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Donald P. Rothschild

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DONALD P. ROTHSCHILD*

I. A SOBERING PROBLEM

A. *Abstaining from Old Habits: The New Federalism*

During the past 20 years, what had been a classic division of functions between the Federal Government and the States and localities has become a confused mess. Traditional understandings about the roles of each level of government have been violated.

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* Professor of Law, National Law Center, The George Washington University; A.B. 1950, University of Michigan; J.D. 1965, University of Toledo College of Law; LL.M. 1966, Harvard Law School.

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> The key to [new federalism] . . . is that the States and localities make the critical choices. . . . A major sorting out of Federal, State and local responsibilities will occur, and the Federal presence and intervention in State and local affairs will gradually diminish.[1]

President Reagan, in his 1982 State of the Union Address, heralded a "New Federalism," through which "after 50 years of taking power away from the hands of the people in their states and local communities, we have started returning power and resources to them."[2] Despite President Reagan's efforts to reverse the trend of the federal government's exercise of power, major obstacles must be conquered before he can reach his goal of returning power to the states.[3] One such obstacle is classical political inertia.[4] Another significant obstacle is the federal doctrine of preemption, which impedes the states' protection of the vital interests of their

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1. President's Message to the Congress Transmitting the Fiscal Year 1983 Budget, 18 WEEKLY COMP. PRES. DOC. 141 (Feb. 15, 1982).

2. *State of the Union: "Seize These New Opportunities,"* U.S. NEWS & WORLD REP., Feb. 8, 1982, at 73.

3. The author has long advocated permitting states, counties, and local communities to regulate for the benefit of their citizens. *See, e.g.*, Rothschild, *Consumer Protection at Last through Local Control of Retail Installment Sales Contracts*, 37 GEO. WASH. L. REV. 1067, 1068 (1969) (District of Columbia as state regulating consumer protection); Rothschild & Davis, *How to Protect Consumers Through Local Regulation and Arbitration*, 1 LOY. CONSUMER PROTECTION J. 26 (1972) (county consumer protection through local regulation). *See generally* 2 D. ROTHSCHILD & D. CARROLL, CONSUMER PROTECTION REPORTING SERVICE pt. IV (1982). The policy basis of this article, however, is only tangentially related to "states' rights" issues arising out of new federalism proposals. The thrust of this article is that present preemption doctrines interfere with a state's right to *supplement federal regulation* in order to afford greater protection for citizens residing within its borders. Insofar as "states' rights" notions promote state action in lieu of federal regulation, such ideas are contrary to the purposes of this article and to the author's concept of federalism.

4. Reactions to the President's proposals varied. A bipartisan coalition of governors and mayors, headed by Republican Governor Richard Snelling of Vermont, concluded that "sweeping across the board changes in the service of theoretical or ideological goals, and unrelated to the real needs and problems of citizens served by government, are inappropriate." Kaplan, *New Federalism, Taxes, and Cities*, U.S.A. Today, Nov. 1982, at 48-49. Senator Robert Dole (R. Kans.), chairman of the Senate Finance Committee, expressed the fears of many members of Congress about turning the food stamp program over to the states. Dole stated that it "sounds good at first blush, but I'm not so certain a program that vast could be administered 50 different ways. We're having enough trouble administering it one way." *Reagan's Bold New Blueprint*, U.S. NEWS & WORLD REP., Feb. 8, 1982, at 20, 21. In addition to political inertia, there was also social protest. An anti-new federalism coalition of civil rights organizations stated that "transfer of federal programs to the states would mean 'leaving critical national concerns to the uncertain mercies of 50 colonies with uneven resources, capabilities and commitment to equity for the least advantaged.'" *Id.*

citizens.[5]

The purpose of this article is to propose a new approach to federal preemption, which would remove existing impediments to overly broad preemption of states' policy-making decisions.[6]

B. *Broken Promises: The Obstacle of Federal Preemption*

No one questions the fact that the federal government has grown. It is also clear that this growth has resulted in broader application of state law preemption. A massive 1981 study of the federal role in our political system revealed the following facts:

> Over the past 20 years the federal role has become *bigger, broader,* and *deeper*—bigger within the federal system, both in the size of its intergovernmental outlays and in the number of grant programs, broader in its program and policy concerns, and the wide range of subnational governments interacting directly with Washington; and deeper in its regulatory thrusts and *preemption proclivities.*[7]

A testimony to the growth of the federal role is contained in a study of judicial opinions between 1945 and 1960 by Professor Archibald Cox of the labor-management field, which concluded that "[t]hese decisions clearly established that federal law and federal procedures alone govern the obligations of employers in relation to the organizational activities of employees, and of the employer and employee representatives in collective bargaining . . . ."[8] To explain the rationale for the application of a strong preemption doctrine in the labor field, Justice Brennan recently indicated in a dissent that "the Court stated that '[i]n determining the extent to which state regulation must yield to subordinating federal authority, we have been concerned with delimiting areas of potential conflict; potential conflict of rules of law, of remedy, and of administration.' "[9] The Court had earlier noted in *San Diego Building*

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5. D. ROTHSCHILD & D. CARROLL, *supra* note 3, at § 2.07B.

6. *See, e.g.*, Engdahl, *Preemptive Capability of Federal Power*, 45 U. COLO. L. REV. 51 (1973); Weinstein, *New Federalism - or New Feudalism?*, CHALLENGE, May-June 1982, at 38.

7. ADVISORY COMMISSION ON INTERGOVERNMENTAL RELATIONS, THE FEDERAL ROLE IN THE FEDERAL SYSTEM: THE DYNAMICS OF GROWTH - AN AGENDA FOR AMERICAN FEDERALISM: RESTORING CONFIDENCE AND COMPETENCE 1 (June 1981) (emphasis added and supplied).

8. Cox, *Labor Law Preemption Revisited*, 85 HARV. L. REV. 1337, 1338 (1972); *see also* Lesnick, *Preemption Reconsidered: The Apparent Reaffirmation of* Garmon, 72 COLUM. L. REV. 469 (1972); Meltzer, *The Supreme Court, Congress, and State Jurisdiction Over Labor Relations: I & II*, 59 COLUM. L. REV. 6, 269 (1959); Smith & Clark, *Reappraisal of the Role of the States in Shaping Labor Relations Law*, 1965 WIS. L. REV. 411.

9. Belknap, Inc. v. Hale, 103 S. Ct. 3172, 3192-93 (1983) (Brennan, J., dissenting) (quot-

Trades Council v. Garmon[10] that when state power "threaten[s] interference" with industrial relations policy, "it has been judicially necessary to preclude the States from acting."[11] Even though the labor field represents judicial reaffirmation of federal preemptive power,[12] as this article will demonstrate, this is not atypical of other fields where preemption of state action frequently occurs.

Discussion of the scope of the federal preemption doctrine is not new. A decade ago, Professor David Engdahl cautiously predicted a return to federalism:

> If lawyers now examine constitutional doctrine more closely than has been fashionable in the recent past, it can be expected that American federalism might indeed enter a significant new phase—not by cutting back any of the modern powers of the federal government, but by developing the nascent principles of state power and the inherent qualifications on the supremacy of federal policy discretion.[13]

He suggested that the political reality of the early 70's "has conditioned the public to expect at least a piecemeal and limited return to the states of policy discretion in some of the areas in which centralization had been the dominant trend in previous years."[14] He even anticipated that "New Federalism" would come into political vogue.[15] Engdahl saw no proclivity on the part of lawyers in any branch of government to assist the public in achieving these objectives.[16] Unfortunately, this apathetic attitude on the part of lawyers has remained unchanged.

The premise of this article is that the current interpretation of the federal doctrine of preemption actually impedes the states from protecting the health, safety, and welfare of their citizens

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ing San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 241-42 (1959)).

10. 359 U.S. 236 (1959).

11. *Id.* at 243.

12. *See, e.g., Garmon*, 359 U.S. at 246 (activity that is arguably protected or prohibited by sections 7 or 8 of the National Labor Relations Act is preempted by federal law).

13. Engdahl, *supra* note 6, at 88.

14. Engdahl, *supra* note 6, at 51.

15. *Id. See supra* notes 1-5 and accompanying text for a discussion of New Federalism.

16. *See also* Gelfand, *The Burger Court and the New Federalism: Preliminary Reflections on the Roles of Local Government Actors in the Political Dramas of the 1980's*, 21 B.C.L. REV. 763, 764 (1980), in which the author observes that the Burger Court is deferring to Congress to redefine federalism. As Jack Meyer, a resident fellow at the American Enterprise Institute, opined, "[t]he federal stalemate seems to result equally from disenchantment with old ideas and suspicion of anything new." Meyer, *Health Care Reform and Market Discipline - Federalism Strikes Back*, REG., Nov.-Dec. 1982, at 16. *See generally* Engdahl, *supra* note 6.

when they desire to regulate for their citizens' benefit. Therefore, it is necessary to consider how the courts approach this obstacle.

The basic legal problem is not complex. The preemption doctrine developed chiefly in commerce clause cases, although it applies in other contexts as well.[17] The doctrine functions in three different ways. It functions to void state action when federal power or federal action is deemed exclusive in a given area. It also functions through the dormant commerce clause to void state regulations that unduly burden commerce among the states. Justice Cardozo explained the basis of this principle almost fifty years ago:

> [A] chief occasion of the commerce clause was "the mutual jealousies and aggressions of the States, taking form in customs barriers and other economic retaliation. . . ."
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> . . . The Constitution was framed under the dominion of a political philosophy less parochial in range. It was framed upon the theory that the peoples of the several states must sink or swim together, and that in the long run prosperity and salvation are in union and not division.[18]

The second part of Cardozo's statement notes that when state law collides with a congressional exercise of the commerce power, the state law must fall.

Although a single usable standard has been set forth for application to the dormant commerce clause,[19] a review of leading commerce clause cases indicates that the Court has not developed a unitary formula for resolving preemption questions. Chief Justice Burger observed in *Goldstein v. California*[20] that "[n]o simple formula can capture the complexities of this determination; the conflicts which may develop between state and federal action are as varied as the fields to which congressional action may apply."[21] As the Chief Justice indicated, there are literally hundreds of types of conflicts that can develop between state action and federal action in a given area.[22] One potential area of conflict—that of regulation pertaining to mental health—is current, significant, and illustrative.[23]

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17. *See* Engdahl, *supra* note 6, at 52.

18. Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 522-23 (1935) (citations omitted).

19. *See infra* notes 60-70 and accompanying text.

20. 412 U.S. 546 (1973).

21. *Id.* at 561.

22. *See, e.g., infra* note 55.

23. *See, e.g.*, Ferster, *Hospitalization of the Mentally Ill: A Decade After the Ervin Act*, in READINGS IN LAW AND PSYCHIATRY 284, 286 (R. Allen, E. Ferster, & J. Rubin eds. 1975).

Regulation of the treatment of mental illness and, indeed, of medical problems in general, is clearly within the states' exercise of their traditional police powers.[24] Likewise, the federal government has a long-standing involvement in the regulation of certain aspects of medical treatment, such as drugs, medical devices, and radiological health.[25]

The field of mental health is of great consequence to our society. A recent news article indicates that "[a]n influx of 18-to-34-year-olds . . . has started refilling the nation's mental hospitals . . . . accounting for approximately 162,000 hospital admissions each year [which] threatens to reverse more than a quarter-century of steady decline in state mental hospital populations."[26] Many of these young patients who are flooding mental wards have "shattered personalities" and appear to have lost touch with reality. They are likely to be diagnosed as schizophrenics, and treated with electroconvulsive therapy or major tranquilizers.[27] On any given day, there are about 600,000 people, in and out of institutions, who have been diagnosed as schizophrenics, and who are under active treatment.[28] In addition, there are millions of others with similar problems who go undiagnosed. The numbers are staggering, and estimated to be between two and six million persons in the United States.[29] These people are "by no means all in the hospital. . . . They are actually extremely mobile, and move from city to city, living any way they can and putting tremendous demands on local services for food, shelter, clothing and medical care."[30] Most of

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24. Aden v. Younger, 57 Cal. App. 3d 662, 673, 129 Cal. Rptr. 535, 542 (1976) ("Regulation of intrusive and possibly hazardous forms of medical treatments is a proper exercise of the state's police power. Public health and safety protection in the field of medical practice is an acknowledged, legitimate function of the police power.").

25. D. ROTHSCHILD & C. KOCH, FUNDAMENTALS OF ADMINISTRATIVE PRACTICE AND PROCEDURE 7-9 (1981).

26. Cohn, *Relics of the Drug Culture: Young Patients Flood Mental Wards*, Wash. Post, July 12, 1983, at A1, cols. 1-3.

27. E.F. TORREY, SURVIVING SCHIZOPHRENIA 99-131 (1983). The author is a psychiatrist at St. Elizabeths Mental Hospital in Washington, D.C. He cites National Institute of Mental Health statistics which estimate that 42% of the population is 18 to 34 years old — the highest risk age group for schizophrenia. *See* Cohn, *supra* note 26.

28. *See* TORREY, *supra* note 27, at 1.

29. *See* TORREY, *supra* note 27, at 196-206.

