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Umpiring Agency Action Under National League Rules: Chaney v. Heckler

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COMMENTS

UMPIRING AGENCY ACTION UNDER *NATIONAL LEAGUE* RULES: *CHANEY V. HECKLER*

The scope of jurisdiction of an agency is defined by the act of Congress administered by the agency.[1] Such enabling legislation may confer broad constitutional power.[2] Since the Federal Food, Drug, and Cosmetic Act[3] was enacted pursuant to the Commerce Clause power, the Food and Drug Administration (FDA or Agency) may regulate any activity within the scope of the statute that could be reached by Congress through the Commerce Clause.[4] Although

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[1] *See, e.g.*, Mourning v. Family Publications Serv., 411 U.S. 356, 368-70 (1973) (upholding agency authority reasonably related to purpose of enabling statute); Pharmaceutical Mfrs. Ass'n v. FDA, 634 F.2d 106, 108 (3d Cir. 1980) (FDA power must be exercised pursuant to congressional objectives); *see also* F. HEFFRON & N. MCFEELEY, THE ADMINISTRATIVE REGULATORY PROCESS 99 (1983) (statute is the primary source for the creation of the agency).

[2] *See, e.g.*, NLRB v. Reliance Fuel Oil Corp., 371 U.S. 224, 226 (1963) (NLRB's jurisdiction is coterminous with the Commerce Clause). While Congress may legislate to the fullest extent of its constitutionally delegated powers, it need not do so in every case. Therefore, the jurisdiction of an agency is only as broad as Congress intends it to be when enacting the enabling legislation. *See, e.g.*, United States v. American Bldg. Maintenance Indus., 422 U.S. 271, 282-83 (1975) (congressional intent in delegating authority to Federal Trade Commission and Justice Department to administer Clayton Act is not as broad as allowed by the Commerce Clause of the Constitution) (modified by 15 U.S.C. § 18 (1982)).

[3] Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-392 (1982)).

[4] *E.g.*, 21 U.S.C. §§ 331 (1982). Section 331 of the FDCA prohibits:

> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

Id. § 331(a). The Commissioner of Food and Drugs has been delegated all the authority originally granted to the Secretary of Health and Human Services under the FDCA. *See* 21 C.F.R. § 5.10(a)(1) (1984).

The Commerce Clause of the United States Constitution grants Congress the powers to "regulate Commerce with Foreign Nations, and among the Several States, and with the Indian Tribes." U.S. CONST. art. I, § 8, cl. 3. The Commerce Clause serves a dual function: It operates as a source of national legislative power through its affirmative grant, and it represents a limit on the power of the states to burden interstate commerce through its negative implication. J. BARRON & C. DIENES, CONSTITUTIONAL LAW: PRINCIPLES AND POLICY 120 (2d

the authority of Congress to regulate commerce is broad, it is circumscribed by the rights reserved to the states by the tenth amendment.[5] Thus, if action proposed by an agency impinges upon traditional state functions, it may exceed the jurisdictional boundaries of the agency.[6] Recently, in *Chaney v. Heckler*[7], the Court of Appeals for the District of Columbia Circuit held that the FDA had jurisdiction to regulate the use of drugs by a state for human

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ed. 1982). Early Supreme Court decisions interpreted the Commerce Clause as a delegation of broad power. *See, e.g.*, Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 196-97 (1824). In *Gibbons*, the first Supreme Court interpretation of the Commerce Clause, Chief Justice Marshall described the Commerce Clause as granting Congress a power "complete in itself, [that] may be exercised to its utmost extent, and acknowledges no limitations, other than are prescribed in the constitution." *Id.* at 196. *See generally* F. FRANKFURTER, THE COMMERCE CLAUSE UNDER MARSHALL, TANEY AND WAITE 11-45 (1937) (discussing the impact of *Gibbons*). *Gibbons*, however, was a high-water mark for the Commerce Clause; subsequent Supreme Court interpretation took a much more restrictive approach. Schwartz, National League of Cities v. Usery—*The Commerce Power and State Sovereignty Redivivus*, 46 FORDHAM L. REV. 1115, 1118 (1978); *see, e.g.*, Hammer v. Dagenhart, 247 U.S. 251, 276-77 (1918) (Congress has no power to prevent interstate transport of goods produced by child labor), *overruled*, United States v. Darby, 312 U.S. 100 (1941).

