

Notably, that conclusion has failed to surface in the plethora of recent lower court cases addressing the issue of preemption arising from FDA approval decisions.² It has failed to surface because courts and litigators have followed the agency's lead in characterizing the issue as a matter of congressional intent to preempt. Rather than merely following the agency's lead—which enables the agency to sidestep accountability for preemption decisions made by the agency—it is crucial to carefully analyze the circumstances and to properly identify those instances when, realistically, it is the agency that is the source of the intent to preempt.

This Article also briefly demonstrates the importance of hard-look review when the source of the intent to preempt is the agency. Hard-look review requires courts to engage in a rigorous scrutiny of the agency's authority. In the case of the FDA, careful historical analysis of federal drug regulation brings to light issues relating to the authority of the FDA to regulate prescription drug labeling, at least in the comprehensive way that the FDA today regulates such labeling. Specifically, careful analysis reveals that the delegation of authority to the FDA relating to the content of prescription drug labeling is largely a matter of inference and acquiescence. Because a hard-look review can serve as a proxy for a "presumption against preemption," such evidence can provide sound reasons for a court to decline to uphold the agency's decision that preemption of state tort law is warranted.

Importantly, the key points made in this Article have ramifications beyond the context of the FDA's recent assertion of preemp-

². For example, the briefs submitted to the Supreme Court in Wyeth v. Levine, 129 S. Ct. 1187 (2009), the case in which the Court decided to address the issue of preemption arising from the FDA's market-approval decisions for prescription drugs, have all argued the case as one of congressional intent to preempt. See, e.g., Brief for Petitioner at *26-29, Wyeth v. Levine, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 2273067; Brief for Respondent at *25-29, Wyeth, 129 S. Ct. 1187 (No. 06-1249), 2008 WL 3285388; Brief for the United States as Amicus Curiae Supporting Petitioner at *10, Wyeth, 129 S. Ct. 1187 (No. 06-1249), 2008 WL 2308908; Brief of Amicus Curiae Constitutional & Administrative Law Scholars in Support of Respondent at *4, Wyeth, 129 S. Ct. 1187 (No. 06-1249), 2008 WL 3851604; Brief of the National Conference of State Legislatures as Amicus Curiae Supporting Respondents at *24-26, Wyeth, 129 S. Ct. 1187 (No. 06-1249), 2008 WL 3851606; Brief of Torts Professors Mark P. Gergen & Michael D. Green as Amici Curiae in Support of Respondent at *11, Wyeth, 129 S. Ct. 1187 (No. 06-1249), 2008 WL 3851610; Brief of Amici Curiae Vermont et al. in Support of Respondent at *3, Wyeth, 129 S. Ct. 1187 (No. 06-1249), 2008 WL 3851613.
tion. The issues arise in any case involving an assertion of preemption of state law due to agency regulatory activity and, indeed, the reasoning of the various Justices in Wyeth v. Levine highlights the need to reorient judicial analysis in this area.\(^3\) Reorienting the analysis is important because, if the source of pre-

3. See Wyeth, 129 S. Ct. 1187. In Wyeth, the Court held that the FDA's approval of the drug label at issue did not preempt plaintiff Levine's state law products liability action. The majority's analysis focused heavily on the issue of whether the FDA's view of the preemption issue—as articulated in the preamble to the 2006 Final Rule—was entitled to deference. See FDA Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601). The majority decided that it was not, in part because the FDA's analysis was "suspect" (because it was inserted into the preamble without the issue being raised in the Notice of Proposed Rulemaking), but also because the agency failed to provide a sufficiently reasoned explanation for its dramatic shift in position. Id. at 1201 (applying Skidmore deference). See Skidmore v. Swift & Co., 323 U.S. 124 (1944). In analyzing the issue of conflict preemption, the majority made two findings. First, the majority decided that there was no "'actual conflict'" between the FDA's approval decision and the state law action because insufficient evidence existed showing that it was impossible for Wyeth to comply with federal labeling duties and any state law duty that would be imposed by Levine's tort claims. Id. at 1192 (citations omitted). Second, the majority decided that the state law claims would not "stand as an obstacle" to the purposes or objectives of the federal labeling law because Congress in 1906 decided against including a federal remedy and Congress in later years did not enact a preemption provision as to labeling law. Id. at 1204. Notably, the majority did not raise the issue whether the case should be treated as a case involving agency preemption and, in fact, suggested that the whole notion of agency preemption was inapplicable. The majority noted that this was not a case in which the purported preemption arose from agency regulation or other agency action with the force of law. Id. at 1203.

The dissent correctly recognized that the asserted preemption in the case certainly did arise from agency action—the adjudicative labeling decision. Id. at 1218 (Alito, J., dissenting). Moreover, the dissent confirms the importance of carefully identifying cases of agency preemption. According to the dissenting Justices, the FDA's approval decision—because it rested on some weighing by the FDA of the risks and benefits involved—\textit{ipso facto} preempted any state law that might result in a drug manufacturer reweighing the risks and benefits and opting to use a label that, in the manufacturer's view, might be a safer label. Id. at 1220 (noting that "ordinary principles of conflict preemption turn solely on whether a State has upset the regulatory balance struck by the federal agency"); id. at 1227 (noting that "[g]iven the 'balance' that the FDA struck between the costs and benefits of administering Phenergan via IV push, Geier compels the pre-emption of tort suits (like this one) that would upset that balance"); see also Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000).

In both the majority and the dissenting opinions, the Justices approached the preemption question in such a way that issues of the agency's authority and the appropriateness or reasonableness of preemption were left out of the analysis; a concern alluded to though not fully fleshed out in Justice Thomas's concurring opinion. See id. at 1205 (Thomas, J., concurring) (discussing the flaws in the Geier decision as grounded in the Court's failure to recognize a limitation on the agency's authority contained in the text of the statute). The Wyeth decision thus reinforces the need to reorient judicial analysis in the area of agency preemption.
emptions are the agency, rigorous judicial review becomes a necessary safeguard for federalism concerns.

I. THE IMPORTANCE OF ASSESSING THE TOTALITY OF THE CIRCUMSTANCES WHEN IDENTIFYING THE SOURCE OF THE INTENT TO PREEMPT

Agency action must constitute a valid exercise of delegated power, and thus all agency activity must conform with congressional intent.\textsuperscript{4} However, in effectuating congressional intent, agencies often act with distinct agency intent. That is, agencies sometimes have goals and objectives underlying their actions that are distinct from, although in alignment with, congressional objectives.\textsuperscript{5} In cases addressing preemption of state products liability law by federal agency activity, the possibility of distinct agency intent has been found relevant in two distinct ways. In some cases, agency objectives have been the trigger for implied conflict preemption; that is, preemption arising because a state law "stands as an obstacle" to federal objectives reflected in the agency's regulatory scheme.\textsuperscript{6} In these cases, courts and agencies have treated the preemption as arising from congressional intent.\textsuperscript{7} In other cases, an agency may have asserted that the preemption was grounded not in congressional intent to preempt but in the agency's intent to preempt.\textsuperscript{8}

The distinction is important because the Supreme Court traditionally has analyzed the issue of preemption differently depending on the source of the intent to preempt. Identifying the agency as the source of the intent to preempt opens the door to more rigorous judicial review of the appropriateness of preemption.\textsuperscript{9} Thus, a key threshold task in the preemption analysis when preemption arises

\textsuperscript{4} See Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 154 (1982) ("Where Congress has directed an administrator to exercise his discretion, his judgments are subject to judicial review only to determine whether he has exceeded his statutory authority or acted arbitrarily." (citing United States v. Shimer, 367 U.S. 374, 381-82 (1961))).

\textsuperscript{5} See, e.g., Geier, 529 U.S. 861 (involving a motor vehicle regulation promulgated to promote specific objectives deemed important by the agency but were beyond Congress's central objective of vehicle safety).

\textsuperscript{6} Id. at 873 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)); see also Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88 (1992).


\textsuperscript{9} See infra notes 21 to 33 and accompanying text.
from agency rules or adjudicative decisions is the proper identification of the source of the intent to preempt.

Courts and litigants, however, have generally failed to address the issue, tending instead to simply cast the issue as one of congressional intent—often following the agency's lead in characterizing the issue. The Food and Drug Administration's (FDA) recent assertion of preemption provides a case in point. Beginning in 2000, the FDA has aggressively asserted that its market-approval decisions for prescription drugs preempt state tort claims grounded in failure to warn. In 2006, the FDA more formally asserted its "matured" view in the Federal Register announcing a Final Rule (2006 Rule) amending certain aspects of the FDA's regulation of the content and format of prescription-drug labeling. According to the FDA, its duty to ensure that drugs are safe and effective includes considerations relating to risk management and, thus, the labels on approved prescription drugs constitute the agency's "formal, authoritative conclusions" about what constitutes the right balance of risk and benefit with regard to information communicated to health practitioners. 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 asserted that state law civil actions cause defensive labeling and undermine the purpose of labeling on prescription drugs. The FDA broadly asserted that products liability actions threaten the FDA's statutory role as the expert responsible for evaluating and regulating drugs—and the content of their labeling—and that state laws that frustrate the FDA's objectives were therefore preempted.

10. The movement was initiated when then chief counsel for the FDA affirmatively involved the FDA in several civil suits filed by plaintiffs injured by such drugs. In these lawsuits the FDA asserted a seemingly new view that its labeling decisions preempted the state-law claims at issue. See, e.g., Robert Pear, In a Shift, Bush Moves to Block Medical Suits, N.Y. TIMES, July 25, 2004, at A1 (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]"); see also Jordan, The Shimer Analysis, supra note 1, at 72 n.9.


12. Id. at 3934.

13. Id. at 3935.

14. Id. at 3934-35.
in essence, the variant of conflict preemption that resembles field preemption.  

Importantly, the FDA has pointed to Congress as the source of the intent to preempt. Throughout the 2006 Rule, the FDA consistently pointed to potential conflicts with the statute as the key reason for the preemption. For example, the FDA claimed that “products-liability suits have directly threatened the agency’s ability to regulate manufacturer dissemination of risk information . . . in accordance with the act”; that “[s]tate law actions can rely on and propagate 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”; that courts have wrongly interpreted the statute by characterizing the FDA labeling requirements as representing a minimum safety standard; that, “[i]n fact, FDA interprets the act to establish both a ‘floor’ and a ‘ceiling’ . . . .”; that, “[g]iven 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”; that overwarning “potentially discourag[es] safe and effective use of approved products or encourag[es] inappropriate use,” thereby “undermining the objectives of the act”; and that state actions allow the FDA’s statutorily prescribed, centralized, and expert determinations to be usurped by individualized reevaluation by lay judges and juries.  

The agency asserted, essentially, that its preemption of state laws is what Congress intended. That is, that Congress intended this type of adjudicatory determination to preempt the field of risk disclosure in prescription-drug labeling. Courts and litigants accepted that characterization, but that approach is misguided and inconsistent with key Supreme Court precedent. The approach is misguided because it allows agencies to sidestep accountability for preemption decisions. That is, characterizing the case as one of congressional intent to preempt triggers a traditional preemption analysis wherein the issue becomes largely a matter of statutory

17. See supra note 2.
19. In analyzing the question of preemption by Congress, the Supreme Court has traditionally emphasized three categories of preemption. See, e.g., English, 496 U.S. at
interpretation, thereby requiring an examination of the text, structure, purpose, object, and underlying policy of the statute.\textsuperscript{20} What is often missing from the analysis is meaningful scrutiny of the agency’s authority as to the particular agency activity and of the reasonableness or appropriateness of what may have been a sweeping preemption decision by the agency.

Yet, the Court has used a different analysis in cases where the agency is identified as the source of preemption; that is, cases where, even if Congress was silent about preemption, an agency decided that preemption was necessary to carry out its mission.\textsuperscript{21} In cases where the preemption is grounded in an agency’s expressed intent to preempt, the Supreme Court traditionally has used a distinct analysis.\textsuperscript{22} The reason for the different analysis is that if the agency has expressed its intent to preempt, the case is one of ex-


\textsuperscript{21} For example, \textit{Capital Cities Cable, Inc. v. Crisp} involved the Federal Communication Commission’s (FCC) decision that federal preemption of state and local regulation was necessary and proper in order to effectuate Congress’s mandate to foster and promote “a rapid, efficient, Nation-wide and world-wide wire and radio communication service.” \textit{Capital Cities Cable, Inc. v. Crisp}, 467 U.S. 691, 783 (1984) (quoting 47 U.S.C. § 151 (2000)); \textit{see also In re Amendment of Part 76, 49 F.C.C.2d 470, 478 (1974).} 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 . . . .” \textit{In re Amendment of Part 76, 49 F.C.C.2d} at 480.

\textsuperscript{22} This distinction was articulated by the district court of Maryland in \textit{National City Bank of Indiana v. Turnbaugh}:

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.

press rather than implied preemption. As such, the question for the court is not whether it is proper to infer congressional intent to pre-empt but, rather, whether the agency's decision should be upheld. The issue presented is not a matter of statutory interpretation but, instead, a matter of judicial review of an agency's policy decision.

This analysis was first used by the Supreme Court in United States v. Shimer.23 Under Shimer, the two-pronged inquiry for review of an agency decision to preempt requires a court to assess whether the agency acted within the scope of its authority and, if so, whether the decision to preempt was reasonable.24 As the Court later explained in Capital Cities Cable, Inc. v. 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."25 While at first blush sounding highly deferential, the Shimer analysis actually opens the door for an appropriately rigorous level of scrutiny.26 Precisely because the analysis shifts to one of judicial review of an agency's policy decision, Shimer provides a means for holding accountable agencies that have decided that state law interferes with a comprehensive regulatory scheme put in place by the agency.

In fact, the Shimer analysis can be readily described as a type of hard-look review of agency action; i.e., as involving a rigorous review akin to that formally established by the Court in Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.27 Although technically within the ambit of the arbitrary and


capricious standard of review, 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 will result in better decisions. At the same time, the mode of review allows a type of substantive check on an agency's policy decisions. What seems rational to the agency may not seem rational to a reviewing court. Thus, as recently noted:

28. Under the Federal 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) (2000). In applying the arbitrary and capricious standard of review, a court accords some deference to the agency's decision. See State Farm, 463 U.S. at 45.

