Federal Pre-emption: Time to Reestablish an Old Doctrine

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Abstract

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KEYWORDS: pre-emption, doctrine, federal
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TABLE OF CONTENTS

I. Federal Pre-emption
   A. Importance of Pre-emption
   B. Execution of the Doctrine
   C. History of the Doctrine
   D. Modern Trend
II. Pre-emption in the 1980's
   A. Insecticide Labeling
   B. Cigarette Labeling
   C. Diphtheria, Tetanus and Pertussis Litigation
      1. History of DTP Litigation
      2. Recent Developments
III. Conclusion

I. Federal Pre-emption

State tort claims have traditionally been decided in state courts using state law and without federal interference. For the past fifty years, however, the federal government has played a significant role in shaping the outcome of state common law actions. Federal intrusion on state law has taken the form of an increased federal role in regulating various products, activities and most importantly, the growth, development and implementation of the doctrine of federal pre-emption. The significance of the doctrine has radically altered a state's authority to compensate injured plaintiffs. Today, the doctrine can bar tort remedies by displacing state law with the invocation of the doctrine. This essay focuses on the development of the doctrine and analyzes its current relationship to state tort law. It will also explore the various industries affected by the doctrine, and explain its inconsistent interpretation, but only after a thorough analysis of the doctrine itself.

Pre-emption occurs when a state power interferes with a correlating federal power. In fact, it has long been the view that when a state power interferes with a similar federal power, the federal power
prevails. Federal law is the 'supreme law of the land' and is constitutionally protected by the doctrine of pre-emption. Although no simple definition can be given, it basically relates to an area of the law where conflicts of interest arise between state and federal spheres of power. The Supreme Court defined it as a field in which certain matters are of such national, opposed to local, character that federal laws pre-empt or take precedence over state laws. The doctrine arises from the supremacy clause of the Constitution, and is utilized in a number of ways.

Its origin and application date back to the developing years following Independence. In the early nineteenth century, the Supreme Court first interpreted the rule by declaring a state statute inferior to a correlating federal statute. It was the first time the Supreme Court preempted a state law vis-a-vis the supremacy clause. Chief Justice Marshall set forth the pre-emption doctrine:

The nullity of any act, inconsistent with the constitution, is produced by the declaration, that the Constitution is the supreme law. The appropriate application of that part of the clause which confers the same supremacy on laws and treaties, is to such acts of the State Legislatures as do not transcend their powers, but, though enacted in the execution of acknowledged State powers, interfere with, or are contrary to the laws of Congress, made in pursuance of the constitution, or some treaty made under the authority of the United States. In every such case, the act of Congress, or the treaty, is supreme; and the law of the State, though enacted in the exercise of powers not controverted, must yield to it.

Thus, from 1824 onward, the pre-emption doctrine protected Congressional and administrative acts in furtherance of the federal power by displacing state laws which have encroached on the dominant role of the federal government. Over the last one hundred and sixty four years, courts expanded and clarified the pre-emption question with respect to whether federal law can pre-empt state action.

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1. 2 AM. JUR. 2D, Administrative Law, § 212.
2. BLACK’S LAW DICTIONARY 1060 (5th ed. 1979).
3. "The constitution and the laws of the United States which shall be made in pursuance thereof . . . shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the laws of any state to the contrary notwithstanding." U.S. CONST. art. VI cl. 2.
5. Id. at 210-11.
7. Id. at 144. See also Defendants’ Brief in Support of Motion for Summary Judgment at 8, White v. Wyeth Laboratories, No. 71229 (D. Ohio 1986) (quoting Cooley v. Board of Wardens, 53 U.S. (12 How.) 299, 319 (1851)): “[W]hatever subjects of this power . . . are in their nature national, or admit only of one uniform system, or plan of regulation, may justly be said to be of such a nature as to require exclusive legislation by Congress”).
8. Graves v. Walton County Bd. of Educ., 300 F. Supp. 188, 193 (M.D. Ga. 1968), aff’d, 410 F.2d 1153 (5th Cir. 1969) (the court noted that the pre-emption
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B. Execution of the Doctrine

The doctrine's invocation can be divided to either express pre-emption or some form of judicial implication. The judicial analysis is relatively simple where the area in question is expressly pre-empted; it becomes more complicated, however, where Congress is silent. In Michigan Canners and Freezers Association v. Agricultural Marketing and Bargaining Board, the court summarized the practical application of the doctrine:

Federal law may pre-empt state law in any of three ways. First, in enacting the federal law, Congress may explicitly define the extent to which it intends to pre-empt state law. . . . Second, even in the absence of express pre-emptive language, Congress may indicate an intent to occupy an entire field of regulation, in which case the States must leave all regulatory activity in that area to the Federal Government. . . . Finally, if Congress has not displaced state regulation entirely, it may nonetheless pre-empt state law to the extent that the state law actually conflicts with federal law. Such a conflict arises when compliance with both state and federal law is impossible, . . . or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Express pre-emption is usually clear-cut, but to imply it is a more formidable task. For example, if federal law explicitly provides that the

doctrine was a keystone in the United States federalist system of government).

12. Id. at 469 (citations omitted).

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state are prohibited from regulating in any way, the subject of that law, then unquestionably, the state law must yield. To determine whether to impliedly invoke the doctrine, however, courts must follow this analysis: (1) if Congress evidences an intent to occupy a given field, any state law falling within that field is pre-empted; or (2) if Congress has not entirely displaced state regulation over the matter, state law is still pre-empted to the extent it actually conflicts with federal law, or (3) where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress, the state law is pre-empted. Either vehicle of invocation, however, provides courts the opportunity to stand behind federalism by reasonably accepting the argument that the two laws are not incompatible.

Since no method is applicable in all scenarios, courts have used a case-by-case application. This ad hoc approach to constitutional interpretation is what many courts are presently confronted with even though the Supreme Court has neatly carved out almost all details of its application.

Regardless of the method of invocation, state law is displaced by the correlative federal law. Courts will use the doctrine to pre-empt state laws which include not only legislative enactments, but also the rules established by their respective judiciaries. In addition, the Supreme Court has upheld the equality in the pre-emption analysis of state statutes, state judicial actions, state civil suits and common law tort relief. The effect of these interpretations provides no real distinction since injured plaintiffs, nonetheless, are barred state remedies by the swift invocation of the doctrine.
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1334 Nova Law Review [Vol. 12]

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16. See supra ¶ D.
19. Id.
20. Id.
C. History of the Doctrine

The courts have vacillated in their interpretation of the pre-emption doctrine since its embodiment in the Constitution. During the nineteenth and early twentieth centuries, the doctrine entirely precluded states from regulating in areas already the subject of Congressional action. In Charleston & Western Carolina Railway Co. v. Varnville Furniture Co., the Supreme Court found that where Congress had regulated in a given field, the states were prevented entirely from playing any kind of role in the same area. Justice Holmes, speaking for the court, concluded that "the very exercise of federal power inherently excluded concurrent regulation by the states even where the operation of the state statute was entirely compatible with the federal scheme."20 Generally, this rule resulted in the displacement of any state law if Congress touched upon it in some way. However, a dramatic turnaround occurred during the 1930's. A disturbed Supreme Court abandoned the once settled rule of allowing courts to find pre-emption in all situations.21 Instead, Congress became the more likely forum to decide which areas would be subject to pre-emption. This change in atmosphere can partly be associated with the expanding role of the federal government during this era. Implied pre-emption became the focal point of pre-emption analysis as more and more state laws occupied the same subjects as federal law. The Supreme Court would not implicitly find an area pre-empted by federal law solely because Congress had regulated the area.22 Instead, pre-emption was found only where Congress "clearly indicated"23 or "definitely expressed"24 a desire to displace state law.25 More and more state laws were upheld26 as the court played a less active role in deciding which areas the federal government intended to occupy.27

Under this "state-directed" approach,28 so labeled because it loosened the grip of the federal government on the states, the invocation of the doctrine required a clear or definite sign that Congress intended to solely regulate the areas in question. Still, however, an actual clash between state and federal regulations invoked the doctrine, though this is an area of little debate.29

The trend of case law during this period was not without its problems. For example, the "state-directed approach" upheld most state laws since Congress rarely occupied an entire field. Since most federal laws occupied only bits and pieces of an entire scheme, the federal law was without effect on the correlative state laws.30 In addition, since federal legislation was drafted on an ad hoc basis intended to accomplish limited objectives, Congress was unable to foresee or predict a pre-emption dilemma.31 This restrained approach to federalism appeared only to serve the best interests of the states since each state could inconsistently create its own rules, regulations, and laws different from the federal government. A problem of this judicial era was the lack of uniform or consistent laws in areas of public importance.

Moreover, this period of judicial solace in the pre-emption analysis provided no substantive guidelines by which the courts could decide

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20. Id.
23. Id. at 304.
26. Id. at 598.
27. Id. of Comment, Pre-emption as a Preferential Ground: A New Canon of Construction, 112 Stan. L. Rev. 208 (1959).
28. See id. of Comment, supra note 27.
29. Id. at 626.
30. Id. at 627 n.29.
31. Id. at 632 n.29.
32. Id. ("Federal law is generally interstitial in nature. It rarely occupies a legal field completely . . . . Federal legislation, on the whole, has been conceived and drafted on an ad hoc basis to accomplish limited objectives.") (quoting P. Bator, P. Mitlem, E. Shapiro & H. Wechsler, The Federal Courts and the Federal System 470-71 (2d ed. 1973)).
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21. Id. at 604.