Federal legislation based on the power to regulate commerce became more common after the Court abandoned the distinction between a "direct" and "indirect" effect on interstate commerce in favor of an inquiry into whether the legislation "affected" interstate commerce. Wright, *The Federal Courts and the Nature and Quality of State Law—From the Point of View of a Federal Judge*, in THE FUTURE OF FEDERALISM 58, 74 (S. Shuman ed. 1968). *See generally* Stern, *The Commerce Clause and the National Economy, 1933-1946*, 59 HARV. L. REV. 645, 662-63 (1946) (discussing direct-indirect distinction).

[5] *See, e.g.*, National League of Cities v. Usery, 426 U.S. 833, 851-52 (1976); *see* U.S. CONST. amend. X. The tenth amendment of the Constitution provides:

> The Powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

U.S. CONST. amend. X. At the beginning of the 20th century, the tenth amendment was construed as an affirmative limitation on the power of Congress to legislate. *E.g.*, Massachussetts v. Mellon, 262 U.S. 447, 479 (1923); *see* W. BENNETT, AMERICAN THEORIES OF FEDERALISM 201 (1964); E. CORWIN, THE CONSTITUTION AND WHAT IT MEANS TODAY 40-41 (10th ed. 1948). By the late 1930's, however, the opposite interpretation was applied. *See, e.g.*, United States v. California, 297 U.S. 175, 185 (1936) (Congress has unlimited power to regulate interstate commerce); *see also* E. CORWIN, *supra*, at 41 (reversal of tenth amendment analysis).

[6] *See* National League of Cities v. Usery, 426 U.S. 833, 851-52 (1976). The tenth amendment will operate to invalidate congressional legislation only in areas where the Commerce Clause is the source of the legislative power. *See* City of Rome v. United States, 446 U.S. 156, 178-79 (1980). Certain activities regulated pursuant to Commerce Clause power, however, are not affected by a tenth amendment analysis. Flax, *In the Wake of* National League of Cities v. Usery: *A "Derelict" Makes Waves*, 34 S.C.L. REV. 649, 671-82 (1983). When federal legislation has affected the proprietary activities of a state, *e.g.*, United Transp. Union v. Long Island R.R., 455 U.S. 678, 685-86 (1982), or has implicated matters of national scope, *e.g.*, EEOC v. Wyoming, 460 U.S. 226, 237-39 (1983), the Court has rejected tenth amendment claims.

[7] 718 F.2d 1174 (D.C. Cir. 1983), *cert. granted*, 104 S. Ct. 3532 (1984).

execution.[8]

In *Chaney*, eight condemned prison inmates petitioned the FDA to investigate the safety and effectiveness of the injection of FDA-approved drugs as a method of capital punishment.[9] The FDA asserted that it lacked jurisdiction and refused to take any action.[10] In addition, the Agency determined that even if it did have jurisdiction, it would deny regulation as a matter of its inherent discretion.[11] Plaintiffs subsequently filed suit in the United States District Court for the District of Columbia, seeking to compel the Agency to investigate and regulate the use of the drugs.[12] The district court granted summary judgment for the FDA.[13] De-

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[8] *Id.* at 1182.

[9] *Id.* at 1177. The prisoners' petition to the FDA asserted that, without FDA approval, state use of FDA-approved drugs—barbiturates and paralytics—as a means of execution violated the "new drug" and "misbranding" provisions of the FDCA. *Id.* The FDCA prohibits the introduction of a new drug into interstate commerce unless it has been granted a new-drug approval (NDA) by the FDA. 21 U.S.C. § 355(a) (1982). *See generally* OFFICE OF TECHNOLOGY ASSESSMENT, POSTMARKETING SURVEILLANCE OF PRESCRIPTION DRUGS 3-5 (1982). A drug is deemed misbranded if the label does not specify:

> (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions . . . where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users . . . .