29. State Farm, 463 U.S. at 43. The State Farm Court set out the standard as follows:

[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 for such 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 reasonably be discerned."


30. This type of hard-look review is premised on the understanding that courts may not impose additional procedural requirements on agencies. See Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc., 435 U.S. 519, 524 (1978) (holding that courts are restricted in their ability to impose additional procedures because the APA explicitly details the procedures that federal agencies must use as they engage in various agency actions). Thus, courts have instead required proof that the agency has adequately engaged in the procedures set forth in the APA. Id. at 547. For example, the APA requires agencies to "incorporate in the rules adopted a concise general statement of their basis and purpose." 5 U.S.C. § 553(c). Courts may not add to this requirement. But, in applying hard-look review, courts may ensure the adequacy of the agency's explanation of the "basis and purpose" underlying new rules. Vt. Yankee Nuclear Power Corp., 435 U.S. at 524.

31. At the same time, 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. See Vt. Yankee Nuclear Power Corp., 435 U.S. at 549.
Twenty-two 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 an assessment of both (1) the scope of the agency's general rule-making authority and (2) 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.32

As a type of hard-look review, the Shimer analysis can serve the function of a presumption against preemption in the context of agency preemption.33

As noted, the ability to use hard-look review hinges on a finding that the source of the intent to preempt is the agency, and not Congress. It therefore becomes crucial to properly identify the source of the intent to preempt. The key to correctly identifying the source of the intent to preempt is to use a totality of the circumstances approach. A totality of the circumstances analysis has not been used in recent years, likely due to the Supreme Court's approach in Geier v. American Honda Motor Co.34 Yet, empowering courts to label a case as one of agency preemption whenever a totality of the circumstances so indicates would open the door to a more appropriate hard-look scrutiny of preemption arising from the

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32. See Jordan, The Shimer Analysis, supra note 1, at 123 (noting that, as part of the analysis, the Court looked for evidence that preemption would further the congressional purpose of providing benefits for veterans).

33. See id. at 134-38. As the author noted recently:

A presumption is an evidentiary tool. Its function relates to the burdens of proof allocated to parties involved in litigation. In the context of preemption grounded in congressional intent, the presumption operates by heightening the burden of producing evidence of congressional intent. The essence of the Shimer analysis is similar. An agency's assertion of preemption must survive heightened judicial scrutiny of the totality of the evidence that bears on the authority underlying it, and the reasonableness of, the agency action. Id. at 136.

activities of federal agencies. Using the FDA's recent position on the preemption issue as an example, this Article next illustrates how a totality of the circumstances approach can help in properly identifying the source of the intent to preempt.

II. Applying a Totality of the Circumstances Approach to the Recent FDA Assertion of Preemption

Under a totality of the circumstances approach, the task for a court is to decide whether the relevant facts and circumstances demonstrate that the intent to preempt reasonably can be attributed to the agency, rather than to Congress. Intent to preempt reasonably can be attributed to the agency in a variety of circumstances, for example,

[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 agency action clearly goes beyond any specific directives detailed by Congress. 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—a regulatory scheme involving] rights and duties created by the agency—it would be appropriate to view the matter as one of agency preemption.\textsuperscript{35}

This would be particularly true when the text of the statute and its legislative history lack clear indicators of congressional intent to preempt. In such cases, a more realistic assessment of the circumstances is that the agency intended to preempt state law. A totality of the circumstances approach would also allow courts to take into account any other evidence relevant to the question of the source of preemption.

Given this, in conducting a totality of the circumstances analysis courts must first identify, with precision, the agency activity that purportedly triggers preemption. Scrutiny of the FDA's assertions of preemption of common law drug labeling actions reveals a dual source of preemption. First, the specific agency action that is the source or trigger of the purported preemption is the FDA's approval to allow a drug manufacturer to market its drug.\textsuperscript{36} The ap-

\textsuperscript{35} Jordan, The Shimer Analysis, supra note 1, at 115-16.
\textsuperscript{36} The FDA decision regarding the content of the labeling of prescription drugs was made as part of the decision to allow the drug to be marketed. See infra note 86
proval decision is an adjudicative decision.\textsuperscript{37} An adjudicative decision generally would give rise only to conflict preemption.\textsuperscript{38} 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, 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.\textsuperscript{39} Field preemption ordinarily cannot arise from an adjudicatory decision unless a second source exists that supports a broader scope of preemption. As noted, throughout the 2006 Rule, the FDA consistently pointed to potential conflicts with the statute as the key reason for the preemption.\textsuperscript{40} That, however, is not sufficiently precise for a totality of the circumstances analysis.

Rather, under a totality of the circumstances approach, courts must delve deeper and assess whether the purported conflict arises from the statute or, rather, from a regulatory scheme developed by the agency that clearly extends beyond any specific directives detailed by Congress in the text of the statute. When the regulations

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\item \textsuperscript{37} See Jordan, \textit{The Shimer Analysis}, \textit{supra} note 1, at 86.

\item \textsuperscript{38} The actual decision or order resulting from an adjudication—that is, the agency action that represents application of the law to the facts—of course creates rights and duties that are binding on the agency and the parties to the proceeding. See 5 U.S.C. \textsection 551(4) & (6) (2000) (the APA’s definitions of “order” and “rule” make clear that an “order” has the present effect of creating rights and duties as to the particular parties to the adjudication). An adjudicative decision thus has the force of law and thereby may have a preemptive effect. However, adjudicative decisions 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 rarely, if ever, to 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 tribunal) would create an impermissible conflict for a party subject to the order. Of course, an adjudicative decision could have a broader preemptive scope if that is what Congress or the agency intends. In such a case, however, it is not the adjudicative decision itself that creates the broader preemption. Rather, the source of broader preemption would be the statutory scheme or regulatory scheme that expressly or impliedly establishes that the decision will have a broader preemptive effect. In such cases, a dual source of preemption exists. See Jordan, \textit{The Shimer Analysis}, \textit{supra} note 1, at 86.

\item \textsuperscript{39} FDA Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601); see \textit{supra} notes 11-15 and accompanying text for a summary of the FDA’s reasoning.

\item \textsuperscript{40} See \textit{supra} note 16 and accompanying text.
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triggering preemption reflect a regulatory scheme largely devised by the agency—as opposed to mere “parroting regulations”41—sound reasons support characterizing the source of the intent to preempt as the agency. The assessment requires careful study of the evolution of the statutory and regulatory schemes involved. In the case of the FDA’s recent assertion of preemption, the pertinent statutory and regulatory schemes have evolved and expanded over the course of the last century. A totality of the circumstances analysis also looks to other evidence, and other important evidence exists in this case; namely, the fact that the FDA and many courts for decades took the opposite position on the issue of preemption.

A. The Text of the Food, Drug, & Cosmetic Act of 1938 and Its Amendments: Broad Discretion within Carefully Delimited Bounds

Because the basic parameters of agency regulation of prescription drugs were in place by 1980, this Article focuses on the regulatory scheme put in place by Congress from the inception of its regulation of drugs through the 1962 amendments.42 In analyzing the extent to which the basic regulatory scheme of prescription drugs was devised by Congress, the text of the Food, Drug, and Cosmetic Act of 1938 (FDCA)43 and its amendments is scrutinized primarily for the specific directives put in place by Congress. Also, because it becomes relevant in cases of agency preemption, the analysis highlights the scope of authority delegated to the agency.

1. The 1906 & 1938 Statutes

The Food and Drugs Act of 1906 set the stage for the FDCA. The 1906 Act criminalized the manufacture, shipment, or receipt

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41. Notably, the Supreme Court has recognized a distinction between regulations that merely “parrot the statute” and regulations that reflect a use of the agency’s expertise and experience. See, e.g., Gonzales v. Oregon, 546 U.S. 243, 257 (2006). Where the agency activity reflects a “parroting regulation,” it remains reasonable to attribute preemptive intent to Congress. Id.

42. Amendments after 1962—most notably, amendments made in 1988, 1997, and most recently in 2007—may have a place in the preemption analysis, but they are relevant largely as some evidence of Congress’s acquiescence to the FDA’s regulation of prescription drug labeling. The amendments included new directives and delegations of agency authority regarding the content of labeling following approval. At most, the 1997 drug modernization amendments supply some notion of a congressional objective of what the FDA perhaps has recently referred to as the goal of achieving the “optimal use” of drugs.

"within any Territory or the District of Columbia [of] any article of food or drug which is adulterated or misbranded."44 The 1906 Act defined "drugs" to include "medicines and preparations recognized in the United States Pharmacopoeia or National Formulary," as well as any substance or mixture thereof "intended to be used for the cure, mitigation or prevention of disease."45

The 1906 Act carefully defined what circumstances would constitute adulteration or misbranding. Adulteration included drugs sold under a name recognized in the Pharmacopoeia, but that differed from approved standards for "strength, quality, or purity"—unless the difference was plainly stated on the drug's container—or if a drug's strength or purity fell below the standards represented.46 A drug was misbranded if its label bore a false or misleading statement about the article or its ingredients; if it was an imitation; if it failed to bear a statement regarding the amount of certain dangerous ingredients (alcohol, morphine, opium, cocaine, heroin, etc.); or if its label included a false or fraudulent statement regarding its "curative or therapeutic effect."47

The remainder of the 1906 Act dealt with enforcement by the agency. Congress delegated significant investigative and adjudicatory authority to three distinct agencies.48 In addition to the spe-

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44. Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, § 1, 34 Stat. 768, 768 (repealed 1938). The 1906 Act also prohibited and criminalized selling or offering for sale in the District of Columbia or the Territories of the United States, and the exporting or offering to export to any foreign country, adulterated or misbranded food or drugs. Id. § 2.

45. Id. § 6. The United States Pharmacopoeia (USP) is a private association that deems itself the "official public standards-setting authority for all prescription and over-the-counter medicines" manufactured or sold in the United States. About USP—An Overview, http://www.usp.org/aboutUSP/index.html(last visited Apr. 15, 2009). USP is an independent, science-based public health organization whose goal is "[t]o improve the health of people around the world through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods." Id.

46. See Pure Food and Drugs Act § 7.

47. See id. § 8. The prohibition on a false statement regarding a drug's curative or therapeutic effect was added to the Act in 1912 via the Sherley Amendment. See Sherley Amendment, ch. 352, 37 Stat. 416, 417 (1912).

48. See Pure Food and Drugs Act § 4 (directing the Bureau of Chemistry of the Department of Agriculture to conduct examinations of food and drug specimens); id. § 5 (imposing a duty on any district attorney to initiate appropriate judicial proceedings when sufficient evidence of a violation is presented); id. § 11 (directing the Secretary of the Treasury to police importation by delivering to the Secretary of Agriculture samples of drugs that are being imported). The 1906 Act also provided for the seizure and disposition of adulterated or misbranded articles, and for appropriate due process. Id. §§ 4, 10-11. Furthermore, the 1906 Act provided a defense for a dealer who could establish a signed guaranty to the effect that articles were not adulterated or misbranded. Id. § 9.
pecific directives to various agencies, the 1906 Act included a general delegation of rulemaking authority. The Act provided as follows: "[t]hat the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs . . . ." Although at first blush appearing broad, the delegation is tied to what is necessary to carry out the Act, and the Act itself is narrow. Congress defined, in a limited way, circumstances that constituted adulteration and misbranding of drugs. The thrust of the Act was to ban the sale of drugs that were not what they purported to be, including a ban on drugs whose labels did not disclose substances known to be dangerous. In terms of agency authority over drugs, then, the 1906 Act basically authorized enforcement activity.

In the FDCA, agency authority was expanded but still carefully limited. The FDCA similarly prohibited and criminalized the marketing of adulterated and misbranded drugs in interstate commerce. Regulation of drug safety was strengthened, however, by prohibiting the marketing of a new drug without an “effective” application and expanding the ways in which drug labeling could con-
stitute misbranding and, thus, be in violation of federal law. 54 To enable pre-market agency review, the FDCA defined "new drugs"55 and prohibited persons from introducing or delivering for introduction into interstate commerce "any new drug, unless an application filed ... is effective with respect to such drug."56 As part of the application, the applicant was asked to describe the composition and manufacturing of the new drug, to provide samples of the drug and its components, to provide specimens of the proposed labeling, and to provide full reports of investigations made to show whether the new drug was safe for use.57

Importantly, however, the application automatically became effective on the sixtieth day after the filing of the application unless the Secretary of Agriculture postponed the effective date for study of the application.58 As a procedural matter, this scheme put the burden on the Secretary to preclude the marketing of a new drug through an adjudicatory process. Further, the statute spelled out and thus limited the reasons that would support a refusal to allow an application to become effective.59 The Secretary could issue an order refusing the application to become effective only finding, after notice and hearing, a cause specified by Congress. Such causes include: the reports of investigations failed to include adequate tests to show that the drug was safe for use under the conditions prescribed in the proposed labeling; the results of tests showed that the drug was unsafe—or that there was insufficient evidence to determine whether the drug was safe—for use under the conditions prescribed in the proposed labeling; or the manufacturing controls were inadequate.60

54. Id. § 301.
55. The FDCA defined "new drug" as "[a]ny drug . . . not generally recognized, among experts qualified . . . to evaluate the safety of drugs, as safe for use under the conditions prescribed . . . in the labeling" unless the drug was previously subject to the 1906 Act—or a drug that had become so recognized due to clinical trials, but which had not "been used to a material extent or for a material time" under the conditions prescribed in its labeling. Id. § 201(p). The definition of "drug" was also expanded to include "articles intended to affect the structure or any function of the body," and articles intended as components of drugs. Id. § 201(g).
56. Id. § 505(a) (emphasis added).
57. Id. § 505(b).
58. Id. § 505(c). Section 201(d) defined Secretary to mean the Secretary of Agriculture. Id. § 201(d).
59. Supra notes 55-57 and accompanying text.
60. Federal Food, Drug, and Cosmetic Act of 1938, § 505(d). The Secretary was also empowered to suspend an application that had become effective, or to revoke an order refusing to permit an application to become effective. See id. § 505(e)-(f).
The FDCA's gate-keeping function for new drugs—section 505—was a significant expansion of agency authority and a significant step in helping to ensure the safety of new drugs. But, the agency's adjudicatory authority over new drugs under section 505 was nonetheless carefully delimited. In particular, it is noteworthy that the adequacy of labeling was not one of the specified causes that would allow the agency to preclude an application from becoming effective. Further, although the FDCA also reauthorized agency authority over drugs already on the market, the scope of that authority continued to relate primarily to enforcement of the prohibition on adulterated and misbranded drugs.61

Notably, however, the agency's enforcement authority over labeling of drugs already on the market was increased by way of the FDCA's expansion of what constituted a "misbranded" drug.62 The FDCA expanded the definition of misbranding to include, inter alia: (b) a failure to include on the label "an accurate statement of the quantity of the contents"; (c) a failure to include "any word, statement, or other information required by or under the authority of [the FDCA] to appear on the label"; (f) a failure to include "(1) adequate directions for use; and (2) such adequate warnings against use . . . where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users"; and (g) if the drug is represented as a drug "recognized in an official compendium," a failure to package and label the drug as described in the compendium.63

61. Specifically, the FDCA provided for judicial proceedings in federal district courts for enforcement of penalties for violations, to restrain violations, and to seize and dispose of misbranded or adulterated articles, as well as for initiation of such proceedings by way of a report by the Secretary of Agriculture to any United States attorney. It further added administrative and judicial remedies for orders refusing to allow an application to become effective. See id. §§ 302-305.