30. Cohn, *supra* note 26. E.F. Torrey, a psychiatrist at St. Elizabeths Hospital, cites research estimating that the number of homeless persons living on the streets and in shelters in the nation's capital as between 2,000 and 5,000 persons. "The percentage of these with schizophrenia is at least 25 percent, and a survey in Philadelphia found it to be 44 percent. New York City is estimated to have 36,000 homeless, and they are part of . . . almost every American city - Atlanta, Detroit, Phoenix, Seattle, Columbus, New Haven, San Jose." Torrey, *The Real Twilight Zone*, Wash. Post, Aug. 26, 1983, at A17, cols. 1-5.

them live in quiet desperation, but some have had a profound impact on our social stability. The recent attempted assassination of President Reagan and subsequent trial in which John Hinckley was acquitted by reason of insanity demonstrate this fact.[31]

As a distinguished psychiatrist observed, "'[t]he care and treatment of the severely and chronically mentally ill is the largest problem, numerically, that psychiatry faces, despite the fact that to date the care of the severely and chronically mentally ill has probably had the lowest priority in the entire areas of human services.'"[32] Current psychiatric practices include two significant forms of treatment for these patients—each with purported benefits and apparent dangers, proponents and detractors. These treatments are electroconvulsive treatment (ECT)—the shock therapy of the 1930's, and neuroleptic drugs (major tranquilizers)—the brain chemistry of the 1970's.[33] As a result of the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act (FFDCA), the Food and Drug Administration (FDA) regulates the medical device used during ECT.[34] Major tranquilizers are prescription drugs addressed by the FFDCA and regulated by the FDA.[35] Both ECT and major tranquilizers are dangerous and controversial.[36]

Critics of ECT point out that in addition to a patient's inability to control his or her fate during such treatment, there are risks of memory loss, physical injury, and permanent brain damage which are unbalanced by the purported benefits of treatment.[37] The critics of major tranquilizers are no less vocal in their concern over the destructive side effects of these drugs which include

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31. *See* TORREY, *supra* note 27, at 186-87.

32. TORREY, *supra* note 27, at 1. Torrey notes that:

> [Schizophrenic] research neglect stands in sharp contrast to the numbers: for each person with insulin-dependent diabetes there are three with schizophrenia; for each person with multiple sclerosis there are 20 with schizophrenia; for each person afflicted with muscular dystrophy there are 40 with schizophrenia. Yet the amount of research funds available for finding the causes of schizophrenia is exactly the same as that available for studying tooth decay.

Torrey, *The Real Twilight Zone*, *supra* note 30.

33. L. FRANK, THE HISTORY OF SHOCK TREATMENT 5-14, 69-84 (1978).

34. 21 U.S.C. § 360(c) (1982).

35. 21 U.S.C. § 351 (1982).

36. *See* L. FRANK, *supra* note 33, at 138, 148 (discussion of the use of thorazine family of major tranquilizers in illness and discussion of California ECT debate, respectively).

37. Szasz, *From the Slaughterhouse to the Madhouse*, 8 PSYCHOTHERAPY: THEORY, RESEARCH AND PRAC. 64-67 (Spring 1971); *see* J. GOTKIN & P. GOTKIN, TOO MUCH ANGER, TOO MANY TEARS: A PERSONAL TRIUMPH OVER PSYCHIATRY 194-97 (1975) (a patient's view of ECT).

debilitating, permanent, involuntary, and abnormal muscle movements.[38] Whether proponent or detractor, clearly the treatment of mental illness is a significant public issue for all levels of government.

Prior to the enactment of the Medical Device Amendments in 1976, the FFDCA did not contain an express preemption clause. The Amendments added such a clause,[39] which illustrates the potential for conflict between federal and state regulations in the health area. This preemption clause is of great legal significance and raises the issue of when state regulation of medical devices is permissible.

California law contains an example of state regulation in the area of mental health that potentially conflicts with federal regulation. The California law establishes strict requirements that limit the circumstances under which ECT can be administered and enumerates the rights of patients to receive psychiatric evaluation and treatment and to refuse electroconvulsive treatment.[40] The Medical Device Amendments increase the probability that the courts will invalidate state health regulations such as California's ECT regulatory scheme. The FDA is considering a rule that would decrease federal control of ECT equipment under the Medical Device Amendments.[41] This reclassification of ECT equipment, although a relaxation of federal control, could preempt California's strict control over the administration of ECT. The questions presented are obvious. Is the California Act valid in light of the Medical Device Amendments preemption clause? If not, how can states regulate the administration of ECT? If the law is valid, what limits does the preemption clause place on state regulation? These are typical issues concerning the interaction of federal regulatory activity and state health concerns.

Mental health, however, is not the only area affected by preemption. When addressing the current interests in health

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38. For devastating stories of the impact of neuroleptic drugs on patients, see Szasz, *supra* note 37.

39. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 521(a), 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k(a) (1982)).

40. The Lanterman-Petris-Short Act, CAL. WELF. & INST. CODE §§ 5325, 5326.7, 5326.75, 5326.8, 5326.85 (Deering 1979 & Supp. 1984). Section 5325 provides persons admitted to a state hospital or psychiatric facility with a number of rights, including the right "[t]o refuse convulsive treatment, any treatment of the mental condition which depends on the induction of a convulsion by any means, and insulin coma treatment." *Id.* at § 5325(f).

41. 48 Fed. Reg. 14,758 (1983) (to be codified at 21 C.F.R. § 882.5940) (proposed Apr. 5, 1983).

care—the environment, energy, transportation, and other marketplace activity—the significance of the preemption problem becomes apparent. Indeed, the temptation is great to point to the obstacle of preemption as just another example of the futility of using the judicial system to address some of our society's most complex issues. This article will suggest otherwise.

C. *A Proposed Cure:* Florida Lime

This article assumes that when federal and state attempts to regulate in the public interest conflict, citizen protection is minimized. Citizen protection can be maximized, however, if the federal government's regulations are interpreted as setting the minimum level of citizen protection and state regulations are permitted to supplement that minimum level.[42]

The preemption doctrine, a significant obstacle to maximizing the health, safety, and welfare of our citizens, is based on many concepts. These concepts include, but are not limited to, the dormant commerce clause philosophy of unitary federal control; the federal supremacy doctrine; the congressional intent to dominate a field; and the federal regulatory agency activity which supervises the health, welfare, and safety of United States citizens.[43] Without

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42. The proposed solution does not in any way preclude the federal government from regulating and preempting matters that states could otherwise regulate. It simply requires that Congress explicitly state its intent to preempt. This requirement is consistent with the Supreme Court's statement in Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947): "[Where] Congress [has] legislated . . . in a field which the States have traditionally occupied . . . the assumption [is] that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 230 (footnotes omitted). The Court found such a purpose in *Rice*. *Id.* at 236. A series of cases over the last 20 years has followed this anti-preemption philosophy and adopted a dual compliance test (whether compliance with both the federal and state schemes is possible). *See, e.g.*, Silkwood v. Kerr-McGee Corp., 104 S. Ct. 615, 621 (1984); Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142 (1963); *see infra* notes 154-79 and accompanying text.

43. Actually, the dormant commerce clause favors state regulation of health and safety, which are within the traditional police powers of the state. Indeed, in the Court's balancing test to determine whether a state regulation impermissibly burdens interstate commerce, the nature of the state regulation plays a significant role. A regulation that either admittedly or actually protects an economic interest is generally given less weight than one that falls within traditional police powers. *See, e.g.*, Hunt v. Washington State Apple Advertising Comm'n, 432 U.S. 333 (1977) (North Carolina statute prohibiting display, on closed boxes of apples, of any grade other than Federal grade struck down in spite of its purported consumer protection purpose); Pike v. Bruce Church, Inc., 397 U.S. 137 (1970) (Arizona regulation designed to enhance reputation of state's farmers, by requiring in-state packaging of melons, struck down); *see also* L. TRIBE, AMERICAN CONSTITUTIONAL LAW 340 (1978). The procedural and subjective aspects of this "test" do not lead to certainty.

regard to the policy considerations of each concept, which will be discussed later in this article, the courts' application of the preemption doctrine has led to confusing, uncertain, and even conflicting holdings. A state court justice recently noted this confusion:

> Unfortunately, the United States Supreme Court has not adopted a uniform approach to preemption issues. Many of the cases are inconsistent with each other, but it is extremely rare that a case is overruled. The result is a variety of methods of dealing with preemption problems and some guess-work as to which analysis will be employed in a given case.[44]

This article's proposed solution is that when a state acts to supplement federal regulation, preemption will not occur unless the party claiming preemption can show that "such actual conflict [exists] between the two schemes of regulation that both cannot stand in the same area . . . ."[45] Although this solution sounds deceptively similar to many of the holdings promulgated in recent Supreme Court cases, it differs from current case law in significant detail.

II. PREEMPTION DOCTRINE HEADACHES

A. *The Lingering Hangover of the Commerce Clause*

The dispute over when state regulation of commerce is constitutionally impermissible dates to the early nineteenth century.[46] The initial political concern was that the dormant commerce clause worked to usurp states of all power to regulate commerce. As stated by Professor Mark Tushnet:

> This view, that national power is exclusive of state power, would entail the automatic invalidation of state laws "regulating" interstate commerce. To a mid-nineteenth-century Court, this prospect was distasteful. Congress plainly lacked the resources to develop codes of conduct for every sort of interstate business.

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44. Derenco, Inc., v. Benjamin Franklin Fed. Sav. & Loan Ass'n, 281 Or. 533, 540, 577 P.2d 477, 483 (1978).

45. *Cf.* Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 141 (1963) (Court established dual compliance test).

46. In Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1 (1824), the Court addressed the validity of a state regulation absent congressional action under the commerce clause. Although the Court invalidated the challenged regulation on preemption grounds, the Court considered the states' power to regulate in areas that Congress might also address under its commerce clause power. *See also* Cooley v. Board of Wardens, 53 U.S. (12 How.) 299 (1851) (where the Court stated that the commerce clause could invalidate state legislation).

> The uniform system of nonregulation that exclusive but unexercised national power would erect was a little too robustly laissez faire for an aristocratic federalist like Marshall, or even for an enthusiastic Jacksonian like his successor Chief Justice Taney.[47]

Faced with this dilemma, the Court developed doctrine involving the supremacy clause,[48] express preemption,[49] per se rules,[50] the dormant commerce clause,[51] implied preemption,[52] ad hoc balancing,[53] and a functional approach.[54]

The problem with the doctrine is revealed by reciting it. As expected, this multifaceted preemption doctrine does not suffer from lack of legal scholarship.[55] The problem is that despite all the analysis and reanalysis of judicial doctrine, the Court seems to be "relying more often on an ad hoc balancing of interests based on

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47. Tushnet, *Rethinking the Dormant Commerce Clause*, 1979 WIS. L. REV. 125, 126.

48. *See* Engdahl, *supra* note 6, at 55-56.

49. In discussing the federal/state dilemma in health care reform, Jack Meyer stated that "[t]he federal stalemate seems to result equally from disenchantment with old ideas and suspicion of anything new." Meyer, *supra* note 16, at 16. *Compare* Note, *Environmental Law: A Reevaluation of Federal Pre-emption and the Commerce Clause*, 7 FORDHAM URB. L.J. 649 (1979) (weighing the desire of local legislatures for more responsive environmental regulation against the federal goal of uniform regulation and unrestrained interstate commerce) *with* Note, *Proposed Massachusetts Nutritional Labeling Regulations: Confronting the Question of Federal Preemption*, 11 NEW ENG. L.J. 541 (1976) (area that Congress intends to regulate solely, is "occupied" to the exclusion of all state regulation).

50. *See, e.g.*, City of Philadelphia v. New Jersey, 437 U.S. 617, 624 (1978) ("where simple economic protectionism is effected by state legislation, a virtually per se rule of invalidity has been erected"); Maltz, *How Much Regulation is Too Much - An Examination of Commerce Clause Jurisprudence*, 50 GEO. WASH. L. REV. 47, 48 & n.4 (1981).

51. *See, e.g.*, Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511 (1935).

52. *See, e.g.*, Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963); Hines v. Davidowitz, 312 U.S. 52 (1941).

53. *See* Maltz, *supra* note 50, at 48 & n.5.

54. For an excellent review of the modern focus, see J. BARRON & C. DIENES, CONSTITUTIONAL LAW: PRINCIPLES AND POLICY 202-55 (2d ed. 1982).