21 U.S.C. § 352(f) (1982).

The misbranding claim in *Chaney* stemmed from the prisoners' assertion that use of the drugs in question posed a threat of an unnecessarily painful death. *See Chaney*, 718 F.2d at 1177 (citing ROYAL COMMISSION ON CAPITAL PUNISHMENT, 1949-1953, REPORT (1953)).

[10] *See* Joint Appendix at 86-89, Chaney v. Heckler, 718 F.2d 1174 (D.C. Cir. 1983). The jurisdiction of the FDA is dependent upon a "misbranding of the drugs under the FDCA." *See* 21 U.S.C. § 331(k) (1982). In addition, the FDA asserted that its jurisdiction did not extend to duly authorized state actions. *Chaney*, 718 F.2d at 1177.

[11] 718 F.2d at 1178. In addition to a lack of jurisdiction, the Commissioner cited two reasons for the refusal to take any action: the lack of uniform case law on the subject, and a finding that unapproved uses of approved drugs did not pose a significant danger to the public health where the use was pursuant to a valid state capital punishment statute. *Id.*

[12] *Id.* The original petition to the FDA contained five basic requests. *See id.* The petitioners urged that the FDA require a boxed warning to be affixed to the labels of the drugs used for execution, stating that the drugs were not approved, safe, or effective as a means of execution, and should not be used for that purpose. *Id.* In addition, the petitioners asked that the FDA send notices with the same warning to both the drug manufacturers and the state prison officials responsible for the administration of the drug. *Id.* The third specific request was for the FDA to place an article in the Drug Bulletin stating that the lethal injection of drugs is an unsafe method of execution. *Id.* The final two requests called for more rigorous action by the FDA. *See id.* The FDA was asked to formulate a procedure for the seizure and condemnation of drugs used for execution, and to seek the prosecution of prison officials who "knowingly buy, possess or use drugs for the unapproved use of lethal injections." *Id.*

[13] *Id.*

clining to rule on the jurisdictional issue, the district court held that the decision of the FDA to refrain from regulation was within the parameters of agency discretion and, therefore, beyond the scope of judicial review.[14] The Court of Appeals for the District of Columbia Circuit vacated and remanded the decision of the district court,[15] holding that the power of the FDA extended to the use of drugs by the states for executions.[16] The court found that the refusal by the FDA to exercise its statutory authority was reviewable,[17] and determined that the refusal was impermissible.[18]

Writing for the majority, Judge Wright determined that the jurisdiction of the FDA extended to the regulation of these drugs under the misbranding provisions of the Food, Drug, and Cosmetic Act.[19] In addition, the court found that judicial review of the enforcement discretion of the Agency was proper under the Adminis-

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[14] *Id.* It is submitted that the district court treated the action of the Agency with the deference that should be accorded to a separate branch of government. Therefore, the court found that the decision to refrain from taking action was within the enforcement discretion of the FDA and was unreviewable by the courts. *Id.* at 1178-79.

[15] *Id.* at 1177.

[16] *Id.* at 1182, 1191. The court ordered the FDA to "fulfill its statutory function," indicating that the FDA could be compelled to take action should it fail to give a prompt and acceptable explanation of its failure to do so. *Id.* at 1191. Courts derive their power to compel agency action from the Administrative Procedure Act (APA). *See* F. HEFFRON & N. MCFEELEY, *supra* note 1, at 293-94; *see also* Administrative Procedure Act § 10(e), 5 U.S.C. § 706(1) (1982) (granting courts the power to compel action by agency where unlawfully withheld or delayed).

[17] *Chaney*, 718 F.2d at 1188.

[18] *Id.* at 1192.

[19] *Id.* at 1181-82; *see* H.R. REP. No. 2139, 75th Cong., 3d Sess. 3 (1938) (Congress enacted § 331(k) to "extend the protection of consumers . . . to the full extent constitutionally permissible"). The *Chaney* court found that the use of FDA-approved drugs as a method of capital punishment fell within the jurisdictional ambit of § 331 of the FDCA. 718 F.2d at 1182.