62. Id. § 201(n). The FDCA also defined "label" and "labeling." The term "label" was defined to mean a display of printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper. Id. § 201(k). The term "labeling" was defined to mean "all labels, and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Id. § 201(m).

63. See id. § 502(b)-(c), (f)-(g). More specifically, for a drug recognized in the United States Pharmacopoeia (USP) (and not offered as a homeopathic drug), mis-
These provisions constituted, in essence, an express delegation of interpretive and enforcement power over certain aspects of a drug’s labeling. However, the message was mixed. The provisions also stated that, for any drug recognized in “an official compendium,” section 502(g) required labeling “as prescribed therein,” thereby reflecting a specific recognition by Congress of the appropriateness of private sector decisions regarding the content of labeling. At the time, there was a close relationship between the United States Pharmacopoeia (USP), a private association, and the FDA, with some understanding that the USP could develop a compendium that would then effectively control drug labeling. Although the compendium concept never developed, its inclusion by Congress in the text of the statute raises questions about Congress’s view of the scope of the agency’s authority over the content of labeling.

The statutory provisions specifically addressing rulemaking authority similarly fail to show congressional intent to give the agency unlimited authority over the precise content of the labels on drugs marketed in interstate commerce. The authority that most specifically pertains to the content of labels is an authority “to exempt” branding occurs with a failure to comply with packaging and labeling requirements of the United States Pharmacopoeia. Id. § 502(g).

64. Id. § 502(g).


66. Interview with Alexander M. Schmidt, Commissioner of Food and Drugs 1973-76, in Chi., Ill. (Mar. 8-9, 1985), http://www.fda.gov/oc/history/oralhistories/schmidt/part3.html (explaining that one reason that the compendium concept never got off the ground was due to the FDA’s concerns about letting go of its authority over labeling). Schmidt commented that FDA had the labeling regulations and, of all the tools FDA has, one of the most valuable is the labeling regs. The use of those regs became a very fine art. And the people who were sophisticated and good enough to understand the use of the labeling regs, fended off any challenge to the agency’s authority to declare what was a proper or an improper label. The compendium issue for a large segment of FDA was that FDA, if it gave up its authority to label, would be giving up the whole ship. Giving to some outside, even quasi-governmental group . . . USP, whoever. To give up to them the authority to label—which in effect was what the compendium was—would be giving away the ship.

Id.; see also Interview with J. Richard Crout M.D., Dir. of FDA’s Bureau of Drugs 1973-82, in Rockville, Md. (Nov. 12, 1997), http://www.fda.gov/oc/history/oralhistories/crout/part3.html (explaining the agency’s decision to ask the USP to take over “antibiotic specs”).
drugs from requirements devised by Congress. Section 502, which defines the circumstances under which a drug can be misbranded authorizes the Secretary to "promulgate regulations" that exempt certain drugs from the requirement that a label bear "adequate directions for use," if the directions are unnecessary for the protection of the public health.67 Similarly, the Secretary can exempt drugs dispensed by prescription from certain labeling requirements so long as the drug’s label includes other specific limited information.68

As with the tenor of the 1906 Act, other key rulemaking provisions relate to enforcement. Section 701(a) is the most general grant of rulemaking authority in the FDCA. It provides that "[t]he authority to promulgate regulations for the efficient enforcement of this Act . . . is hereby vested in the Secretary."69 However, the authority to promulgate regulations necessary for enforcement is a limited authority. Such a delegation generally is not construed as including substantive rulemaking authority.70 Agencies entrusted with enforcement authority generally are limited to ensuring that duties imposed by Congress are carried out. For example, the FDCA empowered the agency to decide when a label on a drug on the market is "false or misleading," or has failed to include the directions and warnings required by Congress. In the enforcement action or per rules, the agency could develop general principles or standards relating to the statutory standards. Efficient enforcement

68. See id. § 503(b). The label must include "the name and place of business of the dispenser, the serial number and date of such prescription," and the name of the prescribing physician. Id. § 503(b)(2).
69. See id. § 701(a). Section 702 addresses examinations and investigations, and subsection (b) authorizes the Secretary to make "reasonable exceptions from, and impose such reasonable terms and conditions relating to," the collection of samples for analysis. Id. § 702(b). Section 902, which addressed the effective date of the FDCA, provided that section 701 would become effective immediately on enactment and that, "thereafter, the Secretary is authorized . . . to (1) conduct hearings and to promulgate regulations which shall become effective . . . as the Secretary shall direct." Id. § 902(a).
70. In cases in which courts have stated otherwise, the courts have not been precise. See Pharm. Mfrs. Ass'n v. FDA, 484 F. Supp. 1179, 1182-83 (D. Del. 1980). The key point that courts have addressed relating to the FDA's rulemaking authority is that the FDA has authority to impose duties via rulemaking as opposed to the adjudication process. See, e.g., Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 620 (1973) (noting the appropriateness of "particularizing statutory standards" through rulemaking); Nat'l Nutritional Foods Ass'n v. Weinberger 512 F. 2d. 688, 696 (2d Cir. 1975) (noting that "if the administrative process is to be practically effective, specific regulations promulgated pursuant to a general statutory delegation of authority must be treated as authoritative, whether labeled 'substantive' or 'interpretive'".).
also often requires that agencies create rules relating to procedures. Section 701(a)'s delegation of enforcement power, however, is clearly distinguishable from other delegations in the FDCA in which Congress expressly instructed the agency to promulgate regulations.71

Thus, the text of the FDCA—as to both the agency’s rulemaking authority and the section 505 adjudicatory authority over new drugs—reflects careful and specific decisions delimiting the agency’s authority over the content of prescription drug labeling. Because section 701(a) was drafted in a more restrictive way than the general rulemaking delegation in the 1906 Act,72 it is fair to characterize the FDCA as delegating substantial authority and discretion to the agency, but—at least as to the content of labeling—within carefully delimited bounds.

2. The 1951 and 1962 Amendments

Congress amended the FDCA’s approach to prescription drugs in 1951. The Humphrey-Durham Amendments (HDAs) specified that drugs that could not be used safely except under appropriate medical supervision could be dispensed only upon a proper written or oral prescription, or an authorized refill.73 Further, though, the amendments expressly exempted prescription drugs from some of the labeling requirements of section 502—specifically the requirement that the label bear “adequate directions for use” and “adequate warnings against [dangerous] uses”74—but required use, before dispensing, of a “cautionary legend” advising of the drug’s prescription status.75

71. This understanding is consistent with the Administrative Procedure Act. See 5 U.S.C. § 553(b) (2000) (exempting interpretive rules and rules of agency procedure or practice from the requirements of notice and comment).

72. The 1906 general rulemaking delegation provided that “the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs.” Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, § 3, 34 Stat. 768, 768-69 (repealed 1938).

73. See Humphrey-Durham Amendments, ch. 578, § 1, 65 Stat. 648, 648-49 (1951) (codified as amended at 21 U.S.C. § 353 (2000)). The text and legislative history of the HDAs are of central importance to the issue of preemption arising from the FDA’s market-approval decision for prescription drugs. However, the discussion and analysis of the HDAs are presented infra Part II.B.2, because they are better understood in the context of the agency’s regulatory initiatives.

74. Humphrey-Durham Amendments § 1; see infra note 146.

75. Humphrey-Durham Amendments § 1 (amending subsection 503(b) of the FDCA by adding subsection (4): “A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails
Important amendments were also enacted in 1962. Although often touted as a significant expansion to federal drug regulation, the 1962 amendments to the FDCA do not significantly bear on the issue of preemption that is being explored in this Article because the scope of the agency's authority over the content of prescription drug labeling was expanded in only a limited way.\(^{76}\) Three key changes were made by the 1962 amendments. Congress directed the FDA to assess the "effectiveness" of drugs, required drug manufacturers to offer more robust evidence supporting their claims, and precluded marketing of new drugs without a specific FDA-approval decision. In the 1950s, dangerous drugs such as thalidomide entered the market despite the application process put in place by the FDCA.\(^{77}\) In addition to a lack of resources and the difficulty of taking action within sixty days of the filing of an application, key FDA decision makers focused on the pharmacology of new drugs and their chemical behavior and on how the drugs were promoted, rather than on clinical evidence relating to drug safety.\(^{78}\) Over the course of several years, congressional hearings brought to light the lack of scientific rigor in the drug application process.\(^{79}\) The result-

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76. In particular, the 1962 amendments did not change the risk assessment aspect of the approval process. Under the FDCA as enacted in 1938, the FDA engaged in an assessment of "relative risk, balancing benefit with risk." See Jeffrey E. Shuren, The Modern Regulatory Administrative State: A Response to Changing Circumstances, 38 Harv. J. on Legis 291, 302 (2001) (noting, however, that even with the addition of the duty to assess for effectiveness, the FDA cannot approve an ineffective drug, even if it poses no health risks).


79. Goodrich explained that Kefauver initiated hearings to investigate antitrust violations due to concern about the high cost of drugs. Id. Goodrich noted that, although the drug companies testified as to the cost of clinical research and the cost of advertising and "education" as the reason for high drug costs, further investigation revealed deficiencies in the research and promotion of drugs. Id. Regarding research, Goodrich stated that anyone who had looked at any of the New Drug Applications knew, as I knew, that that was all baloney, and what they were saying to us in those early days was essentially a bunch of testimonials. The way drugs were investigated, a physician from the company would go out in the community with some samples and say to the doctor, "I've got this new drug for so-and-so. Here's some samples. Try it out and let us know how you like it." And they would get back
ing amendments in 1962 were an attempt to address those particular deficiencies in the FDA's practices in assessing drugs.

As a matter of procedure, the agency was provided greater power during the new drug application (NDA) process. The amendments provided that no "new drug" could be marketed unless an "approval" of the NDA was effective.\(^80\) Thus, rather than automatically becoming effective if no action was taken, obtaining an effective NDA required agency action. A statutory time frame was still in place, but it was longer—180 days—and if the agency was not ready to approve within this period, the agency was empowered to simply give the applicant the opportunity for a hearing on whether the NDA was approvable.\(^81\)

As a matter of proof, the amendments modified the FDCA by requiring NDAs to include reports of investigations showing not just the drug's safety, but also the drug's effectiveness in use.\(^82\) Further, they allowed the Secretary to refuse approval of an application based on deficiencies in the type of testing or the results of testing.\(^83\) As to test results, the Secretary was empowered to assess not just safety, but also effectiveness.\(^84\) Moreover, greater scientific rigor would be required in assessing effectiveness. The amendments authorized the Secretary to refuse approval of an NDA if

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\text{evaluated on the basis of the information submitted to him as part of the application and any other information before him on respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof} \ldots .\phantom{.}85
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The expansion of authority over the content of labeling was similarly tied to approval of an NDA. The amendments added a

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\text{a letter from him: "I tried it out on eight patients and they all got along fine." That's the kind of stuff that was coming for the science. Of course, that was completely unsatisfactory, and as soon as people focused on that, that raised the problem.}\phantom{.}86
\]

\(\text{Id.} \) Regarding the cost of "educating" physicians, the companies later reversed themselves "saying none of it was educational—nobody believed it, and therefore, it was no reason to require such a hard line on honesty with it." \(\text{Id.}\)

\(^80\) \(\text{See Drug Amendments of 1962, Pub. L. No. 87-781, § 104(a), 76 Stat. 780, 784 (codified as amended at 21 U.S.C. § 355(a) (2000)); see also id. § 102(a)(1) (adding the words "the effectiveness" to the definition of "new drug").}\)

\(^81\) \(\text{See id. § 104(b).}\)

\(^82\) \(\text{See id. § 102(b).}\)

\(^83\) \(\text{See id. § 102(c).}\)

\(^84\) \(\text{Id.}\)

\(^85\) \(\text{Id. (emphasis added).}\)
reason for refusal: the Secretary could refuse to approve an NDA if, "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular..."

86. Under the FDCA as enacted in 1938, a drug was deemed misbranded if the labeling was false or misleading, thus allowing regulation of the content of labeling via an enforcement action. The 1962 amendments allowed regulation of the content of labeling as part of the pre-market approval process. Thus, the agency's authority was enhanced both by timing and its ability to control but not as a matter of the scope of authority. The scope of authority remained limited; the requirement is one of truthfulness—to serve the purpose of educating prescribing physicians as the manufacturers had claimed that they did during the congressional hearings.

In addition, the 1962 amendments added duties relating to the information flowing from a drug's manufacturer to prescribing physicians. First, a new prohibition was added: the failure of a manufacturer to provide to any practitioner authorized to prescribe a particular prescription drug, who made a written request for information, "true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary." Second, a prescription drug could be deemed misbranded if its advertisements or printed matter—other than labeling—failed to include a "true statement" of the drug's established name, its formula and ingredients, and "such other information in brief summary relating to side effects, contraindications, and effec-

86. *Id.* The amendments also made clear that the Secretary's authority in assessing for safety, effectiveness, and false and misleading labels extended beyond the premarket approval process by virtue of the ability to "withdraw approval of an application." *See id.* § 102(d). In addition, the amendments gave the Secretary the authority to require by general regulation or by order with respect to a particular approved NDA—if found necessary—records or reports that would help the agency to make post-approval assessments. *See id.* § 103(a).