55. *See, e.g.*, Caples, *ERISA, Preemption and California Community Property Law*, 22 SANTA CLARA L. REV. 33 (1982); Kennedy & Lester, *The Future of Federalism: A Report on the Legal and Political Activities of 1982 as They Affected Federalism and Their Implications*, 53 OKLA. B.J. 3079 (1982); Lodge, *Melting Down Preemptive Federal Regulation of Nuclear Power* - Pacific Legal Foundation v. State Energy Resources Commission, 14 U. TOL. L. REV. 57 (1982); Miller, Young & Ruxin, *The Regulatory Status of Cable Television Channels: Issues of Common Carriage and Preemption*, 4 COMM/ENT L.J. 269 (Winter 1981-1982); Renz, *The Effect of Federal Legislation on Historical State Powers of Pollution Control: Has Congress Muddied State Waters?*, 43 MONT. L. REV. 197 (1982); Scott, *The Patchwork Quilt: State and Federal Roles in Bank Regulation*, 32 STAN. L. REV. 687 (1980). *See generally* Gelfand, *The Burger Court and the New Federalism: Preliminary Reflections on the Roles of Local Government Actors in the Political Dramas of the 1980's*, 21 B.C.L. REV. 763 (1980); Schwartz, *Commerce, the States, and the Burger Court*, 74 NW. U.L. REV. 409 (1979).

the particular facts of each case."[56] This process led Justice Rehnquist to caustically dissent in the leading case of *Jones v. Rath Packing Co.*,[57] stating that "[t]his . . . pre-emption is founded in unwarranted speculations that hardly rise to that clear demonstration of conflict that must exist before the mere existence of a federal law may be said to pre-empt state law operating in the same field."[58]

Perhaps the preemption doctrine has proliferated to the stage where there is too much conflicting precedent for the courts to apply the doctrine with precision. Perhaps the combinations and permutations of federal and state action in the same field have increased logarithmically, leading the Court to, in Justice Rehnquist's words, "rel[y] on supposition and inference."[59] In any event, a review of preemption doctrine in light of contemporary cases is necessary to fully comprehend the lingering problem.

B. *Sleeping It Off: The Dormant Commerce Clause*

From the standpoint of legal theory, it is important to distinguish a challenge to state activity based upon the dormant commerce clause from one based upon judicial notions of preemption. A dormant commerce clause challenge involves state regulation alleged to be repugnant to the federal government's enumerated powers, whereas a preemption challenge involves questions of congressional intent in light of the delicate interrelations between federal and state power.[60] Indeed, preemption challenges often concern "relations between the federal government and third parties where those relations involve matters of concern to a state."[61] Given these jurisprudential differences, it is necessary to distinguish contemporary dormant commerce clause cases from preemption doctrine cases before analyzing the contemporary judicial precedent of the latter.

The Burger Court has followed the lead of earlier Supreme Court cases that invalidated state regulations that discriminated

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56. Maltz, *supra* note 50, at 48.

57. 430 U.S. 519, 543 (1977) (Rehnquist, J., concurring in part, dissenting in part).

58. *Id.* at 544.

59. *Id.* at 546. Specifically, Justice Rehnquist explained that "[equally] as troubling as the legal inconsistency, is the Court's reliance on unproved factual speculation in demonstrating the purported irreconcilable undermining of the federal purpose by the state statutory scheme." *Id.* at 547.

60. *See generally* Engdahl, *supra* note 6.

61. *Id.* at 69.

against interstate commerce.[62] Non-discriminatory state regulations may also be invalid under the commerce clause if they unduly burden interstate commerce. The undue-burdens analysis has developed into a balancing test, which is set forth as the general rule for applying the dormant commerce clause in *Pike v. Bruce Church, Inc.*[63] In *Bruce Church,* the Court stated, "[w]here the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits."[64] *Bruce Church* withdrew from earlier decisions that questioned any non-police power purpose,[65] and suggested that the Court generally would not carefully scrutinize the nature of the purported state interest in the challenged regulation.[66] Instead, the Court assumed the state interest was legitimate and applied the balancing test, but accorded very little weight to the state interest.[67] The Court, however, suggested that the monetary burden on interstate commerce in *Bruce Church* would have been tolerated if the state had been protecting interests within its traditional police power—health and safety areas.[68]

Contemporary dormant commerce clause doctrine requires that a suspect state regulation meet the *Bruce Church* balancing test. As the Court recently noted, "the general trend in our modern Commerce Clause jurisprudence [is] to look in every case to 'the nature of the state regulation involved, the objective of the state, and the effect of the regulation upon the national interest in the commerce.' "[69] When a state does not claim that the regulation is

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62. *Compare* Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511 (1935) (Court struck attempt by New York State to forbid the sale of Vermont milk bought at less than "minimum price") *with* Great Atlantic & Pac. Tea Co. v. Cottrell, 424 U.S. 366 (1976) (Court struck Mississippi statute providing that milk from another state might be sold in Mississippi only if other state accepted Mississippi milk on reciprocal basis). *See generally* Schwartz, *supra* note 55.

63. 397 U.S. 137 (1970).

64. *Id.* at 143 (footnote omitted). The Court in *Bruce Church* struck down an Arizona regulation that prohibited the shipment of uncrated Arizona cantaloupes to a packing plant in California which would have required the grower to build a costly packing plant in Arizona.

65. Hunt v. Washington State Apple Advertising Comm'n, 432 U.S. 333 (1977); Dean Milk Co. v. City of Madison, 340 U.S. 349 (1951); Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 522-23 (1935).

66. 397 U.S. at 145.

67. *Id.*

68. *Id.* at 146.

69. Arkansas Elec. Coop. Corp. v. Arkansas Pub. Comm'n, 103 S. Ct. 1905, 1915 (1983)

an exercise of its police power, the courts are likely to accord little weight to the state's beneficial interest but will not strike the regulation down solely on that basis. When, however, the state claims that its regulation is an exercise of its police power, the state still has the burden of showing the significant health and safety benefits of the regulation, in order to tip the scale in favor of the regulation.[70] By definition, a state acts in a void when it applies the dormant commerce clause. Hence, it is appropriate that the person supporting the state action have the burden of proof. In contrast to the dormant commerce clause situation where a state is acting in a void, in a preemption situation, a state is acting to supplement federal regulation in order to increase protection for its citizens. Application of the preemption doctrine thus forces the court to make the extremely delicate determination in each case of the appropriate interaction between the state and the federal government. This author believes that the preemption doctrine would be improved by obviating the need for the courts to make this difficult determination. The author suggests that this goal can be accomplished by using a preemption standard called the "dual compliance" test. The proposed "dual compliance" test for preemption is consistent with the contemporary dormant commerce clause balancing test. The "dual compliance" test disposes of the necessity for analyzing the authority of the state to act under its police power because the court focuses, instead, on whether (dual) compliance with both the federal and state law is possible.

C. *The Delusion of Express Preemption*

Legal theory dictates that one distinguish the doctrine of preemption from the actual effect of the preemptive power.[71] The basic legal issue arising from the interaction of federal and state regulation is whether the federal government has either expressly or

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(footnote omitted).

70. Southern Pac. Co. v. Arizona *ex rel.* Sullivan, 325 U.S. 761, 779-80 (1945) (state statute that limited the length of trains traveling through Arizona was invalidated). The Court distinguished the full crew cases in which it had upheld state full-crew laws, because although the full-crew requirement added to the financial burdens on railroads by requiring crews of certain minimum sizes on trains, the requirement did not affect operations outside of the regulating state. *Id.* at 782. *Accord* Brotherhood of Locomotive Firemen & Enginemen v. Chicago, R.I. & Pac. R.R., 393 U.S. 129 (1968). The Court also distinguished cases involving safety regulations affecting the use of highways, where the state interest is peculiarly of local concern. *Southern Pac. Co.*, 325 U.S. at 783. *See also* Bradley v. Public Utils. Comm'n, 289 U.S. 92 (1933).

71. *See* Engdahl, *supra* note 6, at 52.

implicitly preempted an area of state regulation. As a matter of constitutional law, preemption occurs when Congress acts under either the commerce clause or the necessary and proper clause, and state regulation "collides" with the congressional enactment.[72] Instances of direct conflict, however, are rare.[73] Duplication of federal laws by the states is not considered a conflict, and state legislatures can avoid conflict by distinguishing their regulations.[74] "It is clear that the mere existence of differences between federal and state . . . regulations does not necessitate invalidating the latter."[75] State legislatures, accordingly, pass regulations that address different problem areas or are more stringent than federal legislation. This obviates the issue of direct "conflict," although some decisions blur conflict/preemption issues.[76]

As previously indicated, Congress may express its intent to preempt state law in federal enactments.[77] The majority view is that an explicit statement in a statute that certain federal regulations are exclusive, or a statement prohibiting state action in a given field, bars states from enacting measures that address the same areas as the federal standards.[78]

The doctrine of express preemption is easily stated. Its application, however, is far more problematic, since before an express preemption clause can be applied to state action, one must inquire whether the clause is truly applicable to the particular state action. Since an express provision can bar all state action to which it ap-

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72. U.S. CONST. art. I, § 8, cl. 3. The supremacy clause, U.S. CONST. art. VI, provides that the laws of the United States "shall be the supreme law of the land." This clause denies states the power to retard, impede, burden, or in any manner control, the operations of the constitutional laws enacted by Congress to carry out the powers vested in the general government.

73. Engdahl, *Consolidation By Compact: A Remedy for Preemption of State Food and Drug Laws*, 14 J. PUB. L. 276, 280 (1965).

74. *See* D. ROTHSCHILD & D. CARROLL, *supra* note 3, § 2.07B.

75. *Id.*

76. *See, e.g.*, Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440, 444 (1960) (the Court appears to combine the concepts of conflict and preemption under the heading of "preemption"); California v. Zook, 336 U.S. 725, 729 (1949) (the Court combines conflict and preemption under the heading "conflict with national policy"); *see also* D. ROTHSCHILD & D. CARROLL, *supra* note 3, § 2.07B.

77. *See, e.g.*, Medical Device Amendments of 1976, Pub. L. No. 94-295, § 521(a), 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k(a) (1982).

78. *See, e.g.*, Alessi v. Raybestos-Manhattan, Inc., 451 U.S. 504 (1981) (the Court concluded that since Congress had declared that ERISA superseded all state laws relating to pension plans, the New Jersey statute providing beneficiaries with additional protection by barring reduction of pension benefits by the amount of workmen's compensation awards was preempted); *see also* Rice v. Sante Fe Elevator Corp., 331 U.S. 218 (1947) (U.S. Warehouse Act, declaring power of Secretary of Agriculture to be "exclusive," preempted field).

plies, the dispositive factor in such cases is whether the express preemption provision is applicable, by its own terms, to the particular state action at issue in the case.

Historically, the courts have addressed this question by determining the legislative intent. This approach is frustrating because even after the most thorough examination of relevant legislative history, the intent often is found to be ambiguous or nonexistent.[79] The problem of ascertaining congressional intent is not limited to poorly phrased preemption clauses. Even unambiguous statements of statutory intent require analysis to determine the scope of the preemption clause.[80]

An example of a clear legislative statement of preemption is found in the Medical Device Amendments of 1976,[81] in which Congress provided:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.[82]

In spite of this express statement of preemptive intent, the three reported cases discussed below have sustained state action involving medical devices against preemption arguments.

In one of these three cases, *New Jersey Guild of Hearing Aid Dispensers v. Long*,[83] the Supreme Court of New Jersey set forth three requirements under the Medical Device Amendments: (1) the state's regulation must be a requirement applicable to the medical device; (2) that relates to a matter included in the federal requirement; and (3) that is different from or in addition to the federal requirement.[84] The court, in applying this test, found that most of

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79. *See* Note, *Pre-emption as a Preferential Ground: A New Canon of Construction*, 12 STAN. L. REV. 208 (1959); *cf.* Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n, 103 S. Ct. 1713, 1728 (1983) ("[I]nquiry into legislative motive is often an unsatisfactory venture. What motivates one legislator to vote for a statute is not necessarily what motivates scores of others to enact it.") (citations omitted).

80. *See* Note, *supra* note 79, at 209.

81. Pub. L. No. 94-295, § 521(a), 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k(a) (1982)).

82. *Id.*

83. 75 N.J. 544, 384 A.2d 795 (1978).

84. *Id.* at 572, 384 A.2d at 809. Comparable tests have been applied in different types of preemption clauses. For example, in Chrysler Corp. v. Rhodes, 416 F.2d 319 (1st Cir. 1969),

the New Jersey regulations were not applicable to hearing aids, and therefore were not preempted.[85] The court, however, found that the pre-sale testing requirement was preempted because it "would operate to create a prerequisite to the sale of a hearing aid that is 'in addition to' that specified in the federal regulation, since a dispenser would be forced to comply with two variant rules prior to dispensing a hearing aid."[86] In the second case, the Fifth Circuit adopted the second and third prongs of the *Long* test in sustaining Florida's regulation of hearing aid sales.[87] The Fifth Circuit found no preemption.[88] In the third case, a California court developed a more stringent test, requiring that the challenger prove (1) that the state action was a "requirement;"(2) that it was "different from or in addition to" any requirement of the Act on the subject; *and* (3) that it related to the effectiveness of hearing aids, before preemption could be found.[89] The court found no preemption because the challenger failed to prove all three elements. This California holding is characteristic of state court decisions, which tend to support state regulations against preemption challenges.[90]

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the court, construing the preemption clause of the National Traffic and Motor Vehicle Safety Act, 15 U.S.C. § 1392(d) (1982), held that the federal statute would preempt state action if: (1) a federal standard covering the item or equipment was in effect; (2) the state safety standard for the item was not identical to the federal standard; and (3) the state and federal regulations apply to the same aspect of performance of the item or equipment. 416 F.2d at 321. This "difference of expression" test allows states great latitude in treating fields in which Congress has acted. *See, e.g.*, 7 U.S.C. § 136v(b) (1982); 21 U.S.C. § 1052(a)(7) (1982); *see also infra* note 96.