Section 331 of the FDCA prohibits, in part:

> (b) The adulteration or misbranding of any . . . drug . . . in interstate commerce.
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> . . . .
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> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a . . . drug . . . if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such drug being adulterated or misbranded.

21 U.S.C. § 331(b), (k) (1982). The basis of the claim in *Chaney* that the actions of the states were within the jurisdiction of the FDA, was the FDA mandate prohibiting "the use of certain prescription drugs for a purpose not listed on their label." 718 F.2d at 1182. The court also held that the "practice-of-medicine" exception, which leaves the business of regulating state physicians in their practice of medicine to the states, *id.* at 1179, did not serve to immunize the activity of the states from the misbranding prohibition, *id.* at 1181.

trative Procedure Act (APA).[20] The scope of review, according to the majority, was limited to a determination of whether the action of the Agency was arbitrary or capricious.[21] Applying this standard, Judge Wright concluded that the inaction of the FDA was subject to judicial reversal because there was no rational basis for the decision not to regulate.[22]

In his dissent, Judge Scalia identified a general presumption of unreviewability with respect to agency enforcement discretion that was not rebutted under the facts of *Chaney*.[23] Adopting a narrow view of the scope of FDA authority, the dissent determined that jurisdiction could not be supported by any interpretation of

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[20] *Chaney*, 718 F.2d at 1188. The Administrative Procedure Act mandates that a court reviewing informal agency action review the whole record to determine if the agency has acted arbitrarily or capriciously. Administrative Procedure Act § 10(e), 5 U.S.C. § 706(2)(A) (1982); *see infra* note 44 and accompanying text.

[21] *Chaney*, 718 F.2d at 1188. In order to ascertain whether the Agency action was arbitrary and capricious, the court looked at "the facts relied upon [by the Agency], the other facts in the record, the relevant factors considered, and the available alternatives considered." *Id.* at 1189 n.38.

[22] *Id.* at 1189-90. In an earlier policy statement, the FDA had asserted that it intended to investigate and prevent *all* unapproved uses of FDA approved drugs, and no exception was made for state-authorized activities. *Id.* at 1189 & n.41. Noting this contradiction, Judge Wright indicated that the Commissioner is obligated to explain his refusal to act in light of this agency mandate. *Id.* at 1189; *see also* Kessler, *Regulating the Prescribing of Human Drugs for Nonapproved Uses Under the Food, Drug, and Cosmetic Act*, 15 HARV. J. ON LEGIS. 693, 709 (1978) (failure of agency to adopt the regulation indicates a "rethinking" is in order). *But see Chaney*, 718 F.2d at 1196-97 (Scalia, J. dissenting) (policy statement is not binding on FDA because it merely accompanied a proposed, but unadopted, rule).

The majority also addressed the possibility that unregulated execution by lethal injection would violate the eighth amendment prohibition of cruel and unusual punishment. *Id.* at 1191. The court postulated that misapplication of the drugs could result in a cruel and protracted death. *Id.* Recently, the Supreme Court intimated that a majority of the Court would not hold execution by lethal injection unconstitutional. *See* Gray v. Lucas, ___ U.S. ___, 104 S. Ct. 211, 216 (1983) (Marshall, J., dissenting from denial of certiorari). Indeed, lethal injection has been cited as the method least likely to be cruel and unusual. *See* Gardner, *Executions and Indignities—An Eighth Amendment Assessment of Methods of Inflicting Capital Punishment*, 39 OHIO ST. L.J. 96, 129 (1978).