88. The amendments similarly bolstered the agency's post-approval powers, and power over drugs already on the market, by authorizing the Secretary to "withdraw" approval of a drug if its labeling is false or misleading and not corrected within a reasonable time of being notified of the perceived deficiency. *See* § 102(d).

89. *See* Notice of Proposed Rulemaking, Legal Status of Approved Labeling for Prescription Drugs, Prescribing for Uses Unapproved by the Food and Drug Administration, 37 Fed. Reg. 16,503, 16,504 (Aug. 15, 1972) (explaining that, under the regulatory scheme in place at that time, the FDA was charged with the responsibility of judging the truthfulness of prescription drug labeling).

90. *See* Drug Amendments § 114(a).
tiveness as shall be required in regulations which shall be issued by the Secretary...”

Evidenced by its omission of labeling from the “true statement” requirement, Congress expressly did not delegate to the agency any additional authority over labeling.

Regarding labeling, section 502(g) of the FDCA was amended in some respects, but the amendments did not delete or repeal the clause in section 502(g) regarding the requirement of satisfying the standards for packaging and labeling established by the USP. On the other hand, a provision of the “new” prohibition noted in the last paragraph states that “[n]othing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.” Id. § 114(a). This provision references and shows congressional recognition of agency authority over content of labeling. However, because the agency had not yet regulated extensively, any congressional recognition of agency control would also necessarily be limited.

Through the enactment of the Humphrey-Durham Amendments, Congress signaled its intent that a class of drugs known as

3. Limited Specific Directives Imposed by Congress

The foregoing review of the statutory scheme relating to prescription drug labeling was necessary to help assess the source of the intent to preempt. Because the FDA has asserted conflict preemption—and that variant of conflict preemption that parallels field preemption—an important factor in the totality of circumstances analysis is the extent to which the agency activity that purportedly warrants preemption has actually been devised by Congress. Over time, Congress empowered the FDA to make assessments relating to drugs, both at the pre-marketing and post-marketing stages. Those assessments are tied to specific standards set by Congress: drugs may not be misbranded and their labels may not be false and misleading, and the drugs themselves must be found to be safe and effective under the conditions prescribed, recommended, or suggested in the proposed labeling. Further, Congress provided some guidance regarding these standards, spelling out several specific ways in which drugs could be misbranded, including a failure to provide adequate directions and warnings.

91. See id. § 131(a).

92. See id. § 112(b). On the other hand, a provision of the “new” prohibition noted in the last paragraph states that “[n]othing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.” Id. § 114(a). This provision references and shows congressional recognition of agency authority over content of labeling. However, because the agency had not yet regulated extensively, any congressional recognition of agency control would also necessarily be limited.

93. See supra Part II.A.1.

94. See supra note 63 and accompanying text.
prescription drugs could be treated differently. The HDAs also made clear that the decision regarding which drugs should fall within that class is not solely a matter for the agency to address via rulemaking. When properly dispensed, prescription drugs are exempt from section 502(f); and before being dispensed, their labels must bear the requisite "cautionary legend."

Thus, the agency activity triggering preemption—the approval determination—is, at least in part, activity taken in accordance with a scheme devised by Congress. However, Congress only provided limited guidance and the analysis, therefore, must go deeper. The question becomes whether, in making those assessments, the agency is guided primarily by the statutory terms themselves, or by more refined or new standards put in place by the agency. The analysis must include a careful review of the regulatory scheme put in place by the agency, and a consideration of the interplay between the statutory provisions—in particular the HDAs—and the regulations.

B. The Evolution of the Agency’s Regulation of Prescription Drug Labeling

The following analysis focuses on both the extent to which the agency, in implementing the regulatory scheme, went beyond the directives set by Congress, as well as issues relating to the agency’s authority.

1. Stage One: Minimal Regulation That Laid the Foundation

Agency regulation of drug labeling promptly followed enactment of the FDCA in December of 1938. In support of the regulations, the agency expressly pointed to section 701(a) of the FDCA and, notably, the 1938 regulations largely reflected an understanding that the agency’s powers were enforcement powers. Consis-

96. Id.
97. See supra notes 74-75 and accompanying text.
99. Id. The agency action was simply titled “Promulgation of Regulations Under the Federal Food, Drug and Cosmetic Act and Repeal of Certain Regulations Heretofore Promulgated Thereunder.” Id. The regulations were prefaced by a note stating that “[t]he caption of each of the following regulations designates the section of the Act
tent with an exercise of enforcement power, the regulations dealing with drug labels were interpretive or promulgated pursuant to a power to create “exemptions.”

For example, interpretive regulations included regulations clarifying the definition of “labeling,” and specifying that various types of statements or omissions of types of statements would constitute “misbranding” or render a label “misleading.” The regulations also specified what would be required to ensure compliance with section 502(b), which requires a drug’s label to include an “accurate statement of the quantity of the contents in terms of weight, measure, or numerical count,” and with section 502(e), which requires a drug’s label to include the names of active ingredients. The agency promulgated exemptions from these requirements as authorized by sections 502(b) and (e).

In a similar fashion, the agency promulgated regulations clarifying when a drug’s label complied with section 502(f)’s requirement of adequate directions for use and creating exemptions from that requirement. The regulations provided that direction could be inadequate if they omitted “directions for use in all conditions for which such drug . . . is prescribed, recommended, or suggested in its labeling,” and by omissions of information relating to “quantity of dose . . . frequency of administration . . . duration of administration . . . time of administration . . . route or method of administration . . . or . . . preparation for use.”

under which the regulation is issued.” Id. The agency thus understood the regulations to be necessary for the “enforcement” of several specific sections of the FDCA. To that end, the agency viewed the regulations to have a dual source of authority: section 701 and a specific subsection within the FDCA. Id.

100. Id. at 3161, 3163, 3165.
101. Id. at 3165-67.
102. Id. at 3166-67.
103. Id. at 3167-68.
104. Id. By way of regulations such as these, the agency was, in a sense, creating duties. From an administrative law perspective, however, the regulations readily can be characterized as interpretive. For example, in regard to the regulations requiring directions to include certain types of information, the duty was created by Congress’s decision that a drug is misbranded unless it includes adequate directions for use. Id. at 3167. In enforcing the FDCA, the agency must decide whether the directions on a drug’s label are “adequate.” Id. As a matter of efficient enforcement, it becomes reasonable to interpret what type of information should be included to satisfy Congress’s requirement and to set forth that interpretation by way of regulation. The first part of the regulation clarified that “directions for use” are necessary for each use included on the drug’s label. Id. As to the second part, it is reasonable to characterize information regarding preparation and dosage, and information regarding timing, duration, and method of administration, as relating to how to use the drug. Id. at 3168. Thus, although the agency has been more specific than Congress about what type of informa-

...
The agency also created three exemptions from section 502(f)'s requirement of adequate directions for use. Specifically, the agency exempted three categories of drugs: (1) drugs for which "adequate directions for [use] are known by the ordinary individual"; (2) drugs whose shipment or delivery was limited solely to physicians and dentists, and for which the label bore a statement cautioning that it be used only by prescription and containing medical terms only if they likely would not "be understood by the ordinary individual" (the "cautionary legend"); and (3) drugs appropriately limited to manufacturing use only.

The agency's use of its 502(f) exemption power is of central importance given the focus of this Article on the agency's authority over prescription drug labeling. As a distinct delegation of rulemaking authority, the exemption power is not limited to enforcement and thus regulations can go beyond mere interpretive regulations, or regulations of process or procedure. Nonetheless, authority to promulgate 502(f) exemptions was expressly limited by Congress. Congress empowered the agency to exempt drugs from the duty where "adequate directions for use" are "not necessary for the protection of the public health." The 1938 regulations arguably fall within this limitation. Drugs limited to use for manufacturing purposes will not reach individuals who consume the drugs. As to drugs that could reach individuals, directions arguably are not necessary where "adequate directions" are commonly known, or where an individual will know that directions should be provided by a prescribing physician or dentist. Additionally, the exemptions constituted mere exemptions and imposed no duties. Thus, the exemptions, as created in 1938, were consistent with the agency's authority must be included on a drug's label, the regulations readily conform to the scope of the duty set forth in the text of the statute.

105. Id. at 3168. The agency also created exemptions under section 503(a) and exemptions from section 505 for investigational drugs.

106. Id.

107. See infra Part III.


109. See id. The proviso states: "That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement." It is important to note that section 503(b)'s authorization of the Secretary to exempt from certain labeling requirements drugs dispensed on a written prescription would not have allowed this action by the Secretary. See id. The exemptions permitted via section 503 did not include the requirement of section 502(f). See id. § 503(b).
authority as delimited in the FDCA. In short order, however, the agency amended the section 502(f) exemptions and, via the exemption power, began down the path of more comprehensive regulation of the content of the labeling of prescription drugs.

In 1941, the agency amended the regulations exempting drugs from section 502(f)’s requirement of adequate directions for use.110 The agency again pointed to section 701(a) and section 502(f) for the source of the authority for the regulations.111 The same three categories of drugs were exempted—prescription drugs, drugs intended for manufacturing only, and drugs for which adequate directions are commonly known. However, the agency imposed additional conditions on the exemption for prescription drugs.112 Specifically, the 1941 regulations provided an exemption for a shipment or delivery of drugs intended for use only by prescription only if “adequate directions for so using such drug . . . are available in scientific publications or otherwise” and, in addition, only if “in the case of a drug that is not designated solely by a name recognized in an official compendium and that is fabricated from two or more ingredients, its label also bears the quantity or proportion of each active ingredient.”113

The regulations thus conditioned the exemption on additional requirements,114 which raises the question whether the agency had the authority to begin imposing such requirements. In promulgating the 1941 regulations, the agency pointed to section 502(f) for the source of its authority.115 The question then is whether a delegation of rulemaking authority to create exemptions from a duty

111. See id.
112. Id.
113. Id. at 1920-21. The regulation further specified that if any shipment or delivery of drugs intended for prescription use was disposed of “otherwise,” the exemption would expire and the person causing the exemption to expire would be liable for misbranding unless the drugs were relabeled to comply with section 502(f). Id. at 1920.
114. If the idea underlying the exemption is that prescription drugs do not need “adequate directions for use” because directions will be provided by the prescribing doctor, it makes sense that the prescribing doctors have access to information necessary to provide directions to patients. Further, because doctors often get their information about drugs from an official compendium, a list of active ingredients—which would enable doctors to use a compendium—would be useful information for prescribing doctors.
115. Id. at 1920 (stating: “Under the authority and pursuant to sections 502(f) . . . Paragraphs (b) and (c) of the regulation under section 502(f) of the Act are changed to read as follows . . . ”).
imposed by Congress includes a delegation of authority to impose requirements to obtain the exemption.\textsuperscript{116}

In 1944, the section 502(f) exemption regulations were amended yet again, adding layers of complexity to the exemption scheme and raising additional questions concerning the agency’s authority relating to labeling for prescription drugs.\textsuperscript{117} Again, the agency pointed to sections 502(f) and 701(a) of the FDCA as the dual source of the authority for the amendments to the exemptions.\textsuperscript{118} One controversial aspect of the amendments was the agency’s decision to limit use of the “prescription only” designation. The regulations were amended to prescribe that a shipment of drugs would be exempted from § 502(f)(1) only if the “drug . . . because of its toxicity or other potentiality for harmful effect . . . is not generally recognized among experts . . . as safe and efficacious for use except by or under the supervision of a physician . . . .”\textsuperscript{119} This agency action was a key spur for the 1951 statutory amendments.\textsuperscript{120}

In addition, the regulations added important clarifications,\textsuperscript{121} and prior requirements were changed or new requirements imposed relating to access to the exemption. The exemption now hinged on having information “adequate for use . . . readily available,”\textsuperscript{122} which was a relaxing of the 1941 requirement, and having a label bearing a statement as to the quantity of each active ingredient and the “cautionary legend,”\textsuperscript{123} which was the same as the 1941 require-

\begin{footnotes}
\item[116] This becomes a recurring issue in the history of the FDA’s regulation of prescription drug labeling. \textit{See}, \textit{e.g.}, \textit{infra} notes 121-126, and 156 and accompanying text.
\item[118] \textit{See id.} at 12,255 (“By virtue of and pursuant to the provisions of sections 502(f) and 701(a) . . . the regulations heretofore promulgated under sections 502(f) and 505 of the act are hereby amended . . . . The regulation promulgated under section 502(f) of the act (21 C.F.R., Cum. Supp., 2.106) is amended by striking out paragraphs (b) and (c) and substituting therefor the following paragraphs (b) to (k), inclusive . . . .”).
\item[119] \textit{Id.; see also} Interview with William W. Goodrich, \textit{supra} note 78 (noting that in 1942, Crawford “devised the idea of amending the regulations to limit to prescription drugs all those drugs that could not be sold safely without prescription, and to require all those that could have adequate directions for use to have adequate directions”).
\item[120] \textit{See infra} section II.B.2.
\item[121] For example, the regulations clarified that the exemption required that the drugs be dispensed by physicians or dentists engaged in—and upon prescriptions issued in—professional practice; and that the labeling bear directions for use specified in such prescriptions. Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, 9 Fed. Reg. at 12,255.
\item[122] \textit{Id.} at 12,256.
\item[123] \textit{Id.}
\end{footnotes}
ment. Additionally, however, the exemption now required the label to include the information concerning the drug's use that had been in the proposed labeling submitted in the application process.\(^\text{124}\) As with the earlier regulations, the exemption was conditioned on additional requirements. In the text of the statute, Congress required "adequate directions for use."\(^\text{125}\) The agency exempted prescription drugs from that requirement only upon meeting a labeling requirement that could potentially be more comprehensive than that required by Congress.\(^\text{126}\)

Whether the requirement actually was more comprehensive requires consideration of the 1944 regulations pertaining to the new drug application process. Pointing to its authority over the market approval process, the agency by regulation required applications "to include a statement showing whether the drug is to be exempt" from section 502(f), and, if so, provided that the application may be found insufficient if:

1. The specimen label of the drug fails to incorporate by reference a specifically identified brochure or other printed matter containing information adequate for the use of such drug by physicians [and] dentists . . .; [or]
2. Such label fails to state that the drug is to be used as shown in such brochure . . .; [or]
3. The application fails to contain copies of such brochure . . .; or
4. The application fails to show that such brochure . . . is readily available to physicians . . ..\(^\text{127}\)

The new application requirement, then, was essentially to prepare a "brochure" that contained information "adequate" for the use of the drug, and to use the label to inform doctors of the existence of and the availability of the brochure.\(^\text{128}\) The corresponding new requirement for the exemption thus went beyond the 1941 requirement that a drug manufacturer make available to the prescrib-

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\(^{124}\) Id. (citing 21 C.F.R. § 2.106(h) (1944)).