85. *Long*, 75 N.J. at 577, 384 A.2d at 811.

86. *Id.* at 578, 384 A.2d at 812.

87. Smith v. Pingree, 651 F.2d 1021, 1023-25 (5th Cir. 1981). The court found that a Florida requirement that hearing aid purchasers be given a receipt specifying whether the aid was used or rebuilt, the address of the seller, brand name and serial number, and a statement advising purchasers to contact a state office in event of any difficulties, was not related to any matter included in the federal regulation, even though the federal government required that purchasers be given a brochure specifying whether the aid was used or rebuilt along with information on use and care, and a warning to consult a doctor. *Id.* at 1024-25.

88. *Id.* at 1026.

89. Kievlan v. Dahlberg Elec., Inc., 78 Cal. App. 3d 951, 958, 144 Cal. Rptr. 585, 590 (1978).

90. *Id.* The strict holding of this case is consistent with the holdings of many other state courts in preemption actions. State courts have a tendency to view state action favorably, and preemption claims restrictively. *See, e.g.*, Palm Springs Spa, Inc. v. County of Riverside, 18 Cal. App. 3d 372, 378, 95 Cal. Rptr. 879, 883 (1971) ("the validity of the [preemption] claim cannot be judged by reference to broad statements about the comprehensive nature of federal regulation of Indian affairs"); Grocery Mfrs. of Am., Inc. v. Department of Pub. Health, 379 Mass. 70, 81-82, 393 N.E.2d 881, 890 (1979) ("[p]laintiffs are required to prove their case with hard evidence of conflict, and not merely with unsupported pronouncements as to [federal] 'policy' ") (footnotes omitted).

Although it is clear that Congress has the power to preempt any and all state action regarding medical devices, the courts have held that Congress has not done so. This can be illustrated by applying the medical device preemption tests to the field of mental health; specifically, to the device used to administer electroconvulsive therapy (ECT). As discussed earlier, the effectiveness of ECT as therapy is controversial.[91] The Food and Drug Administration (FDA) pursuant to its authority under the Medical Device Amendments has stated an intent to regulate certain aspects of the device used to administer ECT.[92] In addition, California has legislated strict requirements that limit the circumstances under which ECT can be administered and enumerate the rights of patients to receive psychiatric evaluation and treatment, or to refuse ECT.[93] Federal preemption may occur since the Medical Device Amendments contain an express preemption clause and the FDA has already regulated this device. Application of the *Long* test to the California regulation could result in at least partial preemption.[94]

Yet, it can be argued that the Medical Device Amendments do not preempt the relevant sections of the California Code. First, the provisions of the California statute are not applicable to the device but rather to the treatment of patients receiving mental health services. Second, California's statute contains a number of requirements that are not related to any matter included in the Medical Device Amendments.[95] For example, the federal act does not regulate whether a patient must consent to the use of the device. Third, the state ECT standard is neither "different from nor in addition to" the federal standards on the equipment. Indeed, courts often uphold state statutes against attacks based on preemption clauses by finding that the clauses do not apply to the specific matter that the state is regulating.[96] The questioned state

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91. *See supra* notes 33-39 and accompanying text.

92. 48 Fed. Reg. 14,758 (1983) (to be codified at 21 C.F.R. § 882.5940) (proposed Apr. 5, 1983).

93. The Lanterman-Petris-Short Act, CAL. WELF. & INST. CODE §§ 5325, 5326.7, 5326.75, 5326.8, 5326.85 (Deering 1979 & Supp. 1984).

94. For example, the California Code provision requires a review by at least two physicians. *Id.* at § 5326.7. This result is analogous to the holding in New Jersey Guild of Hearing Aid Dispensers v. Long, 75 N.J. 544, 384 A.2d 795 (1978), in which the court held that state regulations requiring hearing aid salesmen to post retail price lists and banning nonconsensual home visits were not applicable to the hearing aid itself and therefore not preempted. *Id.* at 577-81, 384 A.2d 811-13.

95. This was the basis for the Fifth Circuit's finding that the section 360k preemption provision was inapplicable in Smith v. Pingree, 651 F.2d 1021, 1025-26 (5th Cir. 1981).

96. *See, e.g.*, Chrysler Corp. v. Tofany, 419 F.2d 499 (2d Cir. 1969); Chrysler Corp. v.

actions are held to be outside of the scope of the clause. This contemporary approach, and the policies underlying it, are consistent with the approach to preemption that this article proposes. This author recommends limiting the preemptive effects of express preemption clauses.

This narrow construction technique is used in cases where Congress legislates in an area within the state's traditional police powers and the state also seeks to legislate in that area. "[T]he assumption [is] that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[97] This assumption creates a presumption against preemption whenever a state acts within its police power. Such a presumption requires that courts narrowly construe preemption clauses, thus permitting states to exercise their police powers in a manner that contributes to the federal scheme. This liberal construction in favor of state action saves a wide variety of state regulations from invalidation.

The police power of the state is broad:

> [It] embraces [the] whole system of internal regulation, by which the State seeks not only to preserve the public order and to prevent offenses against the State, but also to establish for the intercourse of citizens with citizens those rules of good manners and good neighborhood which are calculated to prevent a conflict of rights, and to insure to each the uninterrupted enjoyment of his own so far as it is reasonably consistent with a like enjoyment of rights by others.[98]

The extensiveness of states' powers was highlighted in a recent decision in which the Court stated that a state may recognize "liberty interests" and "procedural rights" more extensive than those pro-

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Rhodes, 416 F.2d 319 (1st Cir. 1969) (the National Traffic and Motor Vehicle Safety Act did not preempt state efforts to regulate and require presale clearance of supplementary headlamps on motor vehicles); *see also* Maurer v. Hamilton, 309 U.S. 598 (1940) (Pennsylvania could ban car over cab trucks because in regulating "sizes and weights" it had not regulated a truck's "equipment" and therefore had not acted in an area regulated by the Interstate Commerce Commission (ICC)); Missouri Pac. R.R. v. Norwood, 283 U.S. 249, 256-57 (1931) (provisions of the Interstate Commerce Act giving the Commission exclusive authority to "regulate the practice of carriers" relating to the "supply of trains" did not preempt Arkansas' full crew statutes as the ICC had no authority to fix the number of employees on a given train, and this was, therefore, not a practice over which the ICC had preemptive authority).

97. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) (footnotes omitted).

98. C.G. TIEDEMAN, A TREATISE ON THE LIMITATIONS OF POLICE POWER IN THE UNITED STATES 2 (1886 unabridged republication 1971) (footnote omitted).

tected by the federal Constitution.[99]

Given the breadth of state police powers and the courts' attitude toward supporting state action against express preemption challenges, it is not too great an assumption to argue that in reality, the states have an implied reservation of power to complete the scheme "where Congress has chosen to 'occupy' a field, but has not undertaken to regulate every aspect."[100] It also seems logical that, where Congress elects to provide the states with the right to petition for an exemption to a statutory preemption provision, Congress did not intend to exclude state action.[101] In any event, "[i]n the absence of a clearly expressed purpose so to do Congress will not be held to have intended to prevent the exertion of the police power of the States . . . ."[102]

D. *The Illusion of Implied Preemption*

Even where Congress has not expressly preempted all state action in a given field, courts have sometimes found that Congress has, by implication, preempted the particular field. The doctrines that the courts have traditionally employed in determining whether federal preemption may be implied include: (1) whether the legislative history indicates that Congress intended to preempt the field (congressional intent);[103] (2) whether the federal regulatory scheme is so comprehensive that preemptive intent can be presumed (pervasive interest);[104] (3) whether the federal interest in the field is so dominant that intent to preempt can be assumed (dominant federal interest);[105] and (4) whether the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress (frustration of purpose).[106]

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99. Mills v. Rogers, 457 U.S. 291 (1982) (former mental patients of Massachusetts state hospital brought suit protesting the forcible administration of antipsychotic drugs; appeals court decision based on federal constitutional guarantees vacated and remanded the case for consideration in light of an intervening Massachusetts Supreme Court decision that outlined rights potentially more extensive than federal rights).

100. Chemical Specialties Mfrs. Ass'n v. Clark, 482 F.2d 325, 327 (5th Cir. 1973) (footnote omitted). Despite the use of the phrase "implied reservation of powers," there is no indication that a ninth or tenth amendment issue is involved.

101. 21 U.S.C. § 360k(b) (1982).

102. Missouri Pac. R.R. v. Norwood, 283 U.S. 249, 256 (1931).

103. Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 147-50 (1963); Campbell v. Hussey, 368 U.S. 297, 301-02 (1961).

104. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

105. Hines v. Davidowitz, 312 U.S. 52 (1941).

106. *Id.*

1. THE "CONGRESSIONAL INTENT" DOCTRINE

In most cases, determining congressional intent is an exercise in futility. Committee and conference reports may never address a congressional intent to preempt. In some situations, the congressional debate may indicate both preemptive and nonpreemptive intent, thereby permitting advocates to cite those portions of the debate that aid them and minimize those that do not.

Although the court reporters are replete with examples demonstrating the difficulty in ascertaining congressional intent, one example will suffice. In *Brotherhood of Locomotive Engineers v. Chicago, Rock Island & Pacific Railroad Co.*,[107] Justice Black, writing for the majority, concluded that "Congress had no intention of superseding the state full-crew laws"[108] when it passed a statute that provided for temporary mandatory arbitration of collective bargaining disputes over interim work rules in the railroad industry. As proof of this, Justice Black cites a floor statement by the chairman of the House Committee.[109] Justice Douglas noted somewhat tersely in his dissent that he did not "think that the bits and pieces of legislative debate cited in the Court's opinion can be regarded as a controlling statement of legislative intent."[110]

Because of the competition within Congress between federal and state power advocates,[111] political compromise sometimes results in an ambiguous preemptive intent. In any event, it is important to remember that the difficulties in assessing congressional intent arise from the political process rather than an inability to be precise.

2. THE "PERVASIVE NATURE" DOCTRINE

In a number of cases, courts have concluded that Congress intended to preempt a particular field on the basis of the comprehensiveness of the federal regulatory scheme. For example, in *Hines v. Davidowitz*,[112] the Court found preemption based in part

107. 382 U.S. 423 (1966).

108. *Id.* at 434.

109. *Id.*

110. *Id.* at 444. Justice Black and Justice Douglas also disagreed as to the purpose of the statute. While Justice Black stated that "Congress wanted to do as little as possible in solving the dispute which was before it," *id.* at 433, Justice Douglas believed that Congress was determined to comprehensively resolve the range of problems associated with technological unemployment and not just the dispute that was before it. *Id.* at 447.

111. Immigration and Naturalization Serv. v. Chadha, 103 S. Ct. 2764, 2784 (1983).

112. 312 U.S. 52 (1941).

on the fact that the congressional scheme was a "broad and comprehensive plan" and an "all-embracing system."[113] Application of this doctrine has resulted in discordant judicial constructions. The difficulties that the courts encounter are similar to those which the court encounters when determining congressional intent. The difficulty in applying the "pervasive nature" doctrine depends on the precision with which a congressional act is drafted. Like "congressional intent," the precision with which the legislature drafts the bill depends on the "politics" of the situation.

It is also important to recognize that in some instances Congress enacts legislation that delegates considerable authority to the administrative agency charged with its enforcement to fill in the interstices of the act.[114] Testing an act based on an administrative agency's regulatory action is likely to raise questions as to the extent of pervasiveness that Congress intended. This is especially true in light of a recent Court decision that effectively limits congressional oversight of such agencies.[115]

3. THE "DOMINANT FEDERAL INTEREST" DOCTRINE

In another group of cases, courts have implied an intent on the part of Congress to preempt regulation in a particular field because of the federal government's dominant interest in that area. In *Hines*, the Court upheld the federal preemption of a Pennsylvania alien registration statute, in part, because the legislation belonged "to that class of laws which concern the exterior relation of this whole nation with other nations" and dealt with an area "so intimately blended and intertwined with responsibilities of the national government."[116] Where the federal interest is that dominant,

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113. *Id.* at 69, 74.

114. *See generally* D. ROTHSCHILD & C. KOCH, *supra* note 25, chs. I & II.

115. *See Chadha*, 103 S. Ct. 2764 (1983). Congress frequently makes broad grants of policy-setting power because it is not able to address all of the issues concerning government operation. *See* D. ROTHSCHILD & D. CARROLL, *supra* note 3, § 4.07.

Broad grants of power have been held not to be preemptive. For example, in Head v. New Mexico Bd. of Examiners in Optometry, 374 U.S. 424 (1963), the Court concluded that the Federal Communications Act did not impliedly preempt a state's ability to ban price advertising on the radio by optometrists because the means of enforcement and general substantive standard by which the federal agency operated in regulating radio advertising were so inadequate that they could not have been a "plausible substitute" for state action. *Id.* at 431. Similarly, in AMCA Int'l Corp. v. Krouse, 482 F. Supp. 929 (S.D. Ohio 1979), the court held that since the federal scheme imposed only "moderate requirements" and provided only "limited protections," Congress did not intend to preempt the field. *Id.* at 934.