23. Id. at 627 n.29.
24. Id. (citing Mazer v. Hamilton, 309 U.S. 598, 614 (1940)).
25. Id. (citing H.P. Welsh Co. v. New Hampshire, 306 U.S. 79, 85 (1939)).
26. Id. at 613.
27. Id. at 613.
28. Id. at 627 n.29.
29. Id. ("Federal law is generally interstitial in nature. It rarely occupies a legal field completely. . . . Federal legislation, on the whole, has been conceived and drafted on an ad hoc basis to accomplish limited objectives.").
pre-emption problems. Since the cases from this "state-directed" period left the court with an ad hoc approach to resolving pre-emption defenses, the time was ripe for a conclusive Supreme Court decision.

The 1941 decision of Hines v. Davidowitz provided the solution. There, the Supreme Court abruptly changed the rules of construction in pre-emption cases by pre-empting a state law which shared a field occupied by federal law. What distinguished this opinion was the court's presumption in favor of Congress' pre-emptive capabilities as opposed to the "state-directed" approach which presumed Congress did not intend to occupy a field absent specific desire to displace state law. The Court so found because the statute in question "st[ood] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Hines involved a Pennsylvania statute which provided more stringent criminal sanctions than a similar federal statute for aliens not carrying their identification cards. Justice Black, delivering the opinion of the court, stated that both the state and federal registration laws belong to that class of laws which concerns the exterior relation of this whole nation with other nations and governments... and no intimately blended and intertwined with responsibilities of the national government that where it acts and state also acts on the same subject, the act of Congress... is supreme; and the law of the state, though enacted in the exercise of powers not controverted, must yield to it."

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1338

Nova Law Review, Vol. 12, Iss. 3 [1988], Art. 17

https://nsuworks.nova.edu/nlr/vol12/iss3/17

Federal Pre-emption

1339

Every act of Congress... a number of factors must be considered in deciding whether the federal law or correlative state law must yield. These factors included whether the two laws conflicted, were contrary, occupied the field, were repugnant, different, irreconcilable, inconsistent, or violative, or involved curtailment or interference. Instead of relying on this set of criteria, the court concluded that the Pennsylvania statute was inferior to the federal act since it stood "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." It was also the first time the court confronted the pre-emptive issue in the context other than from a commerce clause question.

What differentiated Hines from its predecessors was that the doctrine was invoked in an instance where Congress, although silent as to the state's role in alien registration, impliedly intended to occupy the entire field of registration. The Court came to this conclusion since Congress intended to preclude enforcement of state laws on the same subject. To determine congressional intent, the court looked to "the nature of the power exerted... the object sought to be attained, and the character of the obligations imposed by the law." It was clear that the definite or clear intent to occupy was thus abandoned. However, notwithstanding an actual conflict of laws or an expressed intent to pre-empt, the court put its full faith in Congress that they must have intended to occupy the field. Thus, the "state-directed" approach which validated virtually all concurrent state laws during the 1930's was replaced by a more lenient 'intent to occupy' requirement.

43. For when the question is whether a Federal act overrides a state law, the entire scheme of the statute must, of course, be considered, and that which needs must be implied is of no less force than that which is expressed. If the purpose of the act cannot otherwise be accomplished—the state law must yield to the regulation of Congress within the sphere of its delegated power.
44. Hines, 312 U.S. at 70.
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33. Id. at 627.
34. 312 U.S. 52 (1941).
35. Note, supra note 22, at 630.
37. Id. at 59-60.
38. Id. at 66 (quoting Henderson v. Mayor of New York, 92 U.S. 259 (1873)).
39. Id. (quoting Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 211 (1824)). See also id. at 17 (quoting Charleston & W. Carolina Ry. Co. v. Varnville Furniture Co., 237 U.S. 597 (1915)). *Cf.* People v. Compagnie Generale Transatlantique, 197 U.S. 59 (1882), where the court, speaking of a state law and a federal law dealing with the same type of control over aliens, said that the federal law "covers the same ground as the New York statute, and they cannot coexist."
Hines also was significant because it relaxed the once rigorous intent requirements. Although not purely a classical pre-emption case since the subject matter involved foreign affairs traditionally reserved to the federal government, it nevertheless radically changed the manner in which courts would interpret Congressional intent by weakening the previously stringent intent requirements for the “occupation” analysis. If the state statute stood as an obstacle to the full purposes and objectives of Congress, then it would be pre-empted, even without an actual conflict or express pre-emption provision in the Act.45

The 1940's were indeed a time of change for the application of the pre-emption doctrine. Although in 1941 Hines reversed the strict standard requiring a clear intention to occupy a field, a more formal breakdown of the once rigid occupation analysis was needed since Hines, as stated, was not a pure pre-emption problem.46 Its application to the state's general police powers, however, remained a burning question.47

The Supreme Court responded to this issue in the 1942 decision of Cloverleaf Butter Co. v. Patterson,48 where the Court for the first time invalidated a state law based on the state's general police powers. The state law in question occupied the same area regulated by the Internal Revenue Code, but was nevertheless struck down by the Congressional scheme.49 The Court stated that a “clear implication” of intent was sufficient to pre-empt state law since obviously Congress did not intend to occupy a small bit of the area, but rather to occupy the entire area.50 Accordingly, the court finally expanded the scope of the pre-emption doctrine by applying it to the state's police powers which traditionally had been left to state control.51

Six years later, the Court further expanded the doctrine set forth

in Hines and Cloverleaf, in Rice v. Santa Fe Elevator Corp.,52 a landmark decision in the pre-emption analysis. Its importance was that it clarified the ambiguities in the “intent to occupy” analysis left unresolved by the Cloverleaf and Hines decisions. To “occupy a field,” the Court listed certain factors which would help the courts determine whether Congress did intend to occupy a field and prevent the states from also participating.

The scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it . . . Or the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of State laws on the same subject . . . Likewise, the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose . . . Or the Policy may produce a result inconsistent with the objective of the federal statute.

No longer would the courts decide intent to occupy challenges on an ad hoc basis; rather a more definite set of rules had finally emerged. “Whether the matter on which the state asserts the right to act in any way regulated by the Federal Act became the new standard.

These decisions of the Supreme Court in the 1940's clearly changed the path of the once predominant “state-directed” approach which usually upheld state laws. An activist court emerged which did not hesitate to imply Congressional “intent to occupy” even without the words themselves.54 Clearly, “Congress can act so unequivocally as to make clear that it intends no [state] regulation except its own.”55 The Court reasoned that since Congress could not possibly foresee all possible ramifications of its enactments, a policy of interpreting its intentions by impliedly finding an intent to regulate these areas was actually meant.56

The demise of the “state-directed” approach was further facili-

45. See Note, supra note 22, at 631.
46. Id.
47. The Hines decision involved a foreign affairs conflict which is always held in favor of the federal government.
49. 315 U.S. 148 (1942).
50. Id. at 150-51 (1942).
51. Id. at 157.
tatuated by the expansion of the federal government following World War Two. This period evidenced a need for more complicated laws and regulations to control the expanding economy. Congress responded by creating new agencies and regulatory branches to carry out this arduous task. These new additions to the federal government added limitless dimensions to the pre-emption aura. During the 1950s, the court addressed these problems. In particular, it confronted the question of whether the regulations promulgated by the new federal agencies would act in the same fashion as federal statutes in regard to Congressional "intent to occupy." The issue now centered around whether the new federal agency regulatory policies could pre-empt state laws. Two decisions from this period help clarify this issue.

In *Farmers Educational & Cooperative Union of America v. WDAY, Inc.*, and *San Diego Building Trades Council v. Garmon*, the Court affirmatively addressed this issue. In *Garmon*, the Court decided that the rules promulgated by the National Labor Relations Board had the same pre-emptive effect as if Congress had itself enacted a statute. Any state legislative or judicial actions which overlapped the policies of the NLRB were impliedly pre-empted according to the rules set forth in the earlier cases. The Supreme Court stated that Congress did not merely lay down a substantive rule of law to be enforced by any tribunal competent to apply law generally to the parties. It went on to confide primary interpretation and application of its rules to a specific and specially constituted tribunal and prescribed a particular procedure for investigation, complaint and notice, and hearing and decision. Congress evidently considered that centralized administration of specially designed procedures was necessary to obtain uniform application of its substantive rules and to avoid these diversities and conflicts likely to result from a variety of local procedures and attitudes.

Thus, the *Garmon* court enlarged the scope of the federal government's pre-emptive powers by expanding binding federal law to include administrative law.