[23] *Chaney*, 718 F.2d at 1192-93 (Scalia, J., dissenting). Judge Scalia determined that the presumption of reviewability applicable to most types of agency action is not applicable to an exercise of enforcement discretion. *Id.* at 1192 (Scalia, J., dissenting) (citing Kixmiller v. SEC, 492 F.2d 641, 645 (D.C. Cir. 1974)). The rationale for this presumption of unreviewability, the dissent contended, was that the courts should defer to the expertise of the Agency in formulating policy. *Chaney*, 718 F.2d at 1192 (Scalia, J., dissenting) (citing Moog Indus. v. FTC, 355 U.S. 411, 413 (1958)). The reason for the majority's interference with the enforcement discretion of the FDA in this instance, Judge Scalia contended, was "the majority's disagreement with the agency's determination that no serious danger to the public health exists." 718 F.2d at 1197 (Scalia, J., dissenting).

the misbranding provisions of the Act.[24]

It is submitted that the affirmative response given by the court to the issue raised in *Chaney*—whether the FDA may exercise jurisdiction over the use of lethal drugs for executions—implicates an intrusion into a traditional area of state sovereignty. Indeed, the concern of the FDA with impinging upon the exercise of a fundamental state power was a factor in its original refusal to regulate.[25] Therefore, it is suggested that the possible intrusion of the rights reserved to the states by the tenth amendment should have been considered the primary factor in the subsequent judicial determination of whether the Agency had abused its discretion. This Comment will examine the permissible extent of commerce regulation in areas traditionally regulated by state government, and will suggest that the decision of the FDA to decline to exercise jurisdiction should have been upheld as within the discretionary power of the Agency.

Tenth Amendment Limits on Federal Agency Jurisdiction

It is indisputable that the congressional mandate to the FDA to prohibit the misbranding of drugs in interstate commerce is valid.[26] However, the existence of an effect on interstate commerce is not sufficient alone to create agency jurisdiction. Where the commerce power is invoked in an attempt to regulate the states as states, the tenth amendment may operate to limit the exercise of Commerce Clause power.[27]

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[24] *Chaney*, 718 F.2d at 1198-99 (Scalia, J., dissenting). FDA jurisdiction does not extend, Judge Scalia reasoned, to drugs in possession of state penal authorities, since the drugs could not be deemed held for sale, a statutory prerequisite to agency action under § 331(k) of the FDCA. *Id.* at 1199 (Scalia, J., dissenting); *see supra* note 19. The dissent argued that the condemned prisoner executed by injection "is no more the 'consumer' of the drug than is the prisoner executed by firing squad a consumer of the bullets." 718 F.2d at 1200 (Scalia, J., dissenting).

[25] *See infra* note 46 and accompanying text.

[26] *See* United States v. Sullivan, 332 U.S. 689, 697-98 (1948); United States v. Walsh, 331 U.S. 432, 437-38 (1947); *cf.* McDermott v. Wisconsin, 228 U.S. 115, 131-32 (1913) (upholding constitutionality of the Food and Drugs Act of 1906). In *Sullivan*, the Court determined that Congress could prohibit the misbranding of articles shipped in interstate commerce as a proper exercise of the power granted to it by the Commerce Clause. 332 U.S. at 697-98.

[27] *See* National League of Cities v. Usery, 426 U.S. 833, 842 (1976); *see also* United States v. California, 694 F.2d 1171, 1175 n.7 (9th Cir. 1982) (tenth amendment is an "affirmative external limitation on federal legislation otherwise within the commerce power"); *infra* notes 28-30 and accompanying text.

In *National League of Cities v. Usery*,[28] the Supreme Court held that amendments to the Fair Labor Standards Act, which mandated federal wage protection for state employees, were impermissible intrusions upon the states in violation of the tenth amendment.[29] Although Congress was empowered under the Commerce Clause to legislate in the area of wages, the *National League of Cities* majority determined that the tenth amendment restrained that power when it impinged on state sovereignty.[30]

Subsequent decisions construing *National League of Cities*

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[28] 426 U.S. 833 (1976).

[29] *Id.* at 852. In *National League of Cities*, the Court held that certain sections of the 1974 amendments to the Fair Labor Standards Act (FLSA) were unconstitutional intrusions upon the "[s]tates' freedom to structure integral operations in areas of traditional governmental functions." *Id.* The *National League of Cities* majority considered the effect of the 1974 amendments on the state police and fire departments. *Id.* at 850. As part of the holding, the Court overruled an earlier decision, Maryland v. Wirtz, 392 U.S. 183 (1968), which held that the FLSA could extend to state school and hospital employees. *See* 426 U.S. at 855.