116. *Hines*, 312 U.S. at 66 (1941) (quoting Henderson v. Mayor of New York, 92 U.S. 259, 273 (1875)).

"states cannot . . . conflict or interfere with, curtail or complement, the federal law."[117] At least one commentator has criticized the application of the dominant federal interest test to decisions involving preemption by federal statute, believing that it relates rather to the dormant commerce clause analysis of whether states have the power to act absent national legislation on the subject.[118] The Court has not, however, utilized this test independently of traditional preemption doctrine.[119]

Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Commission,[120] a recent Supreme Court case involving nuclear power, demonstrates the difficulty of applying the *Hines* test. In *Pacific Gas,* the Court distinguished California's economic interests from the federal government's interest in nuclear power regulation and found no preemption. As the concurring opinion noted, the dominant federal interest in nuclear regulation was not dispositive of the preemption issue. Justice Blackmun stated that "[a] flat ban for safety reasons, however, would not make 'compliance with both federal and state regulations . . . a physical impossibility.' "[121] He explained that "[t]he NRC has expressed its judgment that it is safe to proceed with construction and operation of nuclear plants, but neither the NRC nor Congress has mandated that States do so."[122]

A finding of implied preemptive intent, however, does not fully resolve the preemption issue. A court must also determine whether the state action in question is within the class of actions intended to be preempted.[123] The Court applied this additional

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117. *Id.*

118. Bowden, *A Conceptual Refinement of the Doctrine of Federal Preemption,* 22 EMORY L.J. 391, 397-403 (1973). *See supra* notes 60-70 and accompanying text for a discussion of the dormant commerce clause.

119. In the recent case of Silkwood v. Kerr-McGee Corp., 104 S. Ct. 615 (1984), the Court applied the "dominant federal interest" doctrine and traditional preemption doctrine. The Court determined first that Congress had not entirely displaced state regulation over the matter in question, and then concluded that the state law was not preempted since it did not conflict with federal law. *Id.* at 625-26.

120. 103 S. Ct. 1713 (1983).

121. *Id.* at 1733 (Blackmun, J., concurring) (citing Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 143 (1963)).

122. *Pacific Gas,* 103 S. Ct. at 1733 (Blackmun, J., concurring).

123. This question, however, does not arise with the frustration of federal purpose doctrine. The frustration of purpose test initially examines the specific state regulation and its purpose as compared with the federal regulation and its purpose. If the state regulation is seen as frustrating the federal purpose, it is held to be preempted. Hence, a further examination is not required.

consideration in *Huron Portland Cement Co. v. City of Detroit.*[124] In *Huron,* the Court stated that Congress intended for federal vessel inspection statutes to preempt state safety regulations of federally licensed ships. Yet, the Court upheld Detroit's power to impose criminal sanctions on federally licensed ships that exceeded Detroit's smoke emission standards. The Court upheld the Detroit measure because it found that the measure concerned air pollution and not safety, and thus was outside the field that the federal inspection statute impliedly preempted.[125] Such a determination is analogous to express preemption decisions in which the courts have narrowly construed federal statutes and liberally viewed state actions, in order to find the federal/state regulations in *pari materia* and thus avoid ousting state action on an implied preemption theory.[126]

4. THE "FRUSTRATION OF FEDERAL PURPOSE" DOCTRINE

The "frustration of federal purpose" doctrine originated in 1912 in *Savage v. Jones,*[127] when the Supreme Court stated that a state statute would be preempted "[when] the purpose of the [federal] act cannot otherwise be accomplished."[128] The Court expanded this test in 1941 in *Hines v. Davidowitz.*[129] In *Hines,* the Court stated that implied preemption turned on whether the state "law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[130]

In *Jones v. Rath Packing Co.,*[131] where the state sought to

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124. 362 U.S. 440 (1960).

125. *Id.* at 445-46.

126. *See, e.g.,* Grocery Mfrs. of Am., Inc. v. Department of Pub. Health, 379 Mass. 70, 393 N.E.2d 881 (1979) (preemption denied state statute requiring food package dating); Hillman v. Consumers Power Co., 90 Mich. App. 612 (1979) (state's concern over employment discrimination not preempted); Derenco, Inc. v. Benjamin Franklin Fed. Sav. & Loan Ass'n, 281 Or. 533, 577 P.2d 477 (1978) (preemption denied state court order of a federally chartered institution); *see also* Chemical Specialties Mfrs. Ass'n v. Clark, 482 F.2d 325, 327 (5th Cir. 1973), where there is minimal authority for the view that where the federal government has impliedly preempted the field but has not regulated every aspect of the area, the states have an implied power to fill out the scheme.

127. 225 U.S. 501 (1912).

128. *Id.* at 533. In *Savage,* the Court held that an Indiana statute, requiring that commercial feeding stuffs for animals disclose ingredients on the package, did not prevent the accomplishment of the objectives of the parallel federal act that barred false or misleading statements on packages. This holding allowed the state authority to supplement the federal scheme.

129. 312 U.S. 52 (1941).

130. *Id.* at 67.

131. 430 U.S. 519 (1977).

supplement federal regulation, the Court applied the *Hines* test to bar the state action. The Court considered whether a California statute that required flour packages to list net weight, without permitting variations for loss of moisture after packing, frustrated the objective of a federal statute, which also required labels to list weight but allowed for variations due to moisture loss. The majority concluded that one major purpose of the federal statute was "to facilitate value comparison among similar products."[132] The majority further concluded that California millers would be able to project how much weight would be lost as a result of humidity changes from each package of flour in local markets, and pack accordingly, while national millers, because of their broad range of markets, would have to overpack flour in order to comply with the California statute. Because the products would therefore be dissimilar, the majority felt that the California statute would frustrate the achievement of the federal objective of promoting comparison. Therefore, the Court held that the federal regulation preempted the more rigorous California legislation.[133]

The Supreme Court has, however, used this doctrine on several occasions to uphold state action. Just one year after *Hines*, the Court held that California's comprehensive plan for marketing raisins did not conflict with a federal statute's objective of establishing orderly marketing conditions.[134] A year later, in *Penn Dairies, Inc. v. Milk Control Commission of Pennsylvania*,[135] the Court upheld an order of the Pennsylvania Milk Control Commission that denied a license to a milk dealer who sold milk to the army at a cheaper price than that fixed by the state. The Court stated that the purpose of the federal statute, which required the government to utilize competitive bids when making purchases, was to regulate government purchases, "to prevent favoritism, and to give to the United States the benefit of competition."[136] It was not to reduce costs. The Court concluded, therefore, that the Pennsylvania statute did not frustrate the objective of the federal statute and was not preempted.[137] Twenty years later, in *Head v. New Mexico Board of Examiners in Optometry*,[138] the Court held that a New

132. *Id.* at 541.
133. *Id.* at 542-43.
134. Parker v. Brown, 317 U.S. 341 (1943).
135. 318 U.S. 261 (1943).
136. *Id.* at 273 (quoting 2 Op. Att'y Gen. 257, 259 (1829)).
137. *Id.*
138. 374 U.S. 424 (1963).

Mexico statute banning radio advertising of optometrists' prices "[did] not frustrate any part of the purpose of the federal legislation"[139] regulating radio advertising, but actually complemented it.

The "frustration of purpose" doctrine has been utilized in many implied preemption cases. The *Rath Packing* decision, however, underscores the inherent difficulties in applying the *Hines* test. The first of these difficulties is that the *Hines* type of analysis permits courts to manipulate the challenged statute's purpose to achieve the desired result, much as the courts manipulate congressional intent in the express and other implied preemption models. For example, in *Rath Packing*, if the federal statute's purpose had been viewed as providing consumers with the most accurate information possible about each product, the California statute's requirement for listing a post-moisture loss would not only *not* frustrate the federal purpose, it would promote it.

The second inherent weakness in the "frustration of purpose" doctrine is that the consideration of whether a statute's purpose will be frustrated encourages courts to proceed in a more hypothetical, abstract fashion. If a court is antagonistic to the state's legislation, it will usually hypothesize situations that produce a conflict between the state and federal legislation. *Rath Packing* is a clear example of this, for, as Justice Rehnquist noted in his dissent, there was no information in the record to support the majority's conclusion that national millers would be forced to overpack but local millers would not. He stated that the majority's conclusion was based "on supposition and inference."[140]

E. *New Trends for Dealing with the Headache*

An emerging trend can be seen in a series of cases arising within the last twenty years. The "frustration of purpose" doctrine is being replaced by a simple inquiry, at least where the state's police power is involved, into whether compliance with both the federal and state schemes is possible (dual compliance).[141] While decisions by the Supreme Court, circuit courts, and federal district courts have, to some degree, continued to utilize the frustration of

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139. *Id.* at 432 (quoting Colorado Anti-Discrimination Comm'n v. Continental Air Lines, 372 U.S. 714, 724 (1963).

140. 430 U.S. at 546. *See* Exxon v. Governor of Md., 437 U.S. 117 (1978), in which the Court stated that a hypothetical conflict with the Robinson-Patman Act, which allows price discrimination in certain limited instances, was not sufficient to warrant preemption of a state statute requiring oil companies to grant price reductions to dealers uniformly.

141. *See, e.g.*, Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963).

federal purpose analysis, the far better approach would be to require a person challenging a state regulation to prove that dual compliance is not possible. This scheme would leave the states with enough flexibility to protect vital interests by adding to the protections afforded by federal standards. If Congress felt that the state's additional regulations were inappropriate in light of federal intent, Congress could enact provisions explicitly preempting any additional state requirements.

1. EXPRESS PREEMPTION

Express preemption cases exhibit a new trend toward using the federal regulation as a base upon which the states legislate through their police powers. Generally, a very narrow construction of the subject preemption clause is consistent with the thesis of this article that Congress must state explicitly the scope of its preemptive intent in order to take from the states those powers that are inherent in statehood.

The new trend was set forth in *Chemical Specialties Manufacturers Association v. Clark.*[142] The court stated that "where Congress has chosen to 'occupy' a field, but has not undertaken to regulate every aspect of that area, the states have the implied reservation of power to fill out the scheme."[143] While this language has great potential, the courts have never used it to hold that while Congress has preempted *the field,* the state retains the right to act within its police power. This language, however, has been applied more narrowly. For example, courts have upheld state regulation relating to hearing aids in spite of the express preemption clause of the Medical Device Amendments.[144]

In *Smith v. Pingree,*[145] the Fifth Circuit cited *Chemical Specialties* for support of its determination that the Medical Device Amendments did not preempt minimal procedures for the fitting and selling of hearing aids.[146] The court found that the federal regulations requiring a medical evaluation in advance of the sale of a hearing aid did not address the matter of fitting of hearing aids,

142. 482 F.2d 325 (5th Cir. 1973).

143. *Id.* at 327. Despite the use of the phrase "implied reservation of powers" in this case, there is no indication in *Chemical Specialties* or any of the cases construing it that any ninth or tenth amendment issue is involved.

144. Medical Device Amendments of 1976, Pub. L. No. 94-295 § 521(a), 90 Stat. 539, 574 (codified at 21 U.S.C. 360k(a) (1976)).

145. 651 F.2d 1021 (5th Cir. 1981).

146. *Id.* at 1024.

and thus did not preempt the state requirements. Because the federal regulation did not regulate every aspect of presale procedures for hearing aids, the court found that the state had an implied reservation of power to establish requirements for the fitting and labeling of hearing aids. The state's labeling statute required a disclaimer on hearing aid packages, rather than in an instructional brochure accompanying hearing aids, as specifically required by the federal regulation.[147] Although both the federal and state regulations dealt with labeling, the court found a sufficient difference between an "instructional brochure" and "packaging" so as to distinguish the two schemes, and concluded that the federal requirements did not regulate every aspect of the area at issue.[148]

Admittedly, there are a number of problems with the legal theory supporting this trend. First, one could argue that this theory destroys the idea of a federal regulation occupying the field and finds the reserved right of a state to act from federal inaction. This argument itself seems specious, however, since express preemption deals with congressional action, not inaction, and clearly Congress could expressly preclude any state action.[149] Second, the trend places courts in the position of deciding whether the federal government has sufficiently regulated the field as a preliminary determination to whether the reserved power of the state is present. Arguably, this shortcoming is similar to that which makes the *Hines v. Davidowitz* "frustration of federal purpose" doctrine objectionable. In both situations the courts are able to manipulate the doctrine to reach the desired result. The trend, however, requires that Congress state explicitly the scope of its preemption, and if it fails to do so, the presumption is that Congress did not intend to preempt state power. This presumption, coupled with the placement of the burden of proof on the party claiming preemption under a preemption clause, should be sufficient to avoid judicial manipulation.

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147. *Id.* at 1024-25.

148. *Id.* at 1025. Similarly, in New Jersey Guild of Hearing Aid Dispensers v. Long, 75 N.J. 544, 384 A.2d 795 (1978), the court held that key aspects of hearing aid dispensing sales practices regulated by the state were not preempted by FDA hearing aid regulations because they did not affect devices regulated by the FDA. *Id.* at 577, 384 A.2d 811. The court cited Kelly v. Washington *ex rel.* Foss Co., 302 U.S. 1, 10 (1937) for the principle that "[t]here is no constitutional rule which compels Congress to occupy the whole field." The court held, "[w]e interpret FDCA § 521(a) as expressly envisioning such supplemental state regulations insofar as it limits the definition of the state regulations it supersedes to state requirements 'applicable to' devices, thus permitting a wide variety of conceivable state regulations to remain unaffected." *Id.* at 577, 384 A.2d at 811.