It was clear that the scope of the federal government's pre-emptive power was broadly expanded by these two decisions. The Court would not only enforce the expressed intention of Congress and its implied 'intent to occupy,' but would also do the same for any of the newly created federal agencies. The reasoning was basically simple: "to avoid the endless delays that have tended to paralyze adjudicatory hearings and render them ineffective as a means of utilizing agency expertise." Besides changing the presumption in occupation-of-the-field decisions, the cases following *Rice* and *Hines* also changed the interpretation of "actual conflict" cases. Previously, for an actual conflict of laws to pre-empt state law, the federal law had to actually clash with the law of the state. After *Hines* and *Rice*, however, a perceived conflict of laws was sufficient to act as a bar. In *Pennsylvania v. Nelson*, for example, the court upheld a pre-emption defense reasoning that the "possibility of inconsistent judicial results due to the multitude of courts was sufficient to act as an express conflict." The Supreme Court in the 1960's once again expanded the pre-emption doctrine. In *Florida Lime and Avocado Growers, Inc. v. Paul*, the court examined the issue of whether "the coexistence of federal and state regulatory legislation should depend upon whether the purposes of the two laws are parallel or divergent." The case involved an action by a group of Florida farmers seeking to enjoin a California statute which gauged avocado maturity by oil content rather than the federal certification process. The court decided that the federal regulation should not pre-empt the state regulatory power unless either a persuasive reason existed; the subject matter permitted no other conclusion; or that Congress has unmistakably so ordained. The court held, however, that the record did not demonstrate a "collision between the two schemes of regulation despite the dissimilarity of the standards." The test of whether both federal and state regulations may operate, or

68. Note, supra note 22, at 636 (citing 350 U.S. 497 (1956)).
70. Id. at 142.
71. Id. at 133-34.
72. Id. at 142.
73. Id. at 143.
tated by the expansion of the federal government following World War Two. This period evidenced a need for more complicated laws and regulations to control the expanding economy. Congress responded by creating new agencies and regulatory branches to carry out this arduous task.66 These new additions to the federal government added limitless dimensions to the pre-emption aura. During the 1950’s, the court addressed these problems. In particular, it confronted the question of whether the regulations promulgated by the new federal agencies would act in the same fashion as federal statutes in regard to Congressional “intent to occupy.” The issue now centered around whether the new federal agency regulatory policies could pre-empt state laws. Two decisions from this period help clarify this issue.

In Farmers Educational & Cooperative Union of America v. WDAY, Inc.,67 and San Diego Building Trades Council v. Garmon,68 the Court affirmatively addressed this issue.69 In Garmon, the Court decided that the rules promulgated by the National Labor Relations Board had the same pre-emptive effect as if Congress had itself enacted a statute.69 Any state legislative or judicial actions which overlapped the policies of the NLRA were impliedly pre-empted according to the rules set forth in the earlier cases.70 The Supreme Court stated that Congress did not merely lay down a substantive rule of law to be enforced by any tribunal competent to apply law generally to the parties. It went on to confide primary interpretation and application of its rules to a specific and specially constituted tribunal and prescribed a particular procedure for investigation, complaint and notice; and hearing and decision.70 Congress evidently considered that centralized administration of specially designed procedures was necessary to obtain uniform application of its substantive rules and to avoid these diversities and conflicts likely to result from a variety of local procedures and activities.71

Thus, the Garmon court enlarged the scope of the federal government’s pre-emptive powers by expanding binding federal law to include administrative law.

It was clear that the scope of the federal government’s pre-emptive power was broadly expanded by these two decisions. The Court would not only enforce the expressed intention of Congress and its implied ‘intent to occupy,’ but would also do the same for any of the newly created federal agencies. The reasoning was basically simple: “to avoid the endless delays that have tended to paralyze adjudicatory hearings and render them ineffective as a means of utilizing agency expertise.”

Besides changing the presumption in occupation-of-the-field decisions, the cases following Rice and Hines also changed the interpretation of “actual conflict” cases. Previously, for an actual conflict of laws to pre-empt state law, the federal law had to actually clash with the law of the state. After Rice and Hines, however, a perceived conflict of laws was sufficient to act as a bar. In Pennsylvania v. Nelson,72 for example, the court upheld a pre-emption defense reasoning that the “possibility of inconsistent judicial results due to the multitude of courts was sufficient to act as an express conflict.”

The Supreme Court in the 1960’s once again expanded the pre-emption doctrine. In Florida Lime and Avocado Growers, Inc. v. Paul,73 the court examined the issue of whether “the coexistence of federal and state regulatory legislation should depend upon whether the purposes of the two laws are parallel or divergent.” The case involved an action by a group of Florida farmers seeking to enjoin a California statute which gauged avocado maturity by oil content rather than the federal certification process.74 The court decided that the federal regulation should not pre-empt the state regulatory power unless either a persuasive reason exist; the subject matter permitted no other conclusion; or the Congress has unmistakably so ordained.75 The court held, however, that the record did not demonstrate a “collision between the two schemes of regulation despite the dissimilarity of the standards.”76 In addition, the court amplified the previous pre-emption analysis.

“The test of whether both federal and state regulations may operate, or

68. Note, supra note 22, at 636 (citing 350 U.S. 497 (1956)).
70. Id. at 142.
71. Id. at 133-34.
72. Id. at 142.
73. Id. at 143.
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the state regulation must give way, is whether both regulations can be enforced without impairing the federal superintendence of the field, or whether they are aimed at similar or different objectives."

Thus, by tracing the foregoing cases, the "roots and contemporary developments" of the modern evolution of the doctrine can be more fully understood. Since the pre-emption analysis formulated during this period substantially impacts the outcome of present tort actions, the modern application of the doctrine would be meaningless without this discussion. Moreover, many current state common law actions stand or fall on the rationale presented. A problem has arisen, however, in that today's judiciary have failed to uniformly invoke the doctrine as its pre-cedence dictates. The remainder of this essay will specifically focus on the modern state of the doctrine as it relates to a select group of tort areas.

D. Modern Trend

Modern courts have followed the same principles developed since the 1930's in determining in which situations the doctrine would apply. While the remainder of this article discusses the modern application of the doctrine, the reader should focus on its inconsistent effect on state tort law.

Where Congress expressly states that federal law will be supreme over state law, the courts will adhere to congressional intent by displacing correlative state laws. In Jones v. Rath Packing Co., the Court held that the enforcement of a California statute would prevent "the accomplishment and execution of the full purposes and objectives of Congress" since the federal statute expressly pre-empted state interference. The Court also noted that Congress was acting well within the authority granted it by the constitution to solely regulate a field by expressly prohibiting the states from also regulating the same subject.

The federal act stated that no state could provide laws which are less stringent than or require information different from the require-

74. Id. at 142.
75. Note, supra note 22, at 624.
76. Id. at 639.


81. Jones, 430 U.S. at 539.
82. Id. at 539.
83. It is the express intent of Congress to supersede any and all laws of the States or political subdivisions thereof as they may now or hereafter provide for the labeling of the packages of any consumer commodity covered by this chapter which are less stringent than or require information different from the requirements of section 1463 of this title or regulations promulgated pursuant thereto.
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74. Id. at 142.
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77. Modern courts have pre-empted common law claims in many areas. See e.g.,
lation of abandonment of service preempts state tort claims); Old Dominion Brac-
(NLRA preempts certain state libel claims); Sears, Roebuck & Co. v. Stiffel, 376 U.S.
225, 229-33 (1964) (federal patent and copyright laws preempt state actions for unfair
competition, at least in part); Cipollone v. Liggett Group, Inc., 539 F. Supp. 1146,
(Natural Gas Act preempts calculation of damages under state common law of con-
tract), rev'd 789 F.2d 181 (5th Cir. 1986), cert. denied, 107 S. Ct. 907 (1987); Hedges v.
Atkinson, Topps & Santa Fe Railway Co., 728 F.2d 414, 416-17 (10th Cir. 1984)
(Railway Labor Act preempts state common law claims for wrongful discharge);
1983) (Copyright Act preempts state common law claims for conversion and inter-
ference with contract); Howard v. Unioil, 719 F.2d 1552 (11th Cir. 1983) (Rehabilita-
tion Act of 1973 preempts state contract claims); Vistacor Corp. v. Fleming Companies, Inc.,
state actions for wrongful discharge and intentional infliction of emotional distress aris-
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694 (9th Cir. 1978) (NLRA preempts state claims of defamation and business disrup-
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1972) (National Emissions Standard Act preempts state products liability based upon
1984) (ERISA preempts state tort claim for bad faith handling of benefits claim);
Shaw v. International Ass'n of Machinists & Aerospace Workers Pension Fund, 563 F.
Supp. 653, 658-59 (C.D. Cal. 1983) (ERISA preempts certain state common law
claims for breach of contract), citing Lafferty v. Solar Turbines International, 666 F.
1983) (Petroleum Marketing Practices Act preempts conflicting state common law
claims), citing e.g., Meyer v. Amsden Hess Corp., 541 F. Supp. 321, 322 (D. N.J.
1982) (same); Vodotrenco, Inc. v. Bend Electronics, 564 F. Supp. 1471, 1476-77 (D.
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and trade secret violations); Delco v. United Parcel Service, Inc., 580 F. Supp. 1572
(ERISA and NLRA preempt state common law claim for wrongful discharge);
(Railway Labor Act preempts state law claims for emotional distress and intentional
interference with contractual relations); State of North Dakota v. Merchants National
and Trust Co., 466 F. Supp. 953 (D. N.D. 1979) (federal banking laws preempt
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79. Id. at 343.
82. Jones, 430 U.S. at 339.
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ments of the federal act.** It should be noted that Congress has the constitutional authority to unequivocally and expressly enact a statute which prohibits the individual states from supplementing or regulating in any way the express provisions of the federal statute.** Thus, if the federal scheme provides explicitly against any state regulatory intermeddling, the courts will adhere to federal intent by displacing con
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government has the power to positively and expressly pre-empt state
infringement on areas of federal concern.**
Recent case law also reveals that the federal courts will implicitly
find pre-emption using the principles set forth by Hines and Rice. In
Pacific Gas & Electric Co. v. State Energy Resources Conservation &
Development Commission,** the United States Supreme Court, al-
though not finding pre-emption on the facts, noted how the doctrine is
impliedly executed:
Congress' intent to supersede state law altogether may be found from
a "scheme of federal regulation . . . so pervasive as to make
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gations imposed by it may reveal the same purpose."** Even
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conflicts with federal law. Such a conflict arises when "compliance
with both federal and state law is a physical impossibility," . . . or
where state law "stands as an obstacle to the accomplishment and
execution of the full purposes and objectives of Congress."**

Clearly, this method takes into consideration the detailed analysis ar-
ticulated in the earlier decisions since the court directly cited to Rice.