\(^{126}\) Moreover, the agency used the exemption to bolster its regulation of drug advertising. The 1944 regulations provided that no exemption would be available for a drug "if its advertising contained a representation . . . not borne by its labeling and which, if so borne, would make it a new drug." Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, 9 Fed. Reg. at 12,256.

\(^{127}\) Id. at 12,256-57.

\(^{128}\) See Interview with William W. Goodrich, supra note 78
ing doctor, through other means, "adequate directions." The 1944 regulations specified the "other means" that could be used. The regulatory scheme thus gave rise to two distinct issues: whether the agency had the authority to require a brochure as part of the application process, and the recurring issue of whether the authority to create exemptions from Congress's labeling requirement included the authority to impose additional labeling requirements on drug manufacturers. The recurring issue of whether the exemption authority includes authority to impose additional requirements is a thornier issue. 129 The agency's actions raised concerns that were frequently expressed in the hearings on the 1950 statutory amendments, but that were not addressed by a court until after the agency expanded its requirements in what this Article refers to as Stage Two of the evolution of the agency's regulation.

Thus, during the first stage of agency regulation of drug labeling, the FDA distinguished between prescription and non-prescription drugs. While it required "adequate directions" for both, it regulated what constitutes "adequate directions" for prescription drugs by way of the interplay between two sources: its authority over the application process and its authority to exempt drugs from Congress's labeling requirement. Notably, the agency did not in Stage One regulate the content of "information for use"—leaving that as a matter between the manufacturer and prescribing physicians. Although the agency's regulation of content during this stage was minimal, the agency activity laid the foundation for more rigorous regulation of prescription drug labeling.

129. Regarding the brochure, agency rulemaking authority relating to the application process remains subject to the delegation of rulemaking authority in section 701(a). The basic findings that the agency is authorized to make during the application process are that (based on the information before the agency) (1) the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling, and (2) the labeling is not false or misleading. See supra notes 52-56 and accompanying text. The agency thus would have authority to clarify, via interpretive regulations, what Congress intended to ban by the proscription on false and misleading labeling, or what standards the agency would use to determine whether a drug is safe. Additionally, the agency would have authority to issue rules of process and procedure, such as rules that would enhance the agency's ability to evaluate drug labeling or to fully comprehend the substance of the proposed labeling. Requiring that directions for use for prescription drugs be incorporated into a brochure or other printed matter arguably could enhance the agency's ability to evaluate the labeling and arguably relates to safety since the requirement serves as a way of making it more likely that the manufacturer has pertinent information for safe use readily available for prescribing providers. As a requirement of format only, the regulation arguably did not raise concerns about overstepping of the agency's authority.
2. Responses to Stage One of the Agency's Regulations

In the FDCA, as enacted in 1938, Congress did not differentiate between prescription drugs and drugs that could be dispensed without a prescription. Yet, as explained, the agency made a distinction via regulations. The Stage One regulations left the decision regarding which drugs would be prescription to the drug manufacturers and required adequate directions for use only if the drug was dispensed over-the-counter. The 1944 regulations limited the exemption—and thus prescription drugs—to drugs that could not be sold safely without prescription by a licensed health care provider and created distinct labeling requirements for prescription drugs. Although never codified, the agency also later limited the pharmacist's ability to refill prescriptions. Understandably, the agency's approach to prescription drugs and their labeling raised concerns, and those concerns led to the enactment of the 1951 amendments to the FDCA—the Humphrey-Durham amendments.

During the extensive hearings on the HDAs, drug manufacturers raised concerns relating to the agency's authority to regulate prescription drugs differently than other drugs. In particular, it was noted that the agency had left the decision about which drugs should be considered prescription drugs to the manufacturer because "the act conferred no authority upon the Food and Drug Administration to create classes of drugs or to specify the manner in which drugs of each class should be labeled and sold." Further, regarding the agency's view that the statute itself "classifies drugs," it was noted that:

Surely, if this be the proper interpretation of the act, no one should be more surprised than Congress. The battle for the en-

131. In October 1948, the agency decided that no prescription written by a medical practitioner that had once been filled was refillable by the pharmacist. This new ban was not codified. Rather, the agency announced the new ban as an interpretation of the law in a speech to the National Association of Retail Druggists. Later, in a drug journal, the Commissioner stated that a physician's prescription is like a check on a bank: "Once it has been 'cashed,' it cannot be 'cashed' again." See A Bill to Amend Section 503(b) of the Federal Food, Drug, and Cosmetic Act, Hearing on H.R. 3298 Before the H. Comm. on Interstate and Foreign Commerce, 82d Cong. 121 (1951), reprinted in 11 Legislative History of the Federal Food, Drug and Cosmetic Act and Its Amendments 147 (1979) [hereinafter Legislative History] (hearings related to the Humphrey-Durham amendments). Whether to permit prescription refills, and, if so, how, were key issues at the time of the HDAs.
The enactment of the act is portrayed in volumes of committee hearings, committee reports, and congressional debates, and in countless early drafts of the act. All of this material seems to support the conclusion that Congress assumed and intended that a drug consumer would receive adequate protection if the label told him what he was taking, how to take it, and when to stop...

Accordingly, there is little to support the view that anything in the act or in its legislative history requires drugs to be divided into two classes...

The agency itself acknowledged the ambiguity regarding its authority to regulate prescription drugs as a class. In his prepared statement on the HDAs, made to the House Committee on Interstate and Foreign Commerce, the administrator of the Federal Security Agency explained the operation of the existing regulatory scheme, noting in particular its practical effect of limiting "a number of drugs to the prescription departments of retail pharmacies," and the potential difficulty encountered by pharmacists when manufacturers labeled a drug as prescription when it was not clear that the drug could not be dispensed safely without a prescription. The administrator acknowledged that "[t]he present statute does not in so many words authorize us either to differentiate between 'prescription drugs' on one hand, and 'over-the-counter drugs' on the other." He nonetheless asserted, "[w]hile some law-

133. Id. at 752. Additionally, this is borne out by the oft-repeated quotation from the report of the Senate committee on S. 5:

"The bill is not intended to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective. For this purpose provisions are included . . . requiring that labels bear adequate directions for use and warnings against probable misuse. . . ."

Id. (omissions in original).

134. Id. (concluding that "the present regulation, which . . . requires the use of the prescription legend on drugs that may be used safely and effectively only under medical supervision is of questionable validity").


136. Id. (explaining that when a drug is delivered to a pharmacist (or druggist) from a manufacturer with the cautionary label, and the pharmacist sells the drug without a prescription but with "labeling giving adequate directions for use," the agency considered the drug to be misbranded under 502(a) because of the false implication that the drug could be used safely by a layperson).

137. Id.
yers have disagreed, . . . authority for our present regulation and for
its proposed revision is found in the present statute—though it is
contained in one four-line proviso."138

Congress enacted the HDAs but did not delegate to the agency
the full extent of authority that the agency sought. A primary con­
cern of the agency, manufacturers, and pharmacists was the method
used to identify which drugs should be deemed prescription drugs
and thus subject to the requirements established by Congress in sec­
tion 503(b) via the HDAs. Under the Stage One regulatory
scheme, the agency had established a standard, but it left the initial
decision as to whether a drug satisfied that standard to the manu­
ufacturer.139 If the agency disagreed with the manufacturer's assess­
ment, enforcement had to be pursued via a criminal prosecution, an
action for seizure, or an injunction.140 Due to inefficiencies in that
approach, the agency sought a statutory definition of prescription
drugs that included drugs "found by the Administrator, after investi­
gation and opportunity for public hearing, to be unsafe or ineffec­
tive for use without . . . professional diagnosis or supervision . . . ."141 That approach proved to be controversial and eventually
was eliminated. The HDAs, as enacted, did not authorize the FDA
to develop administratively a list of prescription drugs.142

Nonetheless, the HDAs otherwise largely codified the scheme
that had been put in place by the agency.143 As explained, the 1951
statutory amendments required that drugs that could not be used
safely except under appropriate medical supervision be dispensed
only upon a proper prescription; and they expressly exempted from
the requirements of section 502(f) any drug dispensed by prescrip­
tion.144 This exemption was not limited to the first clause of section
502(f), and thus Congress exempted prescription drugs from the re­
quirements of both "adequate directions for use" and "adequate

138. Id. at 44. Ewing noted: "I think we ought to have clear and unequivocal
authority. The bill before you would confer such authority . . . ." Id. at 47.
139. See H.R. REP. No. 82-700, at 4 (1951), reprinted in 11 LEGISLATIVE HIS­
TORY, supra note 131, at 278.
140. Id.
141. H.R. 3298, 82nd Cong. (1951) (enacted), reprinted in 11 LEGISLATIVE HIS­
TORY, supra note 131, at 15.
142. H.R. REP. No. 82-946, at 2-3 (1951), reprinted in 11 LEGISLATIVE HISTORY,
supra note 131, at 665-66.
143. See generally Humphrey-Durham Amendments, ch. 578, 65 Stat. 648 (1951)
144. See supra notes 73-75 and accompanying text.
warnings against use.” This exemption, however, was aimed at prescription drugs upon being dispensed. The term “dispensed” was understood to refer to a retail sale by a druggist under the supervision of a registered pharmacist.

A key question relating to agency authority, then, is how the HDAs may have affected the agency’s authority over the labeling of prescription drugs before the time of being dispensed. If section 502(f) continued to apply to prescription drugs up to the time of being dispensed, the agency’s authority to exempt drugs from the requirement of “adequate directions for use” would remain as a vehicle for agency regulation of prescription drug labeling. As the next stage of agency regulation makes clear, the agency viewed the HDAs as a green light for continued regulation of the content of prescription drug labeling.

3. Stage Two: Transforming the Agency into a Demanding Regulator

During the second stage of FDA activity in relation to prescription drug labeling, the agency built upon the foundation set during Stage One and asserted itself through a comprehensive regulatory scheme. During the 1960s and 1970s, the agency greatly expanded its regulation of the content of prescription drug labeling and shifted away from a mere enforcement approach to regulation. At

145. See Humphrey-Durham Amendments § 1. The provision stated: “Any drug dispensed by filling or refilling a written or oral prescription . . . shall be exempt from the requirements of section [502(f)] . . . .” Id.

146. A Bill to Amend Section 503(b) of the Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 3298 Before the H. Comm. on Interstate and Foreign Comm. H.R., 82d Cong. 76 (1951) (statement of Charley Wesley Dunn, General Counsel, American Pharmaceutical Manufacturers’ Association), reprinted in 11 LEGISLATIVE HISTORY, supra note 131, at 102. It is only at the point of being dispensed that prescription drugs reach the hands of consumers. The rationale was, at that point, that the directions needed by the consumer were simply the specific directions provided by the prescribing health care provider. H.R. REP. NO. 82-700, at 16 (1951), reprinted in 11 LEGISLATIVE HISTORY, supra note 131, at 290. Congress codified two requirements for the exemption. First, a dispensed prescription drug was exempt if its label contained information about the dispenser and the prescriber of the drug, and, “if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription.” Humphrey-Durham Amendments § 1. This requirement was new and different from any imposed previously by regulation. Second, Congress codified the agency requirement that the label include the “cautionary legend”—namely, that it only be used with a prescription. Id. Congress also provided that “[n]othing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included” in federal laws dealing with narcotics or marijuana. Id.
the same time, the source of the agency's authority shifted. Notably, in the 1960 regulations the agency expressly pointed only to section 701(a) of the FDCA as the source of its authority. Yet, the agency regulations being amended were the "exemption regulations." The agency stated in the introductory sentence to the amended subsection (b): "A drug subject to the requirements of section 503(b)(1) of the act," as newly amended by the HDAs, "shall be exempt from section 502(f)(1) if all the following conditions are met . . . ." The agency was clearly acting pursuant to its exemption authority.

The 1960 regulations added several requirements relating to the content of prescription drug labeling. In addition to the "cautionary statement" required by Congress in the HDAs, the agency required the label of the drug to include information about dosage, route of administration, active and inactive ingredients, and the identifying lot or control number. It further required "any labeling" to contain

[a]dequate information for such use, including indications, effects . . . and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all conditions for which it is advertised or represented; and if the article is subject to section 505, 506, or 507 of the act [the market application process] . . . the labeling providing such information is substantially the same as the labeling authorized by the effective new-drug application . . . .

Thus, pursuant to its power to exempt drugs from Congress's requirement, the agency began to regulate the content of prescription drug labels and labeling much more extensively in its 1960 regulations.