149. *Cf.* Immigration and Naturalization Serv. v. Chadha, 103 S. Ct. 2764 (1983).

The case that extends express preemption the furthest is *California v. Department of the Navy*.[150] While acknowledging that section 223 of the Clean Air Act[151] precludes states from enacting dissimilar emission standards for aircraft, the Ninth Circuit stated, "if the state pollution regulations can be met without affecting the design, structure, operation or performance of the aircraft engine then the state emission regulations are not preempted by § 233."[152] Since the trial court had found that California's regulation would not require any such engine modification, the court held that the state was not preempted.[153]

2. IMPLIED PREEMPTION

The trend in express preemption cases toward upholding state police power action on the theory that it complements the federal regulation is consistent with the general rule that has developed in implied preemption cases—that state action is not preempted unless it is an obstacle to the accomplishment and execution of Congress's purposes and objectives.[154] However, as previously indicated, this "frustration of federal purpose" test enunciated in *Hines* has been applied with amazing inconsistency. In *Florida Lime & Avocado Growers, Inc. v. Paul*,[155] the Supreme Court acknowledged the inadequacies of the *Hines* analysis by defining the preemption test to be whether there is "such actual conflict between the two schemes of regulation that both cannot stand in the same area; . . . not whether they are aimed at similar or different objectives."[156] The Court's decision seemed to rest entirely on the question of whether "compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce."[157] Even though the California regulation required Florida avocado growers who wished to sell their produce in California to leave their fruit on the tree slightly longer than required under a federal marketing order, the Court held that the California requirement was not preempted since Florida growers could com-

150. 624 F.2d 885 (9th Cir. 1980).
151. 42 U.S.C. § 7573 (1982).
152. 624 F.2d at 888.
153. *Id.*
154. Hines v. Davidowitz, 312 U.S. 52 (1941).
155. 373 U.S. 132 (1963).
156. *Id.* at 141-42.
157. *Id.* at 142-43 (citations omitted). While the Court's opinion did cite the *Hines* test, it rendered its decision without discussing the federal purpose and looked solely to whether dual compliance was possible.

ply with both schemes by observing the California regulation.[158]

The *Florida Lime* dual compliance test has significant advantages over the *Hines* "frustration of purpose" analysis. First, *Florida Lime* avoids the potential problem of judicial manipulation of congressional purpose.[159] Numerous cases have shown that this is a major strength of *Florida Lime*.[160]

Second, the narrow approach of *Florida Lime* provides the broadest possible protection to state citizens by permitting state regulatory schemes to stand in all cases except where compliance with the federal scheme would not otherwise be possible. Third, and most importantly, the dual compliance doctrine clearly allows each level of government to operate in the most effective manner. States are free to build on federal standards and thereby achieve additional safeguards over those interests that the states protect pursuant to their police power. If the federal government decides that state standards are interfering with federal objectives or that the state standards are simply too burdensome or inappropriate, the governing federal standards can be amended to expressly preempt specified state actions, or any state action at all.

Unfortunately, the *Florida Lime* test has not always been applied as clearly as it was set forth. Ironically, one of the clearest examples of the inconsistent application of this test appears in a concurring opinion by Justice Brennan in *Head v. New Mexico Board of Examiners in Optometry*.[161] Justice Brennan, who wrote the majority opinion in *Florida Lime*, stated in his concurrence that a court should look to see whether there has been "a showing of conflict either *in purpose* or in operation between the state and federal regulations involved"[162] in determining whether, as a prac-

158. *Id.* at 142. Florida avocado growers sued to enjoin state officers of California from enforcing section 792 of the California Agricultural Code, which prohibits the transportation or sale in California of avocados containing less than eight percent of oil by weight, against Florida avocados. The Florida avocados were certified as mature under the Federal Marketing Agreement Act of 1937, but required more days of on-the-tree ripening to obtain the eight percent oil content limit.

159. The Court in *Florida Lime* could have easily struck down the California statute had it applied the *Hines* purpose test. If the Court had found that the purpose of the federal act was to protect farmers, then it could have held that the additional requirements of the California statute frustrated Congress' purpose and, therefore, the statute was preempted. On the other hand, the Court could have upheld the statute by finding that the purpose of the federal regulation was to protect consumers (which seems unlikely).

160. *See infra* note 179. *See also* Jones v. Rath Packing Co., 430 U.S. 519, 547-49, n.5 (1977) (Rehnquist, J., dissenting).

161. 374 U.S. 424 (1963).

162. *Id.* at 445 (emphasis added) (Brennan, J., concurring).

tical matter, both federal and state regulations can be enforced without impairing the federal superintendence of the field. In *Florida Lime*, Justice Brennan stated that the test was *not* whether the two statutes "are aimed at similar or different objectives."[163] This contradiction is significant because it represents the essential difference between the Court's approach in *Hines* and its approach in *Florida Lime*. Adding to this confusion is the fact that the Supreme Court has never expressly overruled *Hines*. Indeed, fourteen years after *Florida Lime*, the Court in *Jones v. Rath Packing Co.*[164] cited *Hines* as the basis for the majority's decision to preempt a California labeling requirement because it frustrated the federal purpose of promoting value comparisons.[165] As Justice Rehnquist pointed out in his dissent, the majority's use of *Hines* in *Rath Packing* "suggest[s] an approach to the question of pre-emption wholly at odds with that enunciated in *Florida Lime* . . . [where] [t]his Court rejected a test which looked to the similarity of purposes . . . ."[166] The different views expressed in *Rath Packing* illustrate the inconsistent ways in which the courts have applied *Florida Lime*.

In *Silkwood v. Kerr-McGee Corp.*,[167] the Court appeared to return to the *Florida Lime* test when it cited *Florida Lime* for the proposition that "[i]f Congress has not entirely displaced state regulation over the matter in question, state law is still preempted to the extent it actually conflicts with federal law, that is, when it is impossible to comply with both state and federal law."[168] The Court held that the Atomic Energy Act of 1954 did not preempt an Oklahoma jury's verdict assessing punitive damages against a nuclear facility.[169] The defendants had argued that the punitive damages were a form of state safety regulation, and that Congress had preempted the field of safety regulation of nuclear energy.[170] The Court first found that Congress had not intended for the Act to preempt traditional state tort remedies.[171] However, rather than simplifying preemption doctrine, the Court went on to apply three different preemption tests. First, it declined to find congressional

163. 373 U.S. at 142.
164. 430 U.S. 519 (1977).
165. *Id.* at 540-43.
166. *Id.* at 549 (Rehnquist, J., dissenting).
167. 104 S. Ct. 615 (1984).
168. *Id.* at 621.
169. *Id.* at 626.
170. *Id.* at 622.
171. *See generally id.* at 622-26.

intent to occupy the field. Then the Court made an apparent shift in its preemption analysis by stating that the burden of proving intent was on the party who was claiming preemption.[172] Citing *Florida Lime,* the Court held that it was possible to pay both federal fines and state punitive damages and, therefore, under the second theory, dual compliance, preemption had not occurred.[173] Citing *Hines,* the Court applied a third preemption test and found that although the purpose of the Atomic Energy Act was to encourage development of atomic energy, the purpose was not to encourage development at all costs. Since Congress was not interested in promoting atomic energy by means that would provide adequate remedies to persons injured thereby, the Act did not preempt the award of punitive damages where Act regulated activity led to personal injuries.[174]

The dissenting Justices in *Silkwood,* on the other hand, stated that the majority had misread congressional intent,[175] had failed to properly delineate the nature of the state regulation said to be preempted,[176] and had misapplied the *Hines* test.[177] Neither dissent, however, purported to apply the *Florida Lime* dual compliance test. The objections raised by the dissenting opinions highlight the problems with current preemption doctrines. By applying a multiplicity of preemption tests in *Silkwood,* the Court paved the way for the judiciary to manipulate congressional intent to reach any conclusion the judiciary desires. Although the Court in *Silkwood* eventually reached the same conclusion that it reached in *Florida Lime,* it still has not enunciated a clear preemption standard.[178]

Most of the preemption challenges since *Florida Lime* cite both *Hines* and *Florida Lime,* but place emphasis upon the *Florida Lime* dual compliance test.[179] Despite this trend, the result of

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172. *Id.* at 625. *See also id.* at 637 (Powell, J., dissenting).

173. *Id.* at 621, 626.

174. *Id.*

175. *See generally id.* at 627-34 (Blackmun, J., dissenting), 634-41 (Powell, J., dissenting).

176. *Id.* at 628 (Blackmun, J., dissenting), 635 (Powell, J., dissenting). The dissenters agreed with the defendant that the issue before the Court was whether punitive damages, as a type of state regulation of behavior, were preempted by the Nuclear Energy Act. The majority, on the other hand, found that punitive damages were part of the state law of torts and that Congress had not intended to preempt tort recoveries. *Id.* at 625.

177. *Id.* at 638-39 (Powell, J., dissenting).

178. *See* Pacific Gas & Elec. Co. v. State Energy Resource Conservation & Dev. Comm'n, 103 S. Ct. 1713, 1722 (1983).

179. See, e.g., Associated Gen. Contractors of Mass., Inc. v. Altshuler, 490 F.2d 9, 14-15 (1st Cir. 1971) where the court mentioned both cases and held that Massachusetts was free

the combined use of the *Hines* "frustration of purpose" test and the *Florida Lime* dual compliance test allows courts almost complete discretion in preemption cases to decide each case on its own factual and political merits without regard to precedent. As a result of this discretion, the law as to the proper method to determine when a federal scheme preempts a state statute remains unsettled.

III. A SUGGESTED CURE FOR THE PREEMPTION HEADACHE

A. *The Concept of "Cure"*

One solution to the problems connected with the confusing state of current preemption doctrine is to create a unitary preemption doctrine. Specifically, any person challenging a state statute on the basis of preemption should be required to prove that dual compliance with both the federal and the state regulatory schemes is not possible. A challenge based on an express preemption clause would use the exact language of that clause to establish the scope

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to impose minority hiring requirements that were more stringent than the federal standards because the purposes of the two plans were "congruent" and "there was no reason to suppose that contractors could not comply with both at the same time." In Pharmaceutical Soc'y of N.Y., Inc. v. Lefkowitz, 586 F.2d 953, 958 (2d Cir. 1978), the court upheld the New York Generic Drug Act against a challenge that it was preempted by the federal Food, Drug and Cosmetic Act, utilizing both tests. The court determined that the objective of the New York statute (regulating the sale of drugs) was not in conflict with the federal purpose (of controlling the safety and efficacy of drugs), and that since the state statute left the federal government to determine the safety and bioequivalency of the generic substitutes, there was no actual conflict between the two statutes. In William Inglis & Sons Baking Co. v. ITT Continental Baking Co., 668 F.2d 1014, 1049 (9th Cir. 1982), the court also utilized both tests in upholding California's Unfair Practices Act, which goes beyond the federal Robinson-Patman Act by barring any sale of a product for less than cost.

Federal district court decisions tend to reach the same result. *See, e.g.*, City of New York v. Diamond, 379 F. Supp. 503 (S.D.N.Y. 1974) where the court described a New York City minority hiring plan as much more demanding than the federal plan but upheld the New York plan as not being inconsistent "since compliance with the [city] plan will not interfere with, but rather will constitute compliance with" the federal plan. *Id.* at 520. In AMCA Int'l v. Krouse, 482 F. Supp. 929 (S.D. Ohio 1979), the court concluded that an Ohio statute requiring fuller disclosure and a longer period of public scrutiny for tender offers than a federal statute was not preempted under either the *Hines* or *Florida Lime* test.

There are also a number of district court opinions that seem to rely exclusively on the dual compliance test announced in *Florida Lime*. *See, e.g.*, Swift & Co. v. Wickham, 230 F. Supp. 398 (S.D.N.Y. 1964) where the court held that since a turkey-packer could comply simultaneously with a federal requirement that the label show the net weight of the stuffed turkey and a New York requirement that the net weight of the unstuffed bird be disclosed, the New York requirement was not preempted. The court added that "it is not inevitably unconstitutional for a state desiring a higher standard for the protection of its consumers to confront a manufacturer in another state with the alternatives of taking steps not required by applicable federal law or not selling his goods in the enacting state." *Id.* at 406.

of the federal regulation. A challenge based on implied preemption would use the actual federal regulatory scheme to establish the scope of the federal regulation. In both situations, the scope of the federal regulatory scheme would be compared with the state regulatory scheme to determine whether dual compliance is possible. If it is possible, preemption should not be found.

B. *Recent Research Concerning the Problem*

This proposed approach is consistent with both the current trend in preemption cases and the policy and holding of *Florida Lime*. The dual compliance test uniformly determines when a state may supplement federal statutes and regulations. The test permits a uniform determination regardless whether a state is acting within its police power or whether the federal government has expressed preemptive intent. There is a more persuasive reason for endorsing a single test than to promote uniformity. To draw an analogy to labor law, when a legal test turns on the definition of a power, ensuing cases tend to become preoccupied with the definition, rather than the application of the test.[180] The rulings become so profuse that they provide ad hoc holdings instead of reliable precedent.