83. Id.
84. Accord Shaw v. Delta Airlines, 463 U.S. 85 (1983) (federal statute may pre-
empt state law, but the extent of the "express" pre-emption may be questioned to
determine whether the state law at issue falls within the category of laws that are pre-
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85. 350 U.S. 497, 509 (1956).
86. See Jones, 430 U.S. at 519.
88. Id. at 203-04. (Citations omitted).

Florida Lime, and Hines.** A more thorough discussion of implied pre-
emption, however, will be discussed further along in this essay as it
relates to the prohibitive effect it has on state tort remedies in federally
regulated areas.

II. Pre-emption in the 1980's
The doctrine has undergone a metamorphosis during the past deca-
ade. Recent federal cases have erased years of pre-emption case law
by allowing state tort awards in federally pre-empted areas.** The most
notable is Silkwood v. Kerr-McGee.** There, the Court upheld a ten
million dollar state tort award against the operators of a nuclear facili-
ity, despite acknowledging the fact that the nuclear energy industry was
completely governed by federal law.** Silkwood is noteworthy because
of its use and misuse as precedent in later cases dealing with pre-
emption of state tort awards.

The Silkwood Court decided that, although the Atomic Energy
Act of 1954** provides the federal government with exclusive control
over the regulation, construction and operation of nuclear facilities,
state tort awards are not inconsistent with the act.** The court ruled
unequivocally in favor of common law relief even though the states
were entirely prohibited from regulating the safety aspects of nuclear
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ern States Power Co. v. Minnesota, 447 F.2d 1143 (8th Cir. 1971), aff'd, 405 U.S.
1035 (1972); KVUE, Inc. v. Austin Broadcasting Corp., 709 F.2d 922 (5th Cir. 1983),
aff'd sub nom., Texas v. KVUE, Inc., 465 U.S. 1092 (1984); Cosmetic, Toilettry and
aff'd, 575 F.2d 1256 (8th Cir. 1978).
90. See generally Comment, Silkwood v. Kerr-McGee Corp., 6 J. ENERGY L. &
POL'y 281 (1985) [hereinafter Comment, Silkwood]; Comment, Parameters of Pre-
emption, 6 U. BRIDGEPORT L. REV. 123 (1985) [hereinafter Comment, Parameters];
Comment, Silkwood v. Kerr-McGee Corp., 60 CCH FEDERAL L. REP. 360 (1980) [herein-
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Law-Federal Pre-emption, 10 J. MARSHALL L. REV. 360 (1985) [hereinafter Comment,
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92. Id. See also Pacific Gas & Elec. Co. v. State Energy Resources Conservation
94. Silkwood, 464 U.S. at 249.
95. Id. at 250.

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the States' inability to formulate effective standards [in the industry]."96 What this did was erase the voluminous case law which had evolved regarding pre-emption and state tort recoveries.

In addition, the court even acknowledged the general rules of implied pre-emption by citing directly to Hines, Rice, and Florida Lime; yet it failed to invoke the doctrine.97 The majority also stated that Congress silently intended to allow state law remedies to those suffering injuries in nuclear power plants.98 This rationale, however, quickly eroded prior case law which had evolved regarding pre-emption and common-law recoveries.

Indeed, Justice Blackmun articulated this point in his dissent.99 Once one result of a punitive damage award in a tort case is to regulate safety in the nuclear industry,100 a state damage award in a pre-empted area is intolerable.101 "The conduct that the jury's punitive damages sought to regulate was the day-to-day safety procedures of nuclear licensees,"102 which is unquestionably pre-empted.103 In addition, since punitive damage awards are regulatory in nature and it is well settled that State tort awards regulate in the same fashion as State statutes,104 they are prohibited in areas pre-empted by federal law.105

96. Id.
97. Id. at 248.
98. Id. at 251.
99. Id. at 258.
100. Id. at 263 (Blackmun, J., dissenting).
101. Id. at 260-61.
102. Punitive damages are "private fines levied by civil juries."..."Deterrence of future egregious conduct is a primary purpose.... punitive damages."..."The basis for allowance of punitive damages rests upon the principle that they are allowed as a punishment of the offender for the general benefit of society, both as a restraint upon the transgressor and as a warning and example to deter the commission of like offenses in the future.... The authority for a State to do so [allow punitive damages] is precisely what the Court held to be pre-empted in Pacific Gas.
103. Id. at 261 (citing Pacific Gas, 461 U.S. at 212).
105. Silkwood, 464 U.S. at 259, 260 (Blackmun, J., dissenting) (Federal pre-emption of nuclear safety is full and complete).

State safety regulation is not pre-empted only when it conflicts with federal law. Rather, the Federal Government has occupied the entire field of nuclear safety concerns, except the limited powers expressly ceded to the States. When the Federal Government completely occupies a given field or an identifiable portion of it, as it has done here, the test of pre-emption is

1988]   Federal Pre-emption  1349

Blackmun also thought the majority had obscured the pre-emption analysis by deciding that because Congress did not expressly make statutory reference to those injured, it silently authorized state remedies to those injured.106 Thus, according to Blackmun, "[t]he Court...tortures its earlier decisions and, more importantly, wreaks havoc with regulatory structure that Congress carefully created."107

Justice Powell also dissented, but on different grounds. He argued that it would be improper to allow State juries to award punitive damages where no violations at the nuclear facility were found by the Nuclear Regulatory Commission.108 Also, since "[t]here is no express authorization in federal law of the authority the Court today finds in a State's common law of torts," as stated in Pacific Gas, state damages are pre-empted by federal law.109 He further stated that since the Nuclear Regulatory Commission was the only authority authorized by Congress to determine the safety standards of federally licensed facilities, it would be improper to allow a lay jury to find otherwise.110 Finally, Powell argued that "[t]he Court cited no authority—in the Statute, its history, or its regulations—for its view that Congress intended that 'adequate remedies' for persons injured should include 'awards[s] of punitive damages.'"111 According to Powell, this decision will leave "this area of the law in disarray."112 Both dissenters, nonetheless, agreed that the Nuclear Regulatory Commission was the only Congressionally authorized source of regulatory power in the nuclear field as a whole.113

What is significant about the Silkwood holding is that it failed to follow a well defined series of pre-emption case law. For years, the Su...
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\textsuperscript{108} Id. at 283. "It is not reasonable to infer that Congress intended to allow juries of lay persons, selected essentially at random, to impose unthoughtful penalties solely for the purpose of punishment and some undefined deterrence. These penalties would have been left within the regulatory authority and discretion of the NRC."
\textsuperscript{109} Id. at 285.
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\textsuperscript{111} Comment, Parameters, supra note 90, at 151.

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A. Insecticide Labeling

In the area of insecticide labeling, the pre-emption dilemma is fur ther confused. In the 1984 court of appeals opinion, Ferebee v. Chevron Chemical Co., the D.C. Circuit held that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) did not pre-empt a state court from awarding tort damages for an alleged injury resulting from inadequate labeling of paratax. The court awarded $60,000 in compensatory damages for the plaintiff's wrongful death caused by the defendant's herbicide (paratax) by completely rejecting the pre-emption defense.

Although the defendant correctly directed the court's attention to § 136v(b) of FIFRA, which provides that a state "shall not impose or continue in effect any requirements of labeling different from those required under this subchapter," the court concluded that the defendant "under the aegis of [FIFRA] ... could not accept the use of paratax and tolerate uncompensated injuries." The court then speculated as to what the defendant might do in the future. For example,

115. 736 F.2d 1529 (D.C. Cir. 1984).
117. Ferebee, 736 F.2d at 1543.
118. Id. at 1529.
119. Id. at 1540 (quoting 7 U.S.C. § 136v(b)).
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fendant's herbicide (paraquat) by completely rejecting the pre-emption
defense.116

Although the defendant correctly directed the court's attention to
§ 136v(b) of FIFRA, which provides that a state "shall not impose or con-
"ine in effect any requirements of labeling different from those re-
quired under this subchapter,"117 the court concluded that the defen-
"ant,"under the aegis of FIFRA ... [could not] accept the use
of paraquat and tolerate uncompensated injuries."118 The court then spec-
ulated as to what the defendant might do in the future. For example,

114. See generally Comment, An Analysis of Silkwood v. Kerr-McGee
Corporation—the Punitive Damage Awards and Exclusive Federal Regulation Continu-
ity, 36 S.C.L. Rev. 689 (1985) (hereinafter Comment, Analysis); Wilson, Federalism Iso-
"ues In "No Airbag" Tort Claims: Preemption and Reciprocal Comity, 61 Notre
115. 736 F.2d 1529 (D.C. Cir. 1984).
116. 624 F.2d 136v(b) (D.C. Cir. 1982).
117. Ferebee, 736 F.2d at 1545.
118. Id. at 1549.
119. Id. at 1540 (quoting 7 U.S.C. § 136v(b)).
120. Id. at 1543.
121. Id.
122. 7 U.S.C. § 136v(c) (5) (C) (Unreasonable adverse effect defined as any
reasonably foreseeable adverse effect on health, safety, and the environment.
123. Ferebee, 736 F.2d at 1543.
124. Id. at 1545. The court makes a tentative argument by stating that the manu-
facturer does not have an obligation to change its labels and the manufacturer is
not under a duty to change its labels and the manufacturer is
125. See Hines v. Davidowitz, 312 U.S. 32, 67 (1941) (state law pre-empted
because it served as an obstacle to the accomplishment and execution of the purposes
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emtion analysis. For example, in *Perez v. Campbell*, the Supreme Court stated that the effect of the state rule, and not its purpose, shall determine whether a state law will be pre-empted. Thus, the Court should have decided whether the effect of the state rule was to frustrate the purpose of the federal regulation, not whether the purposes of the statute were inconsistent. Here, by allowing a damage award, the court would in effect be regulating the manufacturing and distribution process since if the company wanted to remain in business, it would have to change its warning labels. In addition, the court misinterpreted pre-emption case law by not analyzing whether the two laws stood in conflict or whether the tort award would stand as an obstacle to the full purposes and objectives of FIFRA. Instead, the court claimed that by awarding damages, manufacturers might seek more detailed labeling from the EPA.