148. Id. at 12,593.
149. Humphrey-Durham Amendments § 1. Congress required the label on prescription drugs to include the statement, "Caution: Federal law prohibits dispensing without prescription." Id.
151. See Interview with William W. Goodrich, supra note 78 (noting that the agency had never really insisted that the brochure be used by manufacturers, and explaining that the 1960 regulations represented the first real step by the agency in requiring full disclosure in promotional materials such as the Physician's Desk Reference).
The 1960 regulations also amended the application process. Specifically, the amendments to the application process provided that labeling for prescription drugs “should bear information for use under which practitioners can use the drug for the purposes for which it is intended, including all the purposes for which it is to be advertised or represented.”\textsuperscript{152} Further, the label “will also contain substantially the same information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, any relevant hazards, contraindications, side effects, and precautions, contained in the labeling which is part of this application.”\textsuperscript{153} The regulations also provided that representations regarding labeling made during the application process would “apply to the drug produced until an effective supplement to the application provides for a change,”\textsuperscript{154} and revised the process for supplemental applications.\textsuperscript{155}

As with the Stage One regulations, the additional requirements are defensible on one hand, in that the regulations seek to ensure that the manufacturer provides to the prescribing physician information relevant and material to the decision whether to prescribe. Indeed, the agency noted that the purpose of the amendments was to require “manufacturers to furnish adequate information for the professional use of prescription drugs.”\textsuperscript{156} On the other hand, it is the agency that made the decision to regulate the content of prescription drug labeling and that began putting in place significant requirements. Additionally, the issues relating to authority remain: to what extent does the authority to grant an exemption from a requirement for “adequate directions for use” include an authorization to impose new and different labeling obligations? And was that authority in any way limited by the HDA?\textsuperscript{157}

\textsuperscript{153} Id.
\textsuperscript{154} Id.
\textsuperscript{155} Id. at 12,595.
\textsuperscript{156} Id. at 12,593.
\textsuperscript{157} As a result of the precise text used by the agency, a key difference exists between the Stage One and Stage Two regulatory schemes. As noted, in the 1944 regulations, the additional duty of the brochure requirement was imposed via the agency’s authority over the application process and was then merely incorporated into the exemption scheme. See supra notes 125-129 and accompanying text. The 1960 regulations operate in reverse. The regulations pertaining to the application process make clear that applications involving prescription drugs will include labeling—as required by the exemption provision. In addition, it is the exemption regulations that direct that, once approved, the labeling must substan-
The next major amendments to the prescription drug labeling regulations were promulgated in 1979, after, and in part in response to, the 1962 statutory amendments. As explained, however, the 1962 statutory amendments did not significantly affect the agency's authority over the labeling of prescription drugs. The key changes to the statute in the 1962 amendments related to the application process. Pre-market "approval" was necessary; and approval hinged on agency assessment of not only safety, but also effectiveness.\textsuperscript{158} Additionally, the Secretary could refuse approval if the drug labeling was found to be "false or misleading."\textsuperscript{159}

Nonetheless, the 1979 regulations constituted a substantial expansion of the agency's regulation of the content of prescription drug labeling. Consuming five pages of the Federal Register, the regulations described in much greater detail the precise content and format that, in the agency's view, is necessary for physicians to safely and effectively prescribe the drug. Overall, the regulations required labeling to summarize the necessary information for safe and effective use.\textsuperscript{160} More particularly, the regulations specified in detail the precise format and kind of information that manufacturers had to include in the labeling. The regulations directed that all prescription drug labeling must include the following section headings: description; clinical pharmacology; indications and usage; contraindications; warnings; precautions; adverse reactions; drug abuse and dependence; overdosage; dosage and administration; and how supplied.\textsuperscript{161} The regulations also specified the order of the headings and which type of information had to be included within each section.\textsuperscript{162} For example, under the heading "warnings," the labeling was required to describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association

\textsuperscript{158} See \textit{supra} notes 80-81 and accompanying text.
\textsuperscript{159} See \textit{supra} note 86 and accompanying text
\textsuperscript{161} \textit{Id.}
\textsuperscript{162} \textit{Id.} at 37,462-66.
of a serious hazard with a drug; a causal relationship need not have been proved. . . . Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box . . . . If a boxed warning is required, its location will be specified by the Food and Drug Administration.\textsuperscript{163}

The agency's view of the source of its authority for the regulations is found in a statement in the preamble to the rules. The agency stated:

Section 502(f)(1) of the act requires that a drug's labeling bear adequate directions for use. For a prescription drug to be exempt from section 502(f)(1) of the act, §201.100(d) . . . requires that the labeling for the drug contain adequate information for the drug's safe and effective use. In addition, labeling of a drug may be misleading under §1.21(a) if it fails to reveal facts that are material in light of other representations made or suggested by statement, word, design, device, or any combination thereof, or material with respect to consequences that may result from use of the drug under the conditions prescribed in the labeling or the conditions of use that are customary or usual.\textsuperscript{164}

The agency explained its intent in several different ways. It stated that the new formatting and content requirements were intended to provide physicians with a clear and concise statement of the data and information necessary for the safe and effective use of the drug. . . .

. . . [T]o provide the essential information the practitioner needs to use a drug safely and effectively in the care of patients. . . .

. . . [T]o provide a uniform standard for the kinds of data and information necessary to enable physicians to use drugs safely and effectively. . . .

. . . [T]o improve prescription drug labeling to the point where a compendium can be developed. . . .

\textsuperscript{163} Id. at 37,463.
\textsuperscript{164} Id. at 37,436.
... [T]o provide standards so that all prescription drug labeling can be brought up to the level of the best labeling written in the past.\textsuperscript{165}

The FDA also noted that "[t]he efficient enforcement of the act by FDA requires that the regulated industry be apprised of the criteria under which labeling will be in compliance with legal requirements. The purpose of these regulations is to provide a more concise statement of those criteria."\textsuperscript{166}

The 1979 regulations thus reflected a new administrative philosophy. Up until 1970, the agency viewed itself largely as an enforcement agency.\textsuperscript{167} However, Charles Edwards, appointed commissioner in 1969, brought a new vision to the FDA.\textsuperscript{168} Alexander Schmidt, Commissioner from 1973-1976, has explained the extensive influence of Dr. Edwards.

Charlie was brought in to move the agency into the twentieth century, so to speak. . . .

And the question for FDA [was], what business were they in? And Charlie asked that question. And the answer was not, we're in the business of putting people in jail. The answer to the question of what business is the FDA in is, it's a public safety agency. It's insuring safe and effective products on the market. It's not like the FTC; it's not economic regulation. . . .

[T]he question then becomes, what is the most effective, efficient way of insuring safe and effective products. And Charlie's answer was . . . that there were ways other than sticking people in jail. Education, for example. Voluntary compliance with guidelines and with standards, for example. . . .

Charlie revamped the administration of the agency . . . .

The most important thing that happened at FDA while I was there was . . . the re-write of all of the administrative regulations

\textsuperscript{165} Id. at 37,435, 37,437-38.
\textsuperscript{166} Id. at 37,439.
\textsuperscript{167} See Interview with Alexander M. Schmidt, supra note 66. Schmidt explained that while Billy Goodrich was general counsel, from 1939 to 1971, the agency "was a cop agency. It was an enforcement agency. It enforced the law, and that was about it." Id.
of the agency, the revamping of the administration and management of the agency. . . .

. . . . [T]he colossal changes of the administrative regulations and the re-looking at all of the ways we coerced industry into doing what they should do.169

It was during Stage Two—the 1960s through the 1970s—that the agency elected to expand its regulatory role and to become a more demanding regulator of the labeling of prescription drugs. The agency’s shift in approach, combined with a very real and deliberate expansion in terms of agency-imposed requirements and standards, should be accorded appropriate weight in the analysis of the source of the intent to preempt.

C. The Activity Purportedly Triggering Preemption Was Devised Predominantly by the Agency

Application of a totality of the circumstances analysis to the preemption being asserted by the FDA points to the agency as the source of the intent to preempt. As explained, a key inquiry in a totality of the circumstances analysis is the extent to which the agency activity triggering preemption was devised by the agency, as opposed to Congress.170 When the purported conflict has resulted from a regulatory scheme developed by an agency, courts must assess the extent to which that regulatory scheme has been extended beyond any specific directives detailed by Congress in the text of the statute.171

Here, the agency activity triggering the purported preemption is the FDA’s approval decision allowing the marketing of a prescription drug. In making that approval decision, the agency is authorized by Congress to assess whether the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling; whether the labeling is false or misleading; and whether the drug is misbranded. As noted, Congress has provided

169. See Interview with Alexander M. Schmidt, supra note 66. Schmidt noted that the 1970s were an exciting era because it was a time when the agency essentially authorized its own regulations due to the perfunctory executive oversight.

170. See supra notes 34-35 & 41 and accompanying text.

171. The Supreme Court has recognized a distinction between regulations that merely “parrot the statute” and regulations that reflect a use of the agency’s expertise and experience. See, e.g., Gonzales v. Oregon, 546 U.S. 243, 257 (2006). Where the agency activity reflects a “parroting regulation,” it remains reasonable to attribute preemptive intent to Congress. Id.
very limited guidance regarding the standards to use in making these assessments.\textsuperscript{172} Congress directed that a label could be misleading due to both representations and omissions and identified several specific instances that could render a drug misbranded, including a failure to provide adequate directions and warnings as provided in section 502(f).\textsuperscript{173} Congress specifically exempted prescription drugs from the section 502(f) requirement via the HDAs, but only upon being dispensed, and expressly required only a “cautionary statement” on prescription drugs before being dispensed.\textsuperscript{174}

To the extent that Congress’s directive for adequate directions and warnings remained applicable to prescription drugs before being dispensed, the directive as to adequate directions was rendered inapplicable to prescription drugs by the agency through the agency’s exemption authority. In its place, the agency developed and imposed many additional requirements and standards relating to the labeling for prescription drugs. The agency further defined what could render labeling misleading and imposed comprehensive requirements and standards that must be satisfied to be exempt from section 502(f)(1).

Regarding the exemption requirements, the agency in Stage One required only that “information adequate for use” by prescribing physicians be made available, eventually in a brochure or other type of printed matter.\textsuperscript{175} It left the issue of what constitutes “adequate information for use” largely as a matter between the drug manufacturer and prescribing physicians. In Stage Two, the agency made a deliberate move toward more detailed requirements and standards. It first required, in 1960, “adequate information,” explicitly, general categories of information. Later, in 1979, it designed a set format, detailing with much greater specificity the type of information that must be included if available (five Federal Register pages of detail), and establishing standards such as requiring a warning once there exists “reasonable scientific evidence of an association” between the drug and a serious risk.\textsuperscript{176} As to the key assessment of whether a drug is “safe for use under conditions prescribed, recommended or suggested in proposed labeling,” Congress similarly provided no express guidance as to what “conditions

\textsuperscript{172} See supra Part II.A.3.
\textsuperscript{173} See supra notes 50-51 and accompanying text.
\textsuperscript{174} See supra notes 95-97 and accompanying text.
\textsuperscript{175} See supra notes 127-129 and accompanying text.
\textsuperscript{176} See supra notes 160-166 and accompanying text.
in the labeling" it was referring to.\textsuperscript{177} Even if the matter can be inferred by reference to the misbranding provision requirements of "adequate directions" and "adequate warnings," it is still the agency regulations that have given meaning to these phrases. As to prescription drugs, the "conditions in the labeling" became the information required by the exemption regulations.\textsuperscript{178}

Moreover, it was the agency that imposed the requirement that labeling for prescription drugs (and other drugs) remain "substantially the same" as the labeling presented for the application process. In the FDCA and the 1962 amendments, Congress did not include any such provision.\textsuperscript{179} Indeed, even in the 1962 amendments relating to the application and approval process, Congress limited the agency's authority over the labeling content to the assessment of whether the labeling was "false and misleading."\textsuperscript{180} The agency went beyond Congress's limited requirements. In 1944, the agency conditioned the exemption from 502(f)(1) on a requirement that proposed labeling would include information concerning "use" submitted in the application process.\textsuperscript{181} The 1960 regulations reiterated that requirement, expressly stating that the new content requirements being imposed via the exemption authority must be reflected in labeling that is "substantially the same as the labeling authorized by the effective new-drug application."\textsuperscript{182}

Thus, under a totality of the circumstances approach, the contours of the statutory and regulatory schemes strongly suggest that the source of the intent to preempt is the agency. Given the significant refinements and additions to the regulatory scheme in Stage


\textsuperscript{178} Supra notes 98-104 and accompanying text.

\textsuperscript{179} See Federal Food, Drug, and Cosmetic Act §§ 102(b)-(d), 505. The 1938 FDCA did provide that a drug would be misbranded if its "label or labeling" failed to conspicuously include any "word, statement, or other information required by or under authority of this Act." See id. § 502(c). This requirement, however, is more limited than a general requirement that labeling conform to the labeling as it existed at the time of the agency's approval of an NDA. It is directed to instances when the FDA may have required some specific wording or statement as part of the overall labeling of the drug.

\textsuperscript{180} See Drug Amendments of 1962, Pub. L. No. 87-781, § 102(c)-(d), 76 Stat. 780, 781-82 (codified as amended at 21 U.S.C. §§ 355(d)-(e)) (noting that the agency may refuse to approve or withdraw approval if labeling is found to be false and misleading).


Two, the agency activity purportedly triggering preemption has been devised predominantly by the agency. The Stage Two FDA regulatory scheme goes far beyond mere "parroting regulations." In making the assessments directed by Congress, the agency is guided predominantly by the detailed requirements and standards devised by the agency. Indeed, it is fair to say that the labeling requirements devised and imposed via the agency's exemption authority were wholly designed by the agency—given that the agency, via the exemption, replaced Congress's standards with its own standards. This part of the totality of the circumstances approach therefore readily points to the agency as the source of the intent to preempt.

D. The Agency's Shifting View: Important Evidence in the Analysis

A totality of the circumstances approach would also allow courts to take into account any other evidence relevant to the question of the source of preemption. Evidence of other important circumstances exists. 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, not congressional intent. For example, 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 and thus should not influence civil tort liability. Similarly, until very recently the majority of lower

183. See supra note 41.

184. Notably, the rigorous scrutiny required by a totality of the circumstances analysis also brings to light considerations important in a traditional preemption analysis, namely, information relevant to congressional intent. Here, nothing in the text of the statutory provisions reveals any intent on the part of Congress to require uniformity in the content or format of prescription drug labeling. Rather, relevant statutory text reveals that Congress was content to allow case-by-case enforcement of its ban on misbranded and false and misleading labeling. Indeed, the history of the HDAs reveals that Congress deliberately acted to preserve case-by-case, adjudicatory enforcement, even as to the important decision of whether particular drugs would be deemed prescription drugs. With prescription drugs, the uses evolve over time, and post-marketing adverse events create an ever-changing safety environment for every drug. Continued application of the misbranding provisions shows that Congress intended that federal law would continue to apply and that a federal agency would continue to monitor the circumstances surrounding the marketing and use of a particular drug. However, there is no indication that Congress intended to preclude additional monitoring by way of state tort law.

185. Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,435-37 (June 26, 1979) (codi-
courts have historically adopted the view that FDA approval of labeling does not warrant preemption of state law.186 These courts generally found that the FDA's labeling decisions in the premarket-approval process imposed only minimum standards, that is, standards that are "open to supplementation";187 or cited to FDA regulations that allow a drug manufacturer to strengthen warnings in a timely manner when new risk information surfaces.188 The courts also rejected the argument that state tort actions are impliedly preempted because they would frustrate the objectives underlying federal law.189

Importantly, in recent cases where courts have used only a traditional preemption analysis, the fact of the agency's shift in view has raised complex issues related to the appropriate level of deference that courts should accord the agency's interpretation of congressional intent.190 In contrast, in conducting a totality of the circumstances analysis for the purpose of identifying the source of the intent to preempt, the issue of the agency's shift does not raise questions of deference. Instead, the agency's shift becomes other important relevant evidence that should be accorded weight in the analysis.

The evidence is important because it strongly reinforces the conclusion flowing from the foregoing historical analysis. That is, the early expressed view of the FDA—and the judicial understanding of the lack of preemptive effect of the FDA's labeling decisions—readily supports the view that the source of the preemption that is now being asserted by the FDA is not actually Congress via the statute. Rather, it is the FDA via the ever-broadening scope of


187. See Caraker, 172 F. Supp. 2d at 1033; see also Hill v. Searle Labs., 884 F.2d 741, 746 (11th Cir. 1986) ("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.").

188. See, e.g., Caraker, 172 F. Supp. 2d at 1033-34.


190. As noted, the analysis of the majority in the Wyeth case also heavily focused on the deference issue. Wyeth, 129 S. Ct. 1187; see supra note 3.
its labeling regulations. 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.\footnote{Notably, the FDA in the 2006 Rule conceded that the statute technically allows a drug manufacturer to add risk information to a label with prior FDA approval; yet, the FDA emphasized that prior consultation occurs "in practice." \textit{See} FDA Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601). 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. \textit{Id.} However, because the statute—and regulatory scheme—clearly allows changes that strengthen warnings, the real conflict is with objectives and activities developed by the agency to serve agency concerns.} As demonstrated in this Article, Congress has provided very little direction to the agency relating to regulation of prescription drug labeling. The agency created and developed the regulatory scheme. The field occupied by FDA regulations has grown, and the scope of the labeling decision has become more comprehensive.\footnote{See Jordan, \textit{The Shimer Analysis}, \textit{supra} note 1, at 107 (making a conclusory observation that is confirmed by the rigorous totality of the circumstances analysis in this Article); see also \textit{supra} Parts II.A-C.}

In the case of the FDA activity, then, the totality of the evidence shows that the agency itself initially considered a decision approving a prescription drug and its labeling as a decision about the minimum risk information that a manufacturer must have available for prescribing physicians. Only over time did the agency's perspective shift as it gradually assumed a more encompassing view of its approval decision. At some point during the late 1990s, the FDA decided that, in fact, the agency intended the approval decision to control the totality of the risk information provided. Given this set of circumstances—and when combined with the historical review that shows that the prescription drug labeling regime has always been predominantly within the agency's control pursuant to the exemption proviso—it is misleading to characterize the preemption as arising from congressional intent. A totality of the circumstances approach, therefore, enables courts to reach a more realistic conclusion about the source of the intent to preempt when preemption is triggered by an agency's regulatory activity.
III. HARD-LOOK REVIEW ENABLES SCRUTINY OF AGENCY AUTHORITY

Using a totality of the circumstances approach and accurately identifying cases of agency preemption are important because the focus of the preemption analysis shifts when the agency is the source of the intent to preempt. As explained, careful analysis of the Shimer line of cases reveals that the Supreme Court's inquiry in agency preemption cases can readily be characterized as a type of hard-look review: a rigorous two-fold inquiry that includes an assessment of (1) the scope of the agency’s rulemaking authority and (2) whether the decision to preempt can be reconciled with congressional intent.193 As to the second prong, the Court in the Shimer line of cases conducted a searching inquiry into the agency’s reasons for disregarding state law and affirmatively ensured consistency with goals legitimately attributed to Congress.194 By opening the door to careful scrutiny of agency authority and judicial review of the agency’s policy decision, courts can more readily safeguard the federalism concerns associated with preemption of state law by federal agency activity.

Again, the case of preemption arising from the FDA’s market approval for prescription drugs provides a good snapshot of how a hard-look review can provide a meaningful check on preemption by federal agencies. Hard-look review requires careful inquiry into the scope of the agency’s authority in relation to the particular agency activity that purportedly preempts state law. In the case of preemption being asserted by the FDA, it would become important to carefully consider the recurring issue highlighted in the foregoing analysis regarding the evolution of the agency’s regulation of prescription drug labeling. The issue is whether a delegation of authority to exempt, via rulemaking, particular drugs from Congress’s requirement of “adequate directions for use” includes the authority to develop a distinct regulatory regime that imposes detailed and comprehensive labeling requirements for exemption. Given the history, the analysis involves two distinct issues: whether the authority itself exists and, if so, what is the scope of that authority. The easier issue involves the scope of the authority.

194. Shimer, 367 U.S. at 382-87.
A. The Scope of the Exemption Authority

As explained, Congress, in section 502(f), specified that drugs are misbranded unless their labeling bears "adequate directions for use" and adequate warnings against use, . . . in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) . . . as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.\textsuperscript{195}

Notably, the text of the proviso does not clearly reveal congressional intent to delegate the authority to develop a comprehensive regulatory scheme. Instead, it suggests that Congress simply envisioned unadorned exemptions for drugs that were sufficiently safe such that directions and warnings were not needed. The agency created an exemption for safe drugs,\textsuperscript{196} but also exempted the class of drugs available to consumers via prescription, and, subsequent to the HDAs, the agency significantly expanded its regulatory control in its Stage Two approach to prescription drug labeling.

The agency's Stage Two approach was challenged. In the case most on point, \textit{United States v. Articles of Drug}, the Fifth Circuit addressed the issue of the agency's authority.\textsuperscript{197} Rucker Pharmacal challenged the agency's view that prescription drugs are misbranded unless they either have "adequate directions" or qualify for a regulatory exemption.\textsuperscript{198} The court's opinion carefully walked through this aspect of the regulatory maze, explaining how the agency's interpretation of section 502(f) as requiring "directions which could be understood for a layman to use a drug safely and for


\textsuperscript{196} See Title 21 Food and Drugs: Food and Drug Administration Promulgation of Regulations Under the Federal Food, Drug, and Cosmetic Act and Repeal of Certain Regulations Heretofor Promulgated Thereunder, 3 Fed. Reg. 3161, 3168 (Dec. 28, 1938) (specifically, subsection (b)(1), providing an exemption for "directions for common uses, adequate directions for which are known by the ordinary individual").

\textsuperscript{197} United States v. Articles of Drugs, 625 F. 2d 665, 670 (5th Cir. 1980). In 1976 the FDA notified Rucker that it had determined that three prescription drugs, which Rucker had been marketing for several years, were "new drugs' for which no New Drug Application (NDA) had been approved." \textit{Id.} at 670. "Rucker refused to cease marketing the drugs," and the FDA brought a seizure and condemnation action against the company, on the ground that the drugs "complied with neither [the] adequate directions for use [requirement], nor an agency-created exemption." \textit{Id.} at 666.

\textsuperscript{198} \textit{Id.} at 671.
its intended purpose" meant that prescription drugs could avoid misbranding only by falling within the scope of a section 502(f) exemption.\textsuperscript{199} The argument thus turned on the issue of the agency's scope of authority.

Rucker made the obvious argument that the text of the proviso suggests that Congress envisioned exemptions only for drugs posing no threat to the public health. The Fifth Circuit agreed that Rucker's interpretation was reasonable; however, the court opined that the agency's view that prescription drugs pose no threat so long as they comply with the terms of the exemption was also reasonable and deferred to the agency's interpretation.\textsuperscript{200} Moreover, the Fifth Circuit, in referring to the exemption proviso, noted that "Congress . . . provided for exemptions on terms to be established by FDA"; and, later in the opinion, that "Congress has authorized the exemptions and delegated to FDA the duty of defining their reach."\textsuperscript{201} Thus, the court essentially read the text of the proviso as a broad delegation of authority to establish terms and conditions that must be satisfied to fall within the exemption.\textsuperscript{202} That view has been reaffirmed in analogous contexts.\textsuperscript{203}

\textsuperscript{199} Id. at 668, 671. The agency's interpretation was issued in FDA regulations promulgated in 1952. Id. at 672 (referring to 21 C.F.R. § 201.5 (1952)). The district court had found that the agency's interpretation, as applied to prescription drugs, was unreasonable because prescription drugs, by definition, could never satisfy the standard. Id. at 671. The Fifth Circuit disagreed, looking to the legislative history of the misbranding provisions and the agency's consistent use of this view of section 502(f). Id. at 672. The appellate court noted that the availability of the exemption rendered the agency's approach reasonable. Id. at 673.

\textsuperscript{200} Id. at 674. Today, a court likely would engage in more analysis before "deferring" to the agency. See infra notes 224-227 and accompanying text.

\textsuperscript{201} Articles of Drugs, 625 F. 2d at 673.

\textsuperscript{202} See, e.g., United States v. 9/1 Kg. Containers, More or Less, of an Article of Drug for Veterinary Use, 854 F.2d 173, 175-76 (7th Cir. 1988) (construing the phrase "necessary for the protection of the public health" as a delegation of authority requiring "the agency to make a judgment about where the public interest lies").

\textsuperscript{203} Courts have viewed the FDA's exemption authority similarly in cases addressing the authority of the FDA to create exemptions pursuant to section 503(a) for "bulk" drugs. See, e.g., Arner Co. v. United States, 142 F.2d 730 (1st Cir. 1944). For example, the First Circuit stated that "[s]ection 503(a) does not state the exemption [but] '[i]t authorizes the formulation of the exemption by regulations. Therefore, unless contrary to law, arbitrary, or unreasonable, the terms of the exemption can be prescribed in the discretion of the administration.'" Id. at 736 (quoting James F. Hoge, \textit{An Appraisal of the New Drug and Cosmetic Legislation From the Viewpoint of Those Industries}, \textit{6 Law & Contemp. Probs.} 111, 116 (1939)); accord United States v. Algon Chem. Inc., 879 F.2d 1154, 1158 (3d Cir. 1989). A similar view was also accepted by the Eighth Circuit in the context of exemptions relating to investigational use of drugs pursuant to section 505(i). See United States v. Garfinkel, 29 F.3d 451, 455-57 (8th Cir. 1994). Thus, courts have readily accepted the view that, in giving the agency the author-
The Fifth Circuit also held that the FDA's requirements for prescription drug labeling, as they existed in 1976, were not arbitrary:

By defining more explicitly the statute's terms and creating applicable regulations, FDA ensures that a physician is able to prescribe drugs safely and efficaciously. The agency's overall scheme reasonably enhances the statutory purpose without contravening any of its provisions. The agency's approach is reasonable, and is not due to be invalidated.204

Thus, if the issue is the scope of the agency's authority or whether the agency's approach to prescription drug labeling has been reasonable, the regulatory scheme imposing requirements will likely be found acceptable. Hard-look review of the agency's preemption decision, however, exceeds these issues. The review must ensure that Congress actually delegated to the agency the authority to promulgate the regulations giving rise to the purported preemption. In the case of preemption by the FDA's regulatory activity, the inquiry must focus on the impact of the HDAs on agency authority.

B. The HDAs and Agency Authority

As the historical analysis explained, the agency construed Congress's enactment of the HDAs as a green light for its more extensive Stage Two regulations.205 However, courts have not addressed this issue directly. In a hard-look review of an agency's preemption decision, it is appropriate to explore whether the text and legislative history of the HDAs shed light on congressional intent relating to the need for agency authority under the section 502(f) exemption proviso, as applied to the new, statutorily recognized class of prescription drugs. Notably, the analysis highlights the extent to which the agency's authority is grounded in inference and acquiescence, which, in turn, has significance in a hard-look review of the agency's preemption decision.

In the HDAs, Congress clearly differentiated between classes of drugs, requiring that certain drugs be available to consumers...
only upon proper prescription, or a refilling thereof. Congress also specified that only prescription drugs could lawfully carry the "cautionary legend," and exempted those drugs from section 502(f)’s labeling requirements upon being “dispensed.” In setting the standard for identifying how to determine which drugs would be deemed prescription drugs, Congress rejected the idea of delegating to the agency the authority to develop an administrative list of prescription drugs, opting instead to preserve a role for industry in making the determination. The issue then is whether Congress, through the HDAs, intended to authorize the agency to develop a distinct and comprehensive scheme of regulation for prescription drug labeling. Or, instead, did Congress eliminate the need for agency authority over prescription drug labeling because the labels were not for consumers, thereby electing to preserve industry’s role by leaving the content of labeling as a matter between the drug industry and prescribing health care practitioners?

On the one hand, the actual text of the HDAs regulates the content of prescription drug labeling. Paragraph (1) of amended subsection 503(b) provides the statutory standards for the new class of drugs and imposes the requirement that these drugs may be dispensed only upon a proper prescription or proper refill of a prescription. Paragraph (2) creates the exemption from section 502(f)’s labeling requirements at the point in time when the prescription drugs are dispensed. Paragraph (4) then provides that:

A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement “Caution: Federal law prohibits dispensing without prescription.” A drug to which paragraph (1) . . . does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

Thus, the text of the HDAs could be construed as establishing the way—the one way—in which a prescription drug could be deemed misbranded before the point of dispensing.

The legislative history lends some support to that interpretation. The Report of the Committee on Labor and Public Welfare

207. Id.; see also supra notes 73-75 and accompanying text.
208. See Humphrey-Durham Amendments § 1(b)(1).
209. Id. § 1(b)(2).
210. Id. § 1(b)(4).
noted that the "bill amends the [FDCA] to deal more directly and realistically with the labeling and dispensing of drugs that may be sold only upon the prescription of licensed practitioners." More specifically, the Report states that "the bill provides a statutory definition of prescription drugs; it expressly forbids their sale without a prescription; it specifies how they are to be labeled both at the time of interstate shipment and at the time of ultimate dispensing; and it prohibits unauthorized refilling of prescriptions for them." 