It is as yet unclear what constitutes "integral operations in areas of traditional [state] governmental functions." *See* EEOC v. Wyoming, 460 U.S. 226, 238 n.11 (1983); *see also* Kramer v. New Castle Area Transit Auth., 677 F.2d 308, 309 (3d Cir. 1982) *(National League of Cities* affords little guidance as to definition of traditional governmental function), *cert. denied*, 103 S. Ct. 786 (1983). It is clear, however, that the *National League of Cities* Court did not limit the concept to employer-employee relations. *See National League of Cities*, 426 U.S. at 851 n.16. Some Supreme Court decisions have indicated that zoning laws "are peculiarly within the province of state and local legislative authorities." *E.g.*, Warth v. Seldin, 422 U.S. 490, 508 n.18 (1975); *cf.* Village of Belle Terre v. Boraas, 416 U.S. 1, 7-9 (1974) (upholding village ordinance restricting land to one-family dwellings). In addition, the administration of state prison facilities has been recognized as a state function. *See* Johnson v. Avery, 393 U.S. 483, 486 (1969); *infra* note 55 and accompanying text.

For several years preceding *National League of Cities*, a number of cases decided by the Supreme Court foreshadowed a new concern for state sovereignty. *See* Tribe, *Unraveling* National League of Cities: *The New Federalism and Affirmative Rights to Essential Government Services*, 90 HARV. L. REV. 1065, 1068-69 & nn.18-20 (1977) (citing cases). A footnote in Fry v. United States, 421 U.S. 542 (1975) (Marshall, J.), has been cited as the first recognition since the 1930's of a tenth amendment claim. *See* Matsumoto, National League of Cities—*From Footnote to Holding—State Immunity from Commerce Clause Regulation*, 1977 ARIZ. ST. L.J. 35, 36 (citing Fry v. United States, 421 U.S. 542, 547 n.7 (1975)); Note, *Federal Grants and the Tenth Amendment: "Things as They Are" and Fiscal Federalism*, 50 FORDHAM L. REV. 130, 141 n.57 (1981). Justice Marshall, writing for the Court in *Fry*, understood the tenth amendment to prevent Congress from exercising its "power in a fashion that impairs the States' integrity or their ability to function effectively in a federal system." *Fry*, 421 U.S. at 547 n.7.

[30] *National League of Cities*, 426 U.S. at 845. In United States v. California, 297 U.S. 175 (1936), the Court, commenting on the Commerce Clause, maintained that there is no "limitation upon the plenary power [of Congress] to regulate commerce. The state can no more deny the power if its exercise has been authorized by Congress than can an individual." *Id.* at 185. The *National League of Cities* Court held that this broad dictum was "simply wrong." 426 U.S. at 854-55; *see supra* note 5 and accompanying text.

have dismissed challenges to Congress' power to regulate in areas of state concern.[31] In *Hodel v. Virginia Surface Mining & Reclamation Association*,[32] the Court, although it upheld the challenged federal legislation, reaffirmed the three elements necessary to establish a tenth amendment limitation on the exercise of congressional power.[33] First, the federal legislation at issue must regulate the "States as States;"[34] second, it must concern matters that are "indisputably 'attributes of state sovereignty;' "[35] and third, state compliance with the federal law must impair the ability of the state " 'to structure integral operations in areas of traditional governmental functions.' "[36] However, even if these three inquiries are satisfied, the legislation may be upheld if "the nature of the federal interest advanced" is sufficiently compelling to require regulation.[37]

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[31] *See, e.g.*, EEOC v. Wyoming, 460 U.S. 226, 238 n.11 (1983); Hodel v. Virginia Surface Mining & Reclamation Ass'n, 452 U.S. 264, 292-93 (1981); *see also* Bonnette v. California Health & Welfare Agency, 704 F.2d 1465, 1471-72 (9th Cir. 1983) (citing cases construing *National League of Cities*); *infra* notes 32-42 and accompanying text.