The ForeSee decision clearly reveals the recent trend in pre-emption upheaval. The insecticide industry, however, is not alone in its fight against "states rights advocates." Other product manufacturers are also suffering from this form of constitutional misinterpretation. The following sections will specifically focus on two areas of particular significance: cigarette manufacturers and diphtheria, tetanus and pertussis vaccine manufacturers.

B. Cigarette Labeling

Tobacco manufacturers have also become the target of lawsuits arising from alleged inadequate warning and advertising defects. Injured smokers are now claiming their ailments are not the result of their own doing, but rather the fault of tobacco companies who failed to adequately warn them of their product's potential dangers. While some courts have pre-empted these actions since the federal government completely regulates the warning labels required on each package, many other courts have not. The federal statute which governs this controversy is the Federal Cigarette Labeling and Advertising Act of 1965 whose purpose is to provide the public with a uniform warning of the dangers involved with tobacco use. Every cigarette package, advertisement and billboard must contain a warning which informs of the potential dangers of tobacco use. The Act states in part:

1) [The public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices


136. Comment, Common Law Claims, supra note 133, at 754.

137. Id., citing H.R. Rep. No. 805, 96th Cong., 2d Sess. 12, reprinted in 1984 U.S. Code Cong. & Admin. News 3725, which provides that every cigarette package, advertisement and billboard must have one of the following four warnings:

1. SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

2. SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks To Your Health.

3. SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result In Fetal Injury, Premature Birth, And Low Weight.

4. SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

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The Ferebee decision clearly reveals the recent trend in pre-emption upheaval. The insecticide industry, however, is not alone in its fight against "states rights advocates." Other product manufacturers are also suffering from this form of constitutional misperception. The following sections will specifically focus on two areas of particular significance: cigarette manufacturers and diphtheria, tetanus and pertussis vaccine manufacturers.

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on each package of cigarettes and in each advertisement of cigarettes; and
2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health. In addition, the Act expressly prohibits the states from imposing any additional or prohibitory laws regarding the labeling of any tobacco packages after the manufacturer has complied with the provisions of the Act. Section 1334 of the Act specifically speaks of this pre-emption:

a) No statement relating to smoking and health, other than the statement required by section 1333 of this Title shall be required on any cigarette package.

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

Although the Act prohibits the States from regulating the labeling and advertising of tobacco products, some courts have denied the pre-emption defense.

As a whole, however, tobacco manufacturers have long enjoyed a civil immunity from the injuries associated with tobacco use. This immunity is particularly important because of the large number of persons adversely affected by tobacco use. In fact, over three hundred


139. Id. at 754-55.

140. Id. (citing 15 U.S.C. § 1334 (1982)).


142. See generally, Garner, Cigarette Dependency, supra note 133.

143. Comment, Tobacco Under Fire, supra note 133, at 643. Each year cigarette related illnesses result in the deaths of approximately 350,000 Americans and 1,000,000 worldwide. Blais & Monagas, The First Amendment and Cigarette Advertising, 256 J.A.M.A. 502 (1986). Three main categories of diseases are associated with cigarette smoking: cancers, cardiovascular diseases, and chronic obstructive lung disease. See Koop, Preface to United States Department of Health and Human Services, the Health Consequences of Smoking: Chronic Obstructive Lung Disease, supra note 133.

144. Tobacco Under Fire, supra note 133, at 643.


146. Garner, Cigarette Dependency, supra note 133, at 1425.

147. See generally id.

148. Id.

fifty thousand smoking related deaths occur each year in the United States. The figure is approximately one million worldwide. Moreover, the Surgeon General has announced that “cigarette smoking is the single most important preventable environmental factor contributing to illness, disability and death in the United States.”

Nevertheless, manufacturers produced a nearly unbeaten record in defending claims arising from tobacco use prior to World War Two. This string of victories for the tobacco companies was explainable. For example, since litigation is costly and time consuming, tobacco manufacturers had a colossal advantage due to their financial resources. Favorable legal rulings and expert counsel also added to this immunity. In addition, the repercussions of tobacco use were not yet
on each package of cigarettes and in each advertisement of cigarettes; and 2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.133

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Stettin: Federal Pre-emption: Time to Reestablish an Old Doctrine

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1356 Nova Law Review [Vol. 12

scientifically determined; while the diseases associated with tobacco use were not causally related to using the product.149 Finally, since no concrete evidence linked smoking to injury,150 and no major manufacturer was particularly injured by litigation, the tobacco companies were not required to provide warning labels on their products.

The general hardship of injured tobacco users is revealed in Green v. American Tobacco Co.,151 where the court denied compensation to an injured smoker.152 After more than twenty years of litigation, the court exonerated the manufacturer for the plaintiff's death from cancer allegedly caused by smoking cigarettes.153 What distinguished Green is that it revealed the long and difficult struggle involved in litigating against tobacco manufacturers. Most courts throughout this period held similarly while the tobacco manufacturers, as a whole, were not held liable for the adverse effects of their products.154

For example, the 1961 decision Larigue v. R.J. Reynolds Tobacco Co.155 resulted in the Court not finding the tobacco manufacturer liable because of a failure to warn. Instead, the Court decided that the state of medical and scientific evidence at the time was insufficient to prove the manufacturer's liability.156 This case revealed the widespread judicial indifference to injured smokers. Moreover, the chance of a successful action based on a failure to warn was minimal during this era re-

149. Id.
150. Id.
152. Edell, Cigarette Litigation, supra note 133, at 90.
153. Green, 409 F.2d at 1166.
156. Id.

1888 Federal Pre-emption 1357

vealing the stark reality tobacco litigants had to contend with.157 Nevertheless, the 1964 Surgeon General's Report on smoking158 which warned of the possible dangers involved with tobacco use, and the subsequent Federal Cigarette and Advertising Act of 1965159 (1965 Act), squarely addressed these issues regarding labeling of tobacco products.160 The courts, however, although having only a limited number of cases challenging the Act on labeling grounds, have not consistently applied the pre-emption defense.161 Some have interpreted the Act to mean that Congress has precluded the states from intervening through their judicial processes, while others have interpreted the Act to allow state tort recoveries for injuries alleged to have occurred from misinformed tobacco users.162

Accordingly, courts today have the unique opportunity to rule on the adequacy of cigarette labels in regard to the pre-emption analysis. Since the pre-emption issue in this field has not yet been completely clarified, Supreme Court intervention will ultimately answer this question.163 Nevertheless, some recent decisions centering around the adequacy of labels have shown the nonuniform pre-emption application to the 1965 Act.164 Since these decisions do not appear to establish a meaningful standard, the Supreme Court must voice its opinion.

One view is proposed by Cippolone v. Liggett Group, Corp.,165 where the Third Circuit Court of Appeals decided that "claims relating

157. But cf. Garner, Cigarette Dependency, supra note 133, at 1426-27 (citing Pritchard, 295 F.2d at 292 (the jury found that a smoker's injuries were caused by using tobacco, but the case never went the distance due to the long appeals and the plaintiff did not pursue this issue on the remand for new trial)).
158. UNITED STATES DEPARTMENT OF HEALTH EDUCATION AND WELFARE, SMOKING AND HEALTH REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE 33 (1964) ("Cigarette smoking is a health hazard of significant importance in the United States to warrant appropriate remedial action.").
161. See supra note 133.
163. See generally supra note 133 and authorities collected therein.
scientifically determined; while the diseases associated with tobacco use were not causally related to using the product. Finally, since no concrete evidence linked smoking to injury, and no major manufacturer was particularly injured by litigation, the tobacco companies were not required to provide warning labels on their products.

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to smoking and health that result in liability for non-compliance with warning, advertisement, and promotion obligations other than those prescribed in the Act have the effect of tipping the Act's balance of purposes and therefore actually conflict with the act."166 Because of this, any inadequate labeling challenge will be pre-empted by the 1965 Act. If common law claims were allowed, the states would in effect judicially regulate the labeling and advertising aspect of the tobacco industry located within their borders, thus "creating an obstacle to the full purposes of Congress."167 The third circuit followed this reasoning and impliedly pre-empted the State court from imposing stricter labeling and advertising requirements on the manufacturers following the Hines analysis.168

As stated previously, if a state law conflicts with the federal law, the state law is impliedly pre-empted, thus barring state tort recovery. The Cipollone Court held the federal Act to "pre-empt those state law damage actions relating to smoking and health that challenge either the adequacy of the warning on cigarette packages, or the propriety of the party's actions with respect to the advertising and promotion of cigarettes."169 Nevertheless, this interpretation has not been consistently applied by all courts.