Thus, the HDAs could be construed as legislatively putting in place—on a selective basis—the scheme previously devised by the agency, and thereby eliminating the need for further agency regulation of prescription drug labeling via the section 502(f) exemption proviso. This construction would make some sense because, at the time of the enactment of the HDAs, although the agency regulated prescription drug labeling via its exemption authority, the agency in its Stage One regulations essentially left issues relating to the content and format of such labeling as a matter between the drug manufacturers and the prescribing physicians. The HDAs then reasonably could be construed as congressional approval of that approach to the matter—similar to Congress's decision to preserve industry's role in deciding whether a particular drug should be deemed a prescription drug.

The agency, however, construed the effect of the HDAs differently, as revealed by its continued and expanded regulation of prescription drug labeling pursuant to its section 502(f) exemption authority. The argument for interpreting the HDAs as not eliminating the agency's 502(f) exemption authority—and in fact expanding it—is one of inference. The key problem that Congress sought to address was the confusion resulting from inconsistent identification of drugs as "prescription only." Thus, the argu-

211. See S. Rep. No. 82-946, at 1 (1951), reprinted in 11 Legislative History, supra note 131, at 664, 664 (1979) (hearings related to the HDAs). As noted in the hearings, "[i]ts provisions are remedial in the sense that they are intended to protect the public from abuses in the sale of potent prescription medicines. They will also relieve retail pharmacists of unnecessary restrictions on the dispensing of drugs that are safe for use without medical supervision." Id. at 666.
212. Id. (emphasis added).
213. Under this construction, the agency would still be empowered to regulate via section 701(a).
215. As a result of the Stage One regulatory scheme, retail druggists were often unable to know, until the question was settled by litigation, whether a particular drug could be sold by prescription only. See id. at 278. If a manufacturer wanted to avoid
ment would go, through the HDAs, Congress addressed that problem with a few targeted requirements—some bearing on labeling—but did not intend to preclude the agency from continuing to regulate the labeling of the newly recognized class of prescription drugs in other ways. The text of the HDAs and the legislative history, however, are silent as to this admittedly plausible congressional intent. The issue then is whether the text of the HDAs and affirmative statements in the legislative history should control—or whether the silence of the text and the legislative history should control, as bolstered over time by later congressional acquiescence to the agency’s extensive regulation.

Only one court has squarely addressed this precise issue, and its analysis was far from a hard-look review. In United States v. Articles of Drugs, the Fifth Circuit upheld this aspect of the agency’s view of its authority.216 As noted, Rucker Pharmacal Co. had challenged the agency’s view that prescription drugs are misbranded unless they qualify for a regulatory exemption.217 Part of Rucker’s argument emphasized that “Congress could not have intended that all prescription drugs would be subject to regulations only vaguely authorized by the statute,” especially in light of the text of the proviso that “suggests that [the] exemptions were anticipated only in the case of drugs . . . posing no threat to the public health.”218 Although agreeing that Rucker’s arguments were reasonable, the court upheld the agency’s interpretation, again largely out of deference to the agency.219 For example, regarding the issue of the existence of the agency’s authority, the court noted that the agency had used its exemption authority to regulate prescription drugs since 1938. Moreover, in amending the FDCA, “Congress did not see fit to eliminate or modify a regulatory scheme which provided for a prescription drug exemption.”220 According to the court, “[A]n agency’s long-standing construction of its statutory

preparing “adequate directions for use,” the manufacturer could decide to make the drug prescription-only through use of the “cautionary legend.” If the druggist thought otherwise, and wanted to sell the drug to a consumer, the druggist was left with the responsibility of preparing “adequate directions for use” for the consumer. Id. at 281.

216. United States v. Articles of Drugs, 625 F.2d 665 (5th Cir. 1980); see supra note 197 and accompanying text.

217. See supra notes 197-204 and accompanying text.

218. Articles of Drugs, 625 F.2d at 673-74. Rucker’s argument, however, was weakened by the assertion that section 502(f) itself still applied to prescription drugs.

219. Id. at 674.

220. Id.
mandate is entitled to great respect, 'especially when Congress has refused to alter the administrative construction.'"\(^{221}\)

Notably, the court's analysis suffers from shortcomings. First, the Fifth Circuit failed to consider the fact that, given the agency's very limited Stage One regulation of the labeling of prescription drugs via the exemption proviso, the text of the HDAs itself codified the essence of the agency regulatory scheme. Codification of agency regulation is in itself a means of eliminating agency regulation. Further, even if such codification should not be construed as eliminating the agency's regulatory scheme, the scheme to which Congress would have acquiesced—at the time of the HDAs—was minimal. The Stage One agency regulations regulated the content of prescription drug labeling in a very limited way. Thus, even if Congress did not intend to preclude agency regulation of prescription drug labeling, nothing in the HDAs shows any congressional intent to expand agency regulation of the content of prescription drug labeling.

Moreover, resolving the issue solely as a matter of deference to the agency's interpretation is inappropriate. In fact, five years after the Fifth Circuit decision, the Supreme Court in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*\(^{222}\) clarified that deference to an agency's interpretation of its enabling statute is appropriate only if that interpretation "does not violate plain meaning and is a reasonable interpretation of silence or ambiguity."\(^{223}\) Stated more traditionally, *Chevron* clarified that a court must first use traditional tools of statutory interpretation to determine whether Congress has spoken to the precise issue. "If the intent of Congress is clear, that is the end of the matter; for the court, as well

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\(^{221}\) Id. (alteration in original) (quoting Bd. of Governors v. First Lincolnwood Corp., 439 U.S. 234, 248 (1978)).


\(^{223}\) Miss. Power & Light Co. v. Miss. ex rel. Moore, 487 U.S. 354, 380 (1988) (Scalia, J., concurring); see also *Chevron*, 467 U.S. 842-45. Notably, some courts have questioned whether an agency's determination of its own jurisdiction is entitled to *Chevron* deference. See, e.g., Bush & Burchett, Inc. v. Reich, 117 F.3d 932, 935-36 (6th Cir. 1997) (noting the controversy surrounding deference to an agency regarding its own jurisdiction, but refusing to decide the question); Otis Elevator Co. v. Sec'y of Labor, 921 F.2d 1285, 1288 (D.C. Cir. 1990) (noting the controversy but refusing to decide the question). Others have ruled that judicial review is *de novo* in such a circumstance. See, e.g., Bolton v. Merit Sys. Protection Bd., 154 F.3d 1313, 1316 (Fed. Cir. 1998); United Energy Servs., Inc. v. Fed. Mine Safety & Health Admin., 35 F.3d 971, 974 (4th Cir. 1994). But see Miss. Power & Light Co., 487 U.S. at 380-81 (Scalia, J., concurring) (listing Supreme Court cases suggesting that the usual rules of deference apply even when an agency is interpreting a statute limiting its authority).
as the agency, must give effect to the unambiguously expressed intent of Congress."\footnote{Chevron, 467 U.S. at 842-43.} Of course, the Supreme Court has revealed, in numerous cases, that what constitutes the "unambiguously expressed intent of Congress" is far from predictable.\footnote{See, e.g., Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs \textit{(SWANCC)}, 531 U.S. 159 (2001) (In the five-to-four split among the Justices, both sides stated that congressional intent was discernable but disagreeing as to what the intent was.); FDA v. Brown \& Williamson Tobacco Corp., 529 U.S. 120 (2000) (same).} Therefore, a proper judicial analysis of the issue would involve greater scrutiny of the text, the legislative history, and the context of the HDAs.

Under this analysis, it seems unlikely that a court today would decide that Congress intended to eliminate all regulation of the labeling of prescription drugs. This conclusion is based in part on a consideration of the structure of the FDCA, and in part on later acquiescence by Congress. First, the text and the legislative history of the HDAs can plausibly be read as reflecting Congress's decision and directive as to which drugs lawfully \textit{could} bear the "cautionary legend"—but as not otherwise addressing the issue of labeling. That is, it is not unreasonable to construe the HDAs as specifying how prescription drugs should be labeled during shipment between states—but only to the extent of the issue of whether it must, or could, bear the cautionary statement. Second, it seems unlikely that Congress intended to eliminate application of all of the mis-branding provisions of section 502. If section 502 remains applicable before dispensing, then subsection 502(f) remains applicable, including the proviso that enables agency regulation via the exemption authority.

Plus, the argument that Congress has acquiesced in the FDA's extensive regulation of prescription drug labeling is stronger today than when the Fifth Circuit addressed the issue due to legislation enacted in 1988, 1997, and 2007. While not as weighty generally as other indicators of congressional intent, the Supreme Court has allowed congressional acquiescence to play a role in deciding questions of agency authority.\footnote{See \textit{Brown \& Williamson Tobacco Corp.}, 529 U.S. 120 (relying on later congressional enactments in identifying Congress's intent as to FDA jurisdiction over cigarettes and smokeless tobacco). \textit{But see SWANCC}, 531 U.S. at 160 (declining to rely on apparent congressional acquiescence to the agency's interpretation of "navigable waters").}

Thus, 1988, 1997, and 2007 legislation becomes relevant. Congress, in 1988, established the FDA as a distinct agency within the
Department of Health and Human Services. In the 1988 legislation, Congress noted that "the public health has been effectively protected by the presence of the [FDA] during the last eighty years," and that "the presence and importance of the [FDA] must be guaranteed."\footnote{See Food and Drug Administration Act of 1988, Pub. L. No. 100-607, § 502, 102 Stat. 3048, 3120 (codified as amended at 21 U.S.C. § 393 Congressional Findings (2000)).} As part of the Modernization Act of 1997, Congress expressly set forth the mission of the FDA as that of "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner."\footnote{See Food & Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 406(a), 111 Stat. 2296, 2369 (codified at 21 U.S.C. § 393).} More recently in 2007, in response to recurring post-approval safety problems, Congress delegated to the agency greater responsibilities related to post-market risk management of drugs with the potential for serious risks—responsibilities that generally would come into play in relation to prescription drugs.\footnote{See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901, 121 Stat. 823, 922 (codified at 21 U.S.C. § 355). Specifically, Congress in 2007 authorized the agency to require post-marketing studies or clinical trials to assess for serious risks associated or potentially associated with the use of a drug, or to require a "risk evaluation and mitigation strategy" (REMS) when necessary to ensure that benefits of a drug outweigh its risks. Further, Congress authorized the FDA to preclude marketing if the responsible entity fails to maintain compliance with the requirements of an approved REMS. \textit{Id.} An REMS at a minimum would require periodic assessments of required studies, clinical trials, or other strategies, such as use of patient package inserts, communication plans to health care providers, or limits on access, such as requiring training for prescribers or monitoring patient use. \textit{Id.}} While none of these later enactments bears directly on FDA approval of prescription drug labeling, they nonetheless can be construed as reflecting Congress's approval of FDA regulation and, in 2007, as reflecting a willingness to expand the scope of the FDA's role—even into the realm of post-marketing relations between manufacturers, prescribing health care providers, and consumers. Thus, it is reasonable to think that courts would conclude that Congress did not intend the HDAs to eliminate agency authority to regulate prescription drug labeling via its exemption authority.

Again, however, it is via hard-look review of agency authority that it becomes evident that congressional support for the precise regulatory activity at issue is a matter of inference and acquiescence. Moreover, it is only via hard-look review of the preemption
decision that courts can take into account the fact that evidence of congressional support may be so limited.

Hard-look review empowers a court to consider the extent to which Congress would sanction an agency's decision to preempt state law. That a delegation of authority to the agency can, at best, only be inferred, may be a sound reason for a court to decline to uphold the agency's decision to preempt. If Congress did not clearly and unequivocally delegate to the agency the authority to regulate in a particular area, it becomes difficult to conclude that Congress would sanction or support preemption of state law. This is particularly true given that Congress intended the overall federal regulatory scheme for drugs to protect consumers, and the state law being preempted is state tort law that serves as a back-up to regulatory failures—and, moreover, when the regulatory scheme preempting state law has been wholly devised by the agency. To the extent that a hard-look review serves the role of a presumption against preemption, understanding that the delegation of authority is a matter of inference and acquiescence becomes important.230

Hard-look review—including rigorous judicial inquiry into the scope of the agency's authority in relation to the particular agency activity that purportedly preempts state law—can provide a meaningful check on preemption by federal agencies.

CONCLUSION

When federal agencies take the position that their regulatory activities preempt state law and point to congressional intent as jus-

230. Additionally, the 2007 legislation, while perhaps showing acquiescence in FDA regulation of prescription drug labeling, arguably cuts the other way on the preemption issue—at least as to the agency's argument prior to 2007. A key impetus for the 2007 legislation was the FDA's lack of authority to require drug manufacturers to take post-marketing safety actions. Key reports highlighted that the agency rarely used its authority to withdraw marketing approval and often was limited to negotiating with drug sponsors in developing remedies to potential safety concerns. In the 2007 legislation, Congress gave the agency some additional post-marketing tools. However, although the agency has the authority to "require" and "approve" an REMS, the process leading to an approved REMS still involves "negotiation" with drug sponsors. See id. Given the limited ability for the agency to compel drug manufacturers to change their labels post-approval prior to 2007—and thus the limited ability to ensure consumer safety via the regulatory process—it becomes difficult to conclude that, before 2007, Congress would have sanctioned the agency's decision to preempt state tort law as a remedy. If that is the case, the arguments developed by the agency beginning in 2000 and culminating in the 2006 Rule were lacking a sound basis. However, it is perhaps less difficult since 2007 to conclude that Congress would sanction a decision to preempt state tort remedies.
tification of the preemption, courts and litigants should not simply follow the agency's lead. Because properly identifying the source of the intent to preempt is crucial, courts and litigants should instead carefully analyze the entirety of the circumstances. A totality of the circumstances analysis may point to the agency—rather than Congress—as the source of the intent to preempt. Properly identifying cases of agency preemption would then open the door to an appropriate level of judicial review, including judicial scrutiny of both the agency's authority and of the policy decision itself.