It is useful to compare the thoughtful analysis of a recent law review note. The note examines the breadth of preemption cases and the principles of *Florida Lime*.[181] It is a comparative article that illuminates some of the difficulties with contemporary preemption doctrine jurisprudence. The author stated that there is support in leading preemption cases for the proposition that, absent express or implied federal preemption of the area, the states should be free to assert their police power, using congressional enactments as a minimum level of protection.[182] The article says that state statutes are generally not preempted when a challenged statute involves the exercise of a state police power that merely hinders or interferes with opportunities created by federal law or with the performance of federal duties. Preemption occurs, however, when the state law requires a breach of national law in order to

180. Under the National Labor Relations Act, as amended, 29 U.S.C. § 159(a), the parties are required to bargain, *inter alia*, about "terms and conditions of employment." The plethora of cases defining this phrase have led to an almost ad hoc approach. *See, e.g.*, Cox, *Labor Decisions of the Supreme Court at the October Term, 1957*, 44 VA. L. REV. 1057, 1075 (1958); Note, *Proper Subjects for Collective Bargaining: Ad Hoc v. Predictive Definition*, 58 YALE L.J. 803 (1949).

181. Note, *A Framework for Preemption Analysis*, 88 YALE L.J. 363 (1978).

182. *Id.* at 389.

protect the asserted state interest.[183] These findings are consistent with *Florida Lime* and its dual compliance test. The Supreme Court stated firmly in *Florida Lime* that a challenged statute is not preempted unless "the nature of the regulated subject matter permits no other conclusion, or . . . Congress has unmistakably so ordained."[184] This suggests that far more than a mere hindrance is required before preemption can be found. The Court further stated that preemption was inescapable when compliance with both federal and state schemes was impossible.[185] Where, however, the state regulates an area traditionally within its powers and imposes a higher standard than the federal standard with respect to a purely intrastate matter, preemption is not required under the *Florida Lime* test.[186]

The article sets forth another standard with respect to state regulations not involving the exercise of police powers. This standard results in preemption when a state action substantially hinders conduct essential to the achievement of the overall objective of a federal statute.[187] This is actually a rephrasing of the *Hines* "frustration of purpose" test.[188] Although the article notes that such hindrance has frequently been the basis for preemption when no police power interest is involved,[189] *Florida Lime* expressly rejects this test[190] and supplants it with a dual compliance test[191] after pointing out that the *Hines* "frustration of purpose" test has been inconsistently applied.[192]

In spite of *Florida Lime*'s admonition, both Justice Brennan's concurrence in *Head v. New Mexico Board of Examiners in Op-*

183. *Id.* at 363-64.

184. 373 U.S. at 142.

185. *Id.* at 142.

186. *Id.* at 144-45.

187. *Framework for Preemption, supra* note 181, at 372-82.

188. Hines v. Davidowitz, 312 U.S. 52 (1941).

189. *Framework for Preemption, supra* note 181, at 378-80.

190. 373 U.S. at 142.

191. *Id.* ("The test of whether both federal and state regulations may operate, or the state regulation must give way, is whether both regulations can be enforced without impairing the federal superintendence of the field, not whether they are aimed at similar or different objectives.").

192. The *Florida Lime* Court responded to the suggestion "that the coexistence of federal and state regulatory legislation should depend upon whether the *purposes* of the two laws are parallel or divergent," by pointing out that "[t]his Court has, on the one hand, sustained state statutes having objectives virtually identical to those of federal regulations, and has, on the other hand, struck down state statutes where the respective purposes were quite dissimilar." *Id.* (citations omitted).

tometry[193] and the majority opinion in *Jones v. Rath Packing Co.*[194] were based on whether the purpose of the state and federal statutes were consistent. It is plausible to conclude, as the note does, that the *Hines* test of "frustration of purpose" should be used only where the police power of the state is not involved. It may be plausible, but the analysis does not successfully account for all of the leading cases that do not use this distinction. The article's distinction is merely an opportune argument based upon a convenient definitional distinction which avoids the central issue of when a state may act to supplement federal legislation. The better approach, the dual compliance test, resolves this issue consistently. It allows a state to supplement federal regulation whenever there is compliance with both federal and state regulatory schemes.

C. *A Treat Instead of a Treatment*

An appealing unitary preemption doctrine is one that does not require making tedious distinctions based on the nature of the state regulations or the nature of the preemption. Any proposed test, however, must meet the requirements of constitutional and administrative law, as well as the practical requirements of our political form of government.

The most serious potential legal challenge to this proposed preemption doctrine is that the test ignores the precepts of the supremacy clause[195] by failing to distinguish between express and implied preemption. This argument ignores the nature of the new doctrine. Although the doctrine does not provide a separate test for express preemption cases, it fully accounts for the limits set by Congress in express preemption clauses. To fully comprehend the proposal, it is important to place in perspective the types of cases that would apply this unitary preemption test. The test would be applied in cases where the state wishes to *supplement* federal statutes and regulations, not to overcome them. As the courts have said on many occasions, "where Congress has chosen to 'occupy' a field, but has not undertaken to regulate every aspect of that area, the states have the implied reservation of power to fill out the scheme."[196]

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193. 374 U.S. 424, 444-45 (1963) (Brennan, J., concurring).

194. 430 U.S. 519, 540-43 (1977).

195. U.S. CONST., art. VI, cl. 2.

196. Chemical Specialties Mfrs. Ass'n, Inc. v. Clark, 482 F.2d 325, 327 (5th Cir. 1973). *See also* Smith v. Pingree, 651 F.2d 1021, 1024 (5th Cir. 1981). The Court further stated in

Obviously, Congress can expressly preempt state action if it so chooses. This is the very premise of the dual compliance test. If Congress says *only* federal action can be taken, then dual compliance is not possible. Since Congress can preempt state action, it should be required to do so explicitly before a state's actions are invalidated. Anything less is contrary to the equally important constitutional premise that all powers not granted to Congress are reserved to the states.[197] The basic issue involved in express preemption cases is not whether Congress can preempt state action under the supremacy clause but, rather, how Congress should proceed when it intends to preempt under the ninth amendment.

It is apparent that the powers reserved to the states are broad. The reservation comes not only from the ninth amendment, but is implicit in the grant of power to Congress.[198] As previously stated, the courts find the power so fundamental that the states may increase the basic guarantees to their citizens that are provided by the Constitution.[199]

The importance of state sovereignty has been expressed strongly throughout the life of the Constitution. As the Court noted in *Goldstein v. California*:[200]

> We must also be careful to distinguish those situations in which the concurrent exercise of a power by the Federal Government and the States or by the States alone *may possibly* lead to conflicts and those situations where conflicts *will necessarily* arise. "It is not . . . a mere possibility of inconvenience in the exercise of powers, but an immediate constitutional repugnancy that can by implication alienate and extinguish a pre-existing right of [state] sovereignty."[201]

Although there has been a presumption in favor of state action based on police powers, that presumption is inadequate to protect the full breadth of permissible state action. The Constitution does not distinguish between state action based on police power and state action based on the state's other powers. For example, in the

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Florida Lime that "a State might . . . at least in the absence of an express contrary command of Congress . . . 'because of a higher standard demanded by a state for its consumers' " pass additional regulations. 373 U.S. at 144.

197. U.S. CONST., amend. IX.

198. *See supra* notes 46-59 and accompanying text.

199. *See, e.g.*, Mills v. Rogers, 457 U.S. 291 (1982); *see also* Wash. Post, Apr. 2, 1984, at A1, col. 2.

200. 412 U.S. 546 (1973).

201. *Id.* at 554-55 (quoting THE FEDERALIST No. 32, at 243 (B. Wright ed. 1961)) (emphasis in original).

last term, the Court explained that, even in cases characterized as "go[ing] to the core of federal labor policy,"[202] "[u]nder *Garmon*, a state may regulate conduct that is of only peripheral concern to the [federal] Act or which *is so deeply rooted in local law* that the courts should not assume that Congress intended to preempt the application of state law."[203] A preemption doctrine that raises such distinctions is suspect.

The *Florida Lime* test protects the pre-existing right of state sovereignty in two ways. The dual compliance test maximizes state activity to the point at which there is an immediate and constitutional repugnancy between state action and federal supremacy. Second, by placing the burden on the party claiming preemption, a rebuttable presumption is created that the state is acting within its legitimate sphere of sovereign interest. This presumption comports with reality since, when states act, they generally act within their police powers.[204] The adoption of a unitary standard removes the generally unanswerable and easily manipulated issues of state and federal purposes and intents from judicial consideration, and substitutes the simpler comparison of the relative scopes of the state and federal regulatory schemes.

It is clear that the dual compliance test meets the requirements of the supremacy clause while promoting the policies of the ninth amendment. In addition, the test can potentially provide consistent and predictable results in preemption cases.

Use of the unitary dual compliance test is most problematic in the area of express preemption. It is, therefore, valuable to examine the test in light of a hypothetical. Would a California regulation of electroconvulsive therapy be preempted by the FDA's regulation of the ECT device under the Medical Device Amendments?[205] The legislative intent cannot be clearly discerned from

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202. Belknap, Inc. v. Hale, 103 S. Ct. 3172, 3190 (1983) (Brennan, J., dissenting) (unfair labor practice charge and state court suit for damages).

203. *Id.* at 3182 (referring to San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236 (1959)) (emphasis added). The majority also cited Linn v. Plant Guard Workers, 383 U.S. 53 (1966) (libel); Farmer v. Carpenters, 430 U.S. 290 (1977) (intentional infliction of emotional distress); and Sears Roebuck & Co. v. San Diego County Dist. Council of Carpenters, 436 U.S. 180 (1978) (trespass).

204. The Court has already taken a step toward shifting this burden of proof. *See* Silkwood v. Kerr-McGee Corp., 104 S. Ct. 615 (1984).

205. The relevant federal statute is The Medical Device Amendments of 1976, 21 U.S.C. § 360(c) (1982). The California Code sections dealing with the use of electroconvulsive therapy in state institutions are: CAL. WELF. & INST. CODE, §§ 5325, 5326.7, 5326.75, 5326.8, 5326.85 (Deering 1979, & Supp. 1984). *See generally* Downey, *Laboratories or Puppets? The Challenge of Federal Preemption of State Legislation*, 34 FOOD DRUG COSM. L.J.

the House, Senate and Conference Reports of the Medical Device Amendments.[206] Fortunately, the House Report submitted by the House Committee on Interstate and Foreign Commerce does provide insight into the federal purpose:

> [If] differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened. For this reason, the reported bill contains special provisions (new section 521 of the Act) governing regulation of devices by States and localities . . . .
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> . . . .
>
> Because there are some situations in which regulation of devices by States and localities *would constitute a useful supplement to Federal regulation*, the reported bill authorizes a State or political subdivision thereof to petition the Secretary for exemptions from the bill's general prohibition on non-Federal regulation.[207]

The new petition provision appears to indicate that Congress intended to preempt state action absent petition. In addition, the FDA stated in its interpretation of the preemptive scope of the Device Amendments that:

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334 (1979).

Under section 513(a) of the federal FDCA, the FDA is authorized to classify medical devices into three categories—Classes I, II, and III. Class III devices are the most regulated and restricted of the three categories because they have a potential for causing unreasonable risk of illness or injury, or are used to sustain life or prevent impairment to health. The FDA must issue a pre-market clearance for all Class III devices in order to provide reasonable assurance of their safety and effectiveness. Under section 513(c), an interested party can petition to change the existing classification of a device. However, where the petitioner requests a change from Class III to Class II (a lessening of restrictions), the regulation that gives notice of the recommended change may stipulate that the reclassification shall not take effect until the effective date of performance standards established under section 514 for such device. *See* D. ROTHSCHILD & CONSUMER H-E-L-P EDITORIAL STAFF, GEO. WASH. U., FDA: NATIONAL CONSUMER AWARENESS AND ACCESS PROJECT WORKBOOK ON MEDICAL DEVICES (1982) (written and published for the Office of Consumer Affairs, FDA).

Pursuant to these regulations, the American Psychological Association filed a petition to reclassify electroconvulsive therapy equipment from a Class III to Class II device. Subsequent to a hearing on this petition, the FDA announced that it would reclassify the device effective upon the promulgation of appropriate performance standards. Notice of Intent, 48 Fed. Reg. 14,758 (1983).

206. The Senate Report is contained in S. REP. No. 33, 94th Cong., 1st Sess. 1 (1975), *reprinted in* 1976 U.S. CODE CONG. & AD. NEWS 1070. The House Report is contained in H.R. REP. No. 853, 94th Cong., 2d Sess. 1 (1976). The House Conference Report is found in H.R. CONF. REP. No. 1090, 94th Cong., 2d Sess. 1 (1976), *reprinted in* 1976 U.S. CODE CONG. & AD. NEWS 1103.