Other recent decisions reveal this lack of uniformity. In Roydsan v. R.J. Reynolds Tobacco Co.,170 and Stephen v. American Brands, Inc.,171 both tobacco company victories, the courts followed the same reasoning as the Cipollone court by pre-empting the state common law tort action.

However, in Palmer v. Liggett,172 a Massachusetts District Court declined to follow Cipollone and denied a tobacco manufacturer's mo-

166. Id. at 187.
167. Comment, Common Law Claims, supra note 133, at 758-59 (citing Cipollone, 789 F.2d at 187) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).
168. Id. at 759 (citing Hines v. Davidowitz, 312 U.S. 52 (1941)). Under the Hines analysis, the determination of whether a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" involves a two-pronged test. Hines, 312 U.S. at 67-68. The court is required to "examine first the purposes of the federal law and second the effect of the operation of the state law on these purposes." Fineberg v. Sullivan, 634 F.2d 50, 63 (3d Cir. 1980) (en banc) (citing Perez v. Campbell, 402 U.S. 637 (1971)).
169. Cipollone, 789 F.2d at 186.
171. 825 F.2d 312 (11th Cir. 1987).
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However, in Palmer v. Liggetts, a Massachusetts District Court declined to follow Cippollone and denied a tobacco manufacturer's motion to dismiss which was based on a pre-emption defense. The Palmer Court held that "the 1965 Act did not bar state damage claims." The tobacco company claimed that Congress impliedly pre-empted cigarette labeling regulations by occupying the entire field of cigarette warning labels with the passage of the 1965 Act; thus precluding state infringement in the area. The court rejected this, however, stating that:

Neither the pervasiveness of the federal regulatory scheme, the dominance of the federal interest, nor the objectives of and obligations imposed by the federal law indicate that the field Congress meant to occupy included traditionally state-administered products liability law.

The trial court in Cippollone v. Ligget Group, Inc. also ruled for the plaintiff. It held that the 1965 Act does not pre-empt claims arising from inadequate warning labels. Although later reversed, the court stated that Congress had not occupied the field nor expressly pre-empted common law claims. It also concluded that state tort law and the 1965 Act did not conflict or stand as an obstacle to the purposes and objectives of Congress. One major distinction, however, is the court’s erroneous interpretation that state tort awards are different from mandatory regulations. "Tort liability... merely motivates a business to act or refrain from acting by creating certain financial incentives. ..." The third circuit disagreed, however, and noted that on various occasions, the Supreme Court has recognized "the regulatory effect of state law damage claims and their potential for frustrating Congressional objectives." Nevertheless, it appears the trial court was motivated more towards plaintiff compensation than doctrine interpretation.

These courts have also considered the recent passage of the Comprehensive Smokeless Tobacco Health Education Act of 1986. This
Stettin: Federal Pre-emption: Time to Reestablish an Old Doctrine

Act was modeled after the 1965 Act and deals with the effect of labeling and advertisement defects of smokeless tobacco. Although the older act deals with tobacco and the latter with smokeless tobacco, the principles and purposes are essentially the same. One major change, however, is that in the later Act, Congress specifically addressed the pre-emption issue: “Effect of Liability Law: Nothing in this Act shall relieve any person from liability of common law under state statutory law to any person.”

The effect of this section reflects congressional approval of a tort recovery based on any claims of inadequate labeling or advertisements of smokeless tobacco products. However, since Congress has not amended the 1965 Act to concern with the Smokeless Tobacco Act, the latter has no effect on present litigation. It could even be inferred that this language was purposefully excluded from the 1965 Act, which in effect bolsters the pre-emption argument proffered by tobacco manufacturers. In light of these arguments, all appellate courts considering the pre-emption defense have ruled in favor of the manufacturers.

The question still remains, however, whether pre-emption prevents the states from awarding tort awards based on inadequate labeling. The courts confronting this issue basically differ on the question of whether pre-emption should be impliedly found. On the one hand, state laws in the area of cigarette labeling and advertising create obstacles to the accomplishment of the full purposes and objectives of the 1965 Act since the fulfillment of both would be impossible. This is shown from the Act itself, which prohibits the states from requiring tobacco manufacturers to label cigarette packages in any manner not prescribed by the Act. On the other hand, the plaintiffs’ victories at trial in Cipollone

181. Compare Cipollone, 789 F.2d at 181 with 15 U.S.C. §§ 4406 et seq. (Supp. II 1986) (purpose is to require manufacturers of smokeless tobacco to inform the public of its adverse health effects by placing warning labels on their products).


183. Comment, Common Law Claims, supra note 133, at 758-59.

(a) No statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package.
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See also Comment, Common Law Claims, supra note 133, at 762-63 (Congress made

185. David & Jillian-Marian, DTP: Drug Manufacturer’s Liability In Vaccine-Related Injuries, 7 J. OF LEGAL MED. 187 (1986) [hereinafter David & Jillian-Marian, Drug Manufacturer’s Liability]. The DTP inoculation is used to prevent the diseases of diphtheria, tetanus and pertussis.

186. See generally Reitz, Federal Compensation For Vaccination Induced Injuries, 13 ENVTL AFFAIRS 169 (1986) [hereinafter Reitz, Federal Compensation];

187. David & Jillian-Marian, Drug Manufacturer’s Liability, supra note 185.

188. Hurley, 651 F. Supp at 995.

189. David & Jillian-Marian, Drug Manufacturer’s Liability, supra note 185.

190. Hurley, supra note 188, at 114-45. (There is a considerable economic and disease reduction benefit associated at 188 n.4.)
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188. Harley, 651 F. Supp. at 995.
189. David & Jallilian-Marian, Drug Manufacturer’s Liability, supra note 185.
of the vaccine causes adverse side effects in a small minority of cases which is the center of the present controversy.

Pertussis is an acute respiratory infection which is most common and serious in young children. It can often be deadly and was once a major cause of death among infants and children. However, the introduction of the vaccine in the 1940’s has nearly eradicated the disease. From 1943 to 1976, for example, “the country showed a 99% reduction in the reported cases of pertussis per 100,000 population, and an even more dramatic reduction in the number of deaths.”

The more common name for pertussis is “whooping cough.” It is so named because of the characteristic cough associated with the disease. “The cough comes in explosive bursts . . . [a] highpitched crowing sound, or whooping . . . the child is going ‘cough, cough, cough, whoop,’ and is close to strangling. The child’s face becomes red or blue, the eyes bulge, the tongue protrudes . . . the attacks get worse and worse.” However, the discovery of the pertussis antigen has substantially eradicated the disease.

with pertussis vaccine. Without a vaccination program, there would be 101,876 cases of pertussis occurring in a hypothetical cohort of one million children from birth to six years of age, with a program, there would be 9,728 cases. Among the cases without a program, 11,098 would be hospitalized versus 1,260 with a program. With a vaccination program in this cohort, there would be 1.8 million minor reactions associated with the vaccine and 41 cases of vaccine-associated encephalitis. A vaccination program reaching 90% of children would reduce disease incidence and disease-related costs by 96%. Taking into account costs associated with vaccine and vaccine reactions, the costs would be reduced by 8.2%. The ratio of overall costs without a program to those with a program is 5:1. The benefit-cost ratio (reduction in disease costs divided by program costs) is 11:1.1 (citing Himan & Kaplan, Pertussis and Pertussis Vaccine: Reanalysis of Benefits, Risks, and Costs, 251 J. A.M.A. 3109 (1984)).

190. David & Jillian-Marian, Drug Manufacturer’s Liability, supra note 185, at 189 n.10.

191. Harley, 651 F. Supp. at 995. For example, in 1934, there were 265,000 reported cases of pertussis in the United States which resulted in over 7500 related deaths. See also David & Jillian-Marian, Drug Manufacturer’s Liability, supra note 185, at 190.


193. David & Jillian-Marian, Drug Manufacturer’s Liability, supra note 185, at 190-91 (citing Immunization and Preventative Medicine 1982 Hearsings Before the Senate Subcommittee on Investigations and General Oversight of the Committee on Labor and Human Resources, 97th Cong., 2d Session 87 (1982) (Statement by Dr. Patricia Smith, VA, D.C., Children’s Hospital)).
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191. Hurley, 651 F. Supp. at 993. For example, in 1934, there were 265,000 reported cases of pertussis in the United States which resulted in over 7,500 related deaths. See also David & Jallian-Marian, Drug Manufacturer's Liability, supra note 185, at 190.


193. David & Jallian-Marian, Drug Manufacturer's Liability, supra note 185, at 190-91 (citing Immunization and Preventative Medicine 1982: Hearings Before the Senate Subcommittee on Investigations and General Oversight of the Committee on Labor and Human Resources, 97th Cong., 2d Session 87 (1982) (Statement by Dr. Robert P. Patruti, Dir., Children's Hospital)).

While pertussis itself was once the source of injury, the vaccine is today’s culprit. The adverse effects associated with the vaccine range from a moderate swelling, redness, or vomiting to convulsions, acute encephalopathy, permanent neurological damage, and even death. Proponents of the vaccine claim that more lives are saved from using the vaccine than without using it. Two purposes of mass vaccination have been propounded by these advocates. First, immunization reduces the risk of contracting pertussis, and second, mass immunizations provide for a “herd immunity.” In addition, most members of the medical profession today recommend vaccination to all children. Opponents of the vaccine, however, claim that since it is not 100% safe from serious side effects, the manufacturers should collect their resources and develop a better and more safe pertussis vaccine while compensating those injured from the inoculations.

Moreover, a catch-22 situation is occurring since in most states children are prohibited from entering the public school systems without first being inoculated with the DTP vaccine. On the one hand, children are forced to expose themselves to possible injury from the vaccine since they must receive it to attend school. On the other hand, the small minority adversely affected by the vaccine should be compensated for their injury since they were effectively forced to receive it in the first place. The manufacturer of the vaccine is the obvious scapegoat because it manufactured the product which caused the harm. The state, however, although the apparent cause of injury since it required the vaccination, is immune from civil liability by the doctrine of sovereign immunity. In light of this, the manufacturer has remained the deep pocket for compensation.

Nonetheless, vaccine injured persons have relied on many different theories of liability in lawsuits against DTP manufacturers. These include breach of warranty, negligence, and strict liability according

194. Id. at 195.
195. Id. at 194.
196. See supra note 189.
to section 402A of the Restatement (Second) of Torts. However, since this essay focuses on the constitutional questions arising from these types of lawsuits, these theories of liability will not be elaborated upon.

DPT litigation is nevertheless particularly important because of the large effect it has on the nation's children. Literally thousands of infants and children are inoculated each week with the DPT vaccine. Unfortunately, a minority react adversely after receiving the shots. These reactions range from a minor discomfort to more serious effects including death. At issue is whether manufacturers of the DTP vaccine should be liable for these injuries. On the one hand, the companies claim that since they strictly comply with federal rules and regulations governing the design, manufacture, testing, labeling, packaging, and distribution of the vaccine, they should not be liable to persons vaccinated. In addition, they claim that the national policy promoting the adequate production and supply of DTP which provides for its exclusive regulation by the federal government insures it will be available despite commercial incentives to cease production. On the other hand, persons injured by the DTP vaccine have no real recourse for compensation except from the manufacturer.

The DTP vaccine is regulated by the Public Health Service Act, the Federal Food Drug and Cosmetic Act, and the regulations promulgated by the Food and Drug Administration (FDA). The manufacturing, testing, packaging and labeling of DTP is also closely regulated and monitored by the Office of Biologic Research. In addition, the manufacturers must hold a license issued by the Secretary of the Department of Health and Human Services, which insures that the drug is manufactured and distributed according to guidelines approved by Congress.

Federal regulation of the DTP vaccine appears to be strict and detailed. For example, Section 351 of the Public Health Service Act which regulates the DTP vaccine, prohibits the manufacturers from altering the design, production or distribution of the drug without violating federal law. In addition, the Secretary of Health and Human Services will issue a license "only upon a showing that the establishment and the products for which a license is desired meet standards designed to insure the continued safety, purity, and potency of such products." Moreover, the Secretary of Health and Human Services is also responsible for promulgating detailed regulations with which the DTP manufacturers must comply. These include the design, manufacture, and distribution of DTP which impose strict testing, design, manufacturing, labeling and distribution guidelines. Other regulations call for inspections without notice, qualifications of personnel,

202. See generally Walsh & Klein, The Conflicting Objectives of Federal and State Tort Law Drug Regulation, 41 FOOD DRUG COMPL. L.J. 171 (1941), provides an in-depth analysis of different, and sometimes creative, legal theories concerning manufacturer liability.
203. David & Jillian-Marx, Drug Manufacturer's Liability, supra note 185. Figures from the 1984 United States Immunization Survey (U.S.I.S.), which is conducted every September by the Bureau of Census in cooperation with the Centers for Disease Control, reveal that the resident United States population for children between the ages of one and four was 14,481,000 and that 84.7% (12,365,000) of this age group were properly immunized with three or more doses of DTP. The percentage of children who are "properly immunized" increases as the children progress to senior school; the U.S.I.S. reports that the population for children between the age of five and six was 6,649,000 and that 93.2% (6,215,000) of these children received a series of DTP shots.
204. Id. at 188.
205. Id.
207. See supra note 193, at 227-29.
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200. See generally Toner v. Lederle Laboratories, 779 F.2d 1429 (9th Cir. 1986), cert. denied, 106 S. Ct. 1122 (1986).
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and physical inspections of buildings; maintenance of records and frequent tests of samples to determine potency, purity, and identity of each lot.

Labeling of DTP is also exclusively federally regulated. The language on the package insert must strictly adhere to federal regulatory requirements. Each package insert must state: "(1) the composition of the product; (2) the product's administration schedule; (3) indications and contraindications for use; and (4) potential adverse reactions which have been associated with the product." In addition, the manufacturer can not unilaterally change the language of the label without regulatory approval. Thus, it appears that the federal government has comprehensively determined that the rules and regulations governing the entire DTP vaccine process should rest solely in federal hands.

The need for national uniformity for DTP vaccines is equally important. If the courts were to establish different standards in the DTP process, an irreconcilable conflict with the federal regulations would occur. Moreover, the FDA has stated that:

It is...apparent that there are very few statements in prescription drug labeling on which some controversy could not be found within

219. 21 C.F.R. § 600.10-11.
220. 21 C.F.R. § 600.12.
223. Id. at 15 (citing 21 C.F.R. §§ 601.3 & 601.12). "[i]t is difficult for the courts to predict with certainty the scope of preemption legislation."
224. Id. at 19 (citing 21 C.F.R. §§ 601.3 & 601.12). "[t]his section does not permit a statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, or cosmetics under the Act..."

Federal control is intensive and exclusive. Planes do not wander about in the sky like vagrant clouds. They move only by federal permission, subject to federal inspection, in the hands of federally certified personnel and under an intricate system of federal commands. The moment a ship takes off on a runway it is caught up in an elaborate and detailed system of clouds.
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the medical profession. Not infrequently, there are several points of view on a single issue. To permit or require statements of conflicting opinion on all of these matters would destroy the present usefulness of prescription drug labeling.

In addition, Congress has vested the FDA with sole authority to determine the safety of drugs. In United States v. 1,048,000 Capsules, the court stated that "[u]nder the scheme of the Act the ultimate determination of the safety of a drug is not a matter given to the courts, but one to be determined by the Food & Drug Administration." Moreover, the court in National Association of Pharmaceutical Manufacturers v. Food and Drug Administration stated that the FDA has the ultimate authority in the area of drug manufacturing. "Beyond question the FDA has authority to promulgate regulations pursuant to [federal law] which are binding as law." 4

2. Recent Developments

In the last few years, the pre-emption doctrine has been utilized quite frequently by DTP manufacturers to challenge lawsuits filed against them by injured persons. However, the courts have established no uniform rule in that some claims are pre-empted while others are not. The plaintiffs claim that state tort actions should be permitted in areas of comprehensive federal dominance, the defendant manufacturers correctly point to the continued validity of the pre-emption doctrine as a means to bar common law tort relief. Some courts have ruled in favor of the manufacturers, while others in favor of the

228. 494 F.2d 1178 (10th Cir. 1974).
229. Id. at 1180.
231. Id. at 414 n.3. The court refers to 21 U.S.C. § 374(a): "The authority to promulgate regulations for the efficient enforcement of this chapter ... is vested in the Secretary of Health, Education, and Welfare." 3.
232. Id. (citing Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 699 (1973); National Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688 (2d Cir. 1975); cert. denied, 422 U.S. 927 (1975)).
233. See supra note 186.
234. See supra note 19 & 77 and text accompanying notes.

https://nsuworks.nova.edu/nlr/vol12/iss3/17
injured persons. Since the courts addressing the pre-emption issue have yet to rule consistently on the liability of DTP manufacturers, the time is now ripe for Supreme Court intervention.

At issue is whether federal law, which solely regulates the entire design, manufacturing, labeling, and distribution of the DTP vaccine, prevents state tort claims arising from its use. DTP manufacturers claim that state tort awards should not be available because the entire DTP field of regulation is pre-empted by federal law. Since federal law provides exclusively for the rules and regulations governing the entire vaccination process, no room is left for state interference in the form of tort awards. In addition, since the nature of its design and labeling require uniformity by federal regulation, state laws which could create different labeling or design requirements should not be allowed.

In Abbott v. American Cyanamid Co., for example, the court held that an injured user of DTP could not receive compensation from the drug manufacturer because the area was pre-empted by federal law. Since the “FDA has comprehensively set out DTP vaccine design regulations . . . [which] must be made within the FDA parameters as promulgated [by federal law],” any state tort award would be contrary to the federal rule. Congress obviously intended to occupy the entire field of DTP regulation, thus precluding state interference. Also, “[a]ny state regulation or judicial restriction of labeling/warning would conflict with the federal statutory and regulatory scheme in this area.”

Abbott is not alone. In Hurley v. Lederle Laboratories, the court granted the manufacturer’s motion for partial summary judgment on the issue of state law claims for damages based on inadequate warning/labeling and defective design. Following the well established principles set forth above, the court implicitly pre-empted the state’s regulation of the design and labeling of the DTP vaccine for three reasons. First, “the comprehensiveness of the FDA regulation as to DTP labeling evidence[s] a pre-emptive intent to occupy the field and preclude state regulation.” Second, “the nature of DTP labeling regulates the federal regulation in order to achieve uniformity vital to federal and national interests.” Since national uniformity is particularly important in drug labeling, any state interference would clearly be inconsistent with the federal role. The court addressed this point by stating that:

FDA has a well established policy of promoting uniformity in the area of labeling. For example, in requiring a warning directed to pregnant and nursing women on all OTC drugs intended for systemic absorption, FDA addressed the need to have the same language appear in the same manner on all labels (C.F.R. 54753, December 3, 1982). This preference for uniformity is also recognized by the judiciary in its construction of the supremacy clause of the United States Constitution.