207. H.R. REP. No. 853, 94th Cong., 2d Sess. 45 (1976) (emphasis added).

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act.[208]

Accordingly, a prima facie argument can be made for preemption of the California ECT administration statute,[209] even though California enacted its legislation to insure protection of the constitutional rights to privacy and freedom of choice of mental patients who are vulnerable and easily susceptible to undue influence.[210]

Three courts, however, did not reach this conclusion when they applied this reasonably clear preemption clause to regulations relating to hearing aid devices. These cases present issues that are analogous to California's regulation of ECT under the same Act. In *Smith v. Pingree*,[211] the Fifth Circuit stated that "[b]ecause . . . federal regulations did not address the mechanics of fitting hearing aids to patients, the state was free to prescribe minimal procedures to be followed and equipment to be used in the fitting of hearing aids."[212] In *New Jersey Guild of Hearing Aid Dispensers v. Long*,[213] the court noted that "[w]here Congress has chosen to 'occupy' a field, but has not undertaken to regulate every aspect of that area, the states have the implied reservation of power to fill out the scheme."[214] As previously indicated, the court did hold that

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208. 21 C.F.R. § 808.1(d)(1)-(9) (1983) (commenting on section 360k(b)). The FDA then went on to list specific types of state or local requirements which it regarded as not preempted by section 360(k), including requirements of general applicability relating to other products in addition to devices, requirements that are equal to or substantially identical to requirements imposed under the Act, and requirements relating to the approval or sanction of the practice of medicine or one of the other healing arts (e.g., licensing and certification of doctors). 21 C.F.R. § 808.1(d)(1)-(9) (1983).

209. New Jersey Guild of Hearing Aid Dispensers v. Long, 75 N.J. 544, 384 A.2d 795 (1978).

210. *See Selected 1976 California Legislation, Health and Welfare*, 8 PAC. L.J. 391, 392 (1976) (citing CAL. STAT. ch. 1109, § 1).

211. 651 F.2d at 1021.

212. *Id.* at 1024 (citing *Chemical Specialties*, 482 F.2d at 327).

213. 75 N.J. 544, 384 A.2d 795 (1978).

214. *Id.* at 577, 384 A.2d at 811 (quoting *Chemical Specialties*, 482 F.2d at 327). Because the federal regulation in *Pingree* did not regulate every aspect of presale procedures for hearing aids, the court found that the state had an implied reservation of power to

the presale testing requirement of the New Jersey act was preempted since it was "in addition to" that specified in the federal regulation.[215] However, the court held that the state requirements as to itemized receipts had no "specific counterpart" in the federal regulation and were therefore not preempted.[216] Significantly, the court declined to consider the impact of the doctrine of implied preemption on the case because: (1) "[i]n specifying a detailed formula for use in determining exactly which state laws are preempted by [Section 360k(a)], Congress has deliberately circumscribed the extent to which its enactment has occupied the field of device regulation,"[217] and (2) "[t]he creation of [the] novel exemption procedure [established in 360k(b)] is persuasive evidence of a Congressional intent to permit supplementary state regulation in the same field."[218] In the third case, *Kievlan v. Dahlberg Electronics, Inc.*,[219] the California court noted that the three part test to be applied in a preemption case was conjunctive. Although the state statute related to the effectiveness of hearing aids, it did not establish a "requirement" and was not "different from" or "in addition to" any federal requirements. Since it did not meet all of the tests, the state statute was not preempted.[220] Applying the rationale of the hearing aid cases to the California ECT Act, it seems clear that

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establish requirements for the fitting of hearing aids. Such an implied reservation of power was held to exist even where the state sought to require a disclaimer on the packaging in which hearing aids were sold, instead of including this in the instructional brochure accompanying the hearing aid, as specifically required by the federal regulation. Despite the fact that both the federal and state requirements dealt with labeling, the court found sufficient difference between the "instructional brochure" and "packaging" to distinguish the two schemes, thus finding that the federal requirements did not regulate every aspect of the area at issue. 651 F.2d at 1025. Similarly, in *Long*, the court held that key aspects of hearing aid dispensing sales practices regulated by the state were not preempted by FDA hearing aid regulations as "requirements applicable to devices" regulated by FDA. Noting that several of the state requirements concerned ethical practices in dispensing hearing aids, the court dismissed the preemption challenge to those state regulations banning the use of misleading professional titles by dispensers, mandating the posting of price lists, and prohibiting nonconsensual home visits by hearing aid dispensers, due to their "manifest inapplicability" to a device under section 521(a) and their total unrelatedness to any federal requirements. *Id.* at 576-79, 384 A.2d at 811-12. The New Jersey court stated that "[w]e interpret FDCA § 521(a) as expressly envisioning such supplemental state regulation insofar as it limits the definition of the state regulations it supersedes to state requirements 'applicable to' devices, thus permitting a wide variety of conceivable state regulations to remain unaffected." *Id.* at 577, 384 A.2d at 811.

215. *Id.* at 578-79, 384 A.2d at 812.

216. *Id.* at 580, 384 A.2d at 813.

217. *Id.* at 581, 384 A.2d at 813.

218. *Id.*

219. 78 Cal. App. 3d 951, 144 Cal. Rptr. 585 (1978).

220. *Kievlan*, 78 Cal. App. 3d at 958, 144 Cal. Rptr. at 590.

the result would be the same—no preemption.

The traditional express preemption clause analysis applied in these three cases seems inconsistent with the language of the federal preemption clause found in the Medical Device Amendments and with the expressed legislative intent behind the clause.[221] The House Committee's report on the Medical Device Amendments stated that there are some situations where state regulation would be a useful supplement to federal regulation, but a petition to the FDA would be required before supplementary regulation would be allowed.[222] There was no such petition made in the hearing aid cases, yet the state regulations were, in large part, sustained. Application of the dual compliance test, on the other hand, would have given consistent results. FDA regulations make it clear that the preemption clause is only effective after regulations have been developed for a specific medical device.[223] This suggests that the scope of the preemption clause extends only as far as the edges of medical device regulations. Absent federal regulation, state action is allowed by the express preemption clause of the Medical Device Amendments. Thus, had the courts compared the FDA hearing aid regulations[224] with the state regulations in the three hearing aid cases, the courts would have found that dual compliance was possible and would have upheld *all* of the state regulations.[225] Application of the "different from" or "in addition to" test promulgated in *Long* creates divergent results.[226] In *Long* a New Jersey court, citing the Supreme Court's holding in *Rath Packing*, disagreed with the contention that the New Jersey regulation was "different from" (frustrated the purpose of) the FDA regulation.[227] The dissent in *Rath Packing*, however, pointed out that "[t]he principle is thoroughly established that the exercise by the State of its police

221. The California Code provisions regulating the administration of ECT are comparable with the hearing aid regulations addressed in *Long*, *Pingree*, and *Kievlan*. A detailed statutory analysis of the California provisions and their relationship to the Medical Device Amendments is outside the scope of this article.

222. H. REP. 94-853, 94th Cong., 2d Sess. 45 (1976).

223. 21 C.F.R. § 808.1(d)(1)-(9) (1983). Although the FDA has stated an intent to reclassify the ECT device, Notice of Intent, 48 Fed. Reg. 14,578 (1983), this has not yet occurred. *Compare* Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta, 458 U.S. 141 (1982) (state limitation of a Federal Home Loan Bank Board regulation was invalid due to preemption).

224 21 C.F.R. §§ 801.420-.421.

225. In only one area would the cases differ, that is in the first section of the New Jersey regulations found to be preempted in *Long*. 75 N.J. at 578-79, 384 A.2d at 812.

226. *Id.* at 571-72, 384 A.2d at 808.

227. *Id.* at 576-81, 384 A.2d 811-13.

power, which would be valid if not superseded by federal action, is superseded only where the repugnance or conflict is so 'direct and positive' that the two acts cannot 'be reconciled or consistently stand together.' "[228] Since, as Justice Rehnquist's dissent indicates, the "state-law labeling requirements [in *Rath Packing*] are neither 'less stringent than' nor inconsistent with [the] federal requirements,"[229] the Court should hold that "Congress has not expressly prohibited state regulation in this field."[230] It is not necessary to argue the *Rath Packing* test from a dissenting vantage to reach the proposed result under the *Florida Lime* test because *Rath Packing* can easily be distinguished. The statute in *Rath Packing*, unlike the statutes involved in the Medical Device Amendments cases, did not provide a state exemption section. Yet, if the *Florida Lime* test of dual compliance is applied to these cases, the consistent use of precedent is obtained without the necessity of tedious distinctions.

As indicated previously, the use of traditional analysis in evaluating California's ECT Act results in a finding of no preemption. The use of the *Florida Lime* dual compliance test is preferable, however, because federal regulatory activity in the area of ECT concerns the safety of the equipment itself while the California regulation concerns the administration of ECT. The federal regulatory activity, particularly in light of the expressed policy against applying the preemption clause absent federal regulations, sets the limits and defines the scope of the federal regulation to which the California Act must be compared to determine whether dual compliance is possible. The California Act concerns patient consent and not standards.

The policy behind the dual compliance test is even more applicable to cases of implied preemption, where statements of intent to preempt are not nearly as clear as in express preemption cases. In implied preemption cases, state action will be tolerated until it becomes repugnant to federal regulation of the field. In *Belknap, Inc. v. Hale*,[231] the Court explained that although the implied preemption test in the labor field is whether the conduct at issue in the state litigation is arguably protected or prohibited by the National Labor Relations Act, state interest "deeply rooted in local law" may outweigh possible interference with the operation of the

228. *Rath Packing*, 430 U.S. at 544 (Rehnquist, J., dissenting).
229. *Id.*
230. *Id.*
231. 103 S. Ct. 3172 (1983).

National Labor Relations Board even if the traditional test is met.[232] The majority explained that in such cases, "[t]he state courts in no way offer . . . an alternative forum for obtaining relief that the Board can provide."[233] In *Belknap*, the state action was predicated on misrepresentation and breach of contract while the Board action focused on the protection of the rights of strikers. Yet, as the dissent vigorously argued, under the traditional preemption approach, "[t]he broad powers conferred by Congress upon the National Labor Relations Board to interpret and to enforce the complex Labor Management Relations Act . . . necessarily imply that potentially conflicting 'rules of law, of remedy, and of administration' cannot be permitted to operate."[234]

The issue regarding when a state may supplement federal regulation was artfully resolved in *Florida Lime*[235] by the Court's application of the dual compliance test. The test overcomes the problems associated with the *Hines* "frustration of federal purpose" test by disposing of the need to address such amorphous issues as legislative intent or purpose, dominant federal interest, or pervasiveness of legislation. "The test of whether both federal and state regulations may operate, or the state regulation must give way, is whether both regulations can be enforced without impairing the federal superintendence of the field, not whether they are aimed at similar or different objectives."[236] Unfortunately, the test has not been consistently applied.[237] As a result, courts have almost complete discretion in deciding cases according to their perceived political and social merits, instead of according to their jurisprudential merits.[238] To properly address the implied preemption issue, the Court must expressly overrule *Hines* and adopt the *Florida Lime* dual compliance test.

IV. THE TONIC

Although the political climate in the United States is favorable to the concept of New Federalism, many obstacles exist

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232. *Id.* at 3182.

233. *Id.* at 3182. *Cf.* Local 926, Int'l Union of Operating Eng'rs v. Jones, 103 S. Ct. 1453 (1983) (issue of whether employee is supervisor is for the Board).

234. 103 S. Ct. at 3193 (Brennan, J., dissenting) (quoting Vaca v. Sipes, 386 U.S. 171, 178-79 (1967)).

235. *See supra* notes 155-60 and accompanying text.

236. 373 U.S. at 142.

237. *Id.*

238. *See supra* note 40 and accompanying text.

in determining the appropriate federal and state roles. One of the ways that the federal government has thwarted state activity is through increased federal regulation. Many states have attempted to continue their traditional roles of protecting the health, safety, and welfare of their citizens by supplementing federal statutes and regulations with their own legislation in order to maximize the protection afforded their citizenry.

The federal courts have aided the expansion of the federal role through the development of preemption doctrines that are not only contrary to the concepts of "New Federalism", but are also so confusing that preemption challenges seem to be tried on an ad hoc basis. Separate doctrine has developed for situations in which Congress has expressly provided that regulation of a given field be limited to that of the federal government, and for those situations in which the courts have found an implied intent by Congress to so limit regulation of the field. In addition to doctrines of express and implied preemption, the courts have stated additional considerations for review of state regulation of matters of vital importance to them. All of these rules were developed and applied on an apparently situational basis.

A perceptible trend has developed in which the Supreme Court has attempted to accommodate both federal and state action wherever practicable. The problem with the trend is that it has been applied with an uncertain and inconsistent hand. The imprecision and unpredictability with which the doctrine has been applied is leading to litigation and relitigation of important issues of federal/state relations, and is impeding state activity where it is needed for the protection of citizens.

This article proposes a simple test. If Congress chooses to preempt an entire field, it should be required to do so expressly and precisely. In all other situations, when a state acts to supplement federal regulation, preemption should not be held to occur unless the party claiming preemption can show that "such actual conflict [exists] between the two schemes of regulation that both cannot stand in the same area . . . ."[239]

239. 373 U.S. at 141.