Finally, the court held that any “state regulation of labeling/warning or a judicial restriction thereof” would seriously and irreconcilably conflict with the federal statutory and regulatory scheme in this area.

The Hurley court also decided that a state could not determine that the DTP design and manufacture was defective. This argument was also analyzed following implied pre-emption case law. The court’s reasoning included the fact that the FDA has exclusively “promulgated rules and regulations which encompass the licensing, testing, production, distribution, review, and approval of all biological DTP vaccines,” thus precluding a state tort award. In addition, the court found that since “there are dominant and overriding federal interests in promoting uniformity in the design and manufacture of DTP vaccines,” it would be improper to allow the states to also regulate the design and manufacture process. Finally, “the possibility of a jury determination under (state law) that the design and production of DTP is defective would stand as an obstacle to the accomplishments of federal objectives in

236. See supra note 106.
240. Id.
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236. See supra note 186.
240. Id.
243. Id. at 999.
245. Hurley, 651 F. Supp. at 999 (see cases cited therein).
246. Id. at 999-1000. See generally Hines v. Davidowitz, 312 U.S. 52, 67-68 (1941).
enacting the FDCA, the PHSA, and their respective regulations which have the force and effect of federal law. Also, if the manufacturers attempt to vary in any way the design, manufacture, or any part of the process, they will face criminal liability. Thus, following the tests established by prior case law, any state laws altering the federal scheme of regulation is properly pre-empted.

Nevertheless, a growing number of courts, however, are erroneously allowing state damage awards for DTP injuries. These courts are rejecting DTP manufacturer's pre-emption defenses for a number of reasons. For example, the court in *McGillivray v. Lederle Laboratories* denied the DTP manufacturer's motion for summary judgment by rejecting the pre-emption defense. Although acknowledging the fact that the federal government has comprehensively addressed the entire DTP process, the court would not impliedly invoke the doctrine. This argument is unreasonable since it is well established that Congressional intent to occupy a given field may be implied where a "scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." The *McGillivray* court further erred by presuming that the states are the traditional forum for redress in these types of actions. However, the national policy underlying the DTP vaccination program is clearly expressed by federal law. The FDA and the Department of Health and Human Services have unequivocally stated that "the FDA agrees that the immunization of children for tetanus, diphtheria, and pertussis should continue to be emphasized. Such immunization programs are a part of national policy." Moreover, the *McGillivray* court also rejected the pre-emption defense determining that the drug manufacturer could comply with both the federal law and pay tort damages. As stated earlier, the proper question is whether the manufacturers can comply with both state and federal standards, and not whether they could comply with one and pay damages to the other. By relying on this argument, the damage award stands as an obstacle to the accomplishment and execution of the purposes and objectives of the federal act because the manufacturer cannot possibly comply with both laws. Accordingly, if the manufacturer can not comply with both, then federal law pre-empts the state regulation.

In *Wack v. Lederle Laboratories*, the court rejected the pre-emption defense on other grounds. There, the court stated that "federal pre-emption should only be implied in very limited circumstances or the courts will run the risk of infringing upon the powers of Congress." This is, however, precisely why the doctrine should have been implicated invoked. Since the courts serve a unique role in protecting the Federal Constitution and the laws, rules and regulations promulgated thereunder, it is their job to ensure uniformity, consistency, and ultimately the supremacy of federal law. "In every case, the act of Congress (or federal agency) is supreme; and the law of the state, though enacted in the exercise of powers not controverted, must yield to it." Finally, *Wack* completely misses the proper constitutional framework by stating that "there is only one way to ensure uniform decisions

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249. See also *Hines*, 312 U.S. at 52.
251. *Hurley*, 651 F. Supp. at 1004-05. Furthermore, any pharmaceutical manufacturer's attempt to produce and market other designs of DTP vaccine (especially the "split cell" design) could result in criminal prosecution. In *Toner v. Lederle Laboratories*, 779 F.3d 1429, 1431 (9th Cir. 1986), cert. denied, 108 S. Ct. 1122 (1988), the Ninth Circuit Court of Appeals held that the principal threat of appellate's negligence argument at trial concerned Lederle's failure to develop a fractionated cell product. In support of this theory, appellellees contend that Tri-Solgen was shown to be a safer yet equally efficacious pertussis vaccine. Appellees' experts testified that the whole cell vaccine was five times more reactive than the fractionated cell product, and that early studies indicated that Tri-Solgen caused fewer local reactions than the "whole cell" vaccine. However, in early 1972, a review panel within the Bureau of Biology of the FDA refused to certify Tri-Solgen as "safe and effective" although it did so certify the whole cell vaccines. Because the FDA has refused to re-license Tri-Solgen or any other fractionated cell product, the manufacturer and sale of such a vaccine by Lederle, or any other pharmaceutical company, would constitute a criminal offense under the Food, Drug and Cosmetic Act. See 21 U.S.C. §§ 331(d), 333(a), 355(a) (1982).
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concerning the pre-emption issue in this field. Congress should be held to a higher standard and forced to expressly state whether federal pre-emption applies. Courts should not be required to grapple with the doctrine of implied pre-emption. It is here where Wack ultimately stumbles. By relying on this type of reasoning, the courts appear to forget over forty years of Supreme Court case law and in a rather cavalier fashion, attempts to construct new law.

Manufacturers, however, are confronted with many obstacles which include a plaintiff oriented judiciary, pre-emption misplacement and a new federal act. In 1986, Congress passed the National Childhood Vaccine Injury Act which nearly pre-empts the pre-emption defense for DTP manufacturers. The validity of state civil suits against DTP manufacturers can reasonably be inferred from this Act since injured vaccinees are first required to pursue administrative relief before filing civil actions. Section 300aa-21(e) squarely addresses the pre-emption issue by stating "[a] State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part." However, despite this new statute, a handful of courts have recognized their role as the guardian of the constitution and have allowed the DTP manufacturers to invoke the doctrine.

Accordingly, it appears the courts in the majority of DTP cases are rejecting the pre-emption defense and are following the recent trend set forth by Silkwood. Courts will now allow claims for compensatory and punitive damage awards in spite of federal intent to regulate or occupy an entire field. By relying on Silkwood, which allowed irreconcilable conflicts between state and federal standards to bar pre-emption, the courts are distorting the basic rationale for the doctrine. A disturbing trend in these cases is the disappearance of the detailed pre-emption case law developed over the past fifty years, and replacement

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267. Id. at § 300aa-22(e).

III. Conclusion

It unfortunately appears from recent pre-emption cases that a once dominant and well-defined doctrine has lost its role as the guardian of federal power. It should be remembered that "the relative importance to the State of its own law is not material when there is a conflict with valid federal law, for the Framers of our Constitution provided that federal law must prevail." Thus, notwithstanding the public policy of making injured plaintiffs whole, today's judiciary should most certainly look to their ancestors for guidance in regard to the pre-emption doctrine.

The time is ripe to reestablish the doctrine as American jurisprudence had defined it. Certainly, a system of uniform regulations in areas of national significance and a consistent application to the industries which create them is an end worth seeking. Since the current ad hoc approach to constitutional interpretation provides little in the way of substantive guidelines, the Supreme Court must now voice its opinion in addition. Congress should look more carefully to the future implications of its enactments and its administrative regulations so that its pre-emption ambiguities may be resolved. Without this approach, the courts may move even further away from the intricate rules established over the years. Clearly, 200 years of judicial experience should not be forgotten.

Eric Lawrence Stettin

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Manufacturers, however, are confronted with many obstacles which include a plaintiff oriented judiciary, pre-emption misplacement and a new federal act. In 1986, Congress passed the National Childhood Vaccine Injury Act which nearly pre-empts the pre-emption defense for DTP manufacturers. The validity of state civil suits against DTP manufacturers can reasonably be inferred from this Act since injured vaccinees are first required to pursue administrative relief before filing civil actions. Section 300aa-22(e) squarely addresses the pre-emption issue by stating "[t]he State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part." However, despite this new statute, a handful of courts have recognized their role as the guardian of the constitution and have allowed the DTP manufacturers to invoke the doctrine.

Accordingly, it appears the courts in the majority of DTP cases are rejecting the pre-emption defense and are following the recent trend set forth by Silkwood. Courts will now allow claims for compensatory and punitive damage awards in spite of federal intent to regulate or occupy an entire field. By relying on Silkwood, which allowed reconcilable conflicts between state and federal standards to bar pre-emption, the courts are distorting the basic rationale for the doctrine. A disturbing trend in these cases is the disappearance of the detailed pre-emption case law developed over the past fifty years, and replacement

267. Id. at § 300aa22 (e).

III. Conclusion

It unfortunately appears from recent pre-emption cases that a once dominant and well-defined doctrine has lost its role as the guardian of federal power. It should be remembered that "the relative importance to the State of its own law is not material when there is a conflict with valid federal law, for the Framers of our Constitution provided that federal law must prevail." Thus, notwithstanding the public policy of making injured plaintiffs whole, today's judiciary must certainly look to their ancestors for guidance in regard to the pre-emption doctrine.

The time is ripe to reestablish the doctrine as American jurisprudence had defined it. Certainly, a system of uniform regulations in areas of national significance and a consistent application to the industries which create them is an end worth seeking. Since the current ad hoc approach to constitutional interpretation provides little in the way of substantive guidelines, the Supreme Court must now voice its opinion. In addition, Congress should look more carefully to the future implications. In any event, Congress should avoid even further away from the intricate rules established courts may move even further away. Clearly, 200 years of judicial experience should not be forgotten.

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