[32] 452 U.S. 264 (1981).

[33] *Id.* at 287-88. *Hodel* involved the Surface Mining Control and Reclamation Act of 1977, which was enacted to regulate the deleterious effects of surface coal mining. Pub. L. No. 87, § 102, 91 Stat. 445, 448 (codified as amended at 30 U.S.C. §§ 1201-1328 (1982)). Section 501 of the Act provides that the states must adopt certain federally established standards controlling surface mining. *Id.* § 1251. Section 503 of the Act provides that a state wishing to regulate surface coal mining operations must institute a program containing the federal standards. *Id.* § 1253. When a private association of coal miners and individual landowners filed suit in district court seeking injunctive relief against the Act, the state of Virginia intervened as plaintiffs. *Hodel*, 452 U.S. at 273. The state charged, among other grounds, that the Act violated the tenth amendment. *Id.* The district court held that the Act displaced integral state functions and, therefore, contravened the tenth amendment. *Id.* at 274. The Supreme Court reversed the decision of the district court. *Id.* at 290-91.

[34] *Id.* at 287 (quoting *National League of Cities*, 426 U.S. at 854). The *Hodel* Court reaffirmed the distinction noted in *National League of Cities* between congressional regulation of private persons and business, and " 'federal regulation directed . . . to the States as States.' " *Id.* at 286 (quoting *National League of Cities*, 426 U.S. at 845). In *Hodel*, the states could opt to avoid regulation of private coal miners, and the regulatory burden would be on the federal government. *Id.* at 288. This was not a regulation of the states directly, as the legislation established, at most, "a program of cooperative federalism." *Id.* at 289.

[35] 452 U.S. at 287-88 (quoting *National League of Cities*, 426 U.S. at 845). The *Hodel* Court held that no "indisputable attribute" of state sovereignty is implicated when Congress enacts a statute preempting state regulation of private activities affecting interstate commerce. *Id.* at 287-88, 290 (quoting *National League of Cities*, 426 U.S. 833, 845 (1976)).

[36] 452 U.S. at 288 (quoting *National League of Cities*, 426 U.S. at 852). The State of Virginia contended that enforcement of the federal requirements would adversely affect the economy of the state. 452 U.S. at 292 n.33. The *Hodel* Court, citing *National League of Cities*, rejected this economic theory, focusing instead on the nature of the federal action. *Id.*

[37] 452 U.S. at 288 n.29. Since the challenged legislation in *Hodel* did not satisfy the

In *Federal Energy Regulatory Commission v. Mississippi*,[38] the Court held that the tenth amendment did not prevent Congress from imposing a duty upon the states to consider federal standards when operating state power utilities.[39] The majority adopted the balancing test identified by Justice Blackmun in his concurring opinion in *National League of Cities*.[40] This test is designed to examine the importance of the federal interest and to allow federal regulation in those instances in which the interest is sufficiently compelling to justify the interference with state sovereignty.[41]

In *EEOC v. Wyoming*,[42] the Court upheld the constitutionality of the Age Discrimination in Employment Act of 1967.[43] The Court held that the act did not impair the ability of the states to struc-

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three-prong test formulated by the *National League of Cities* majority, no analysis was made of the statute under this factor. *See id.* at 287-90; *infra* note 41.

The notion that an overwhelming federal interest may overcome an otherwise valid tenth amendment challenge was identified by Justice Blackmun in a concurring opinion to *National League of Cities*. *See* National League of Cities v. Usery, 426 U.S. 833, 856 (1976) (Blackmun, J., concurring). When a state function is found to conflict with an overwhelming federal interest in the areas of environmental protection, *see* Friends of the Earth v. Carey, 552 F.2d 25, 37 (2d Cir.), *cert. denied*, 434 U.S. 902 (1977), national energy policy, *see* FERC v. Mississippi, 456 U.S. 742, 765 (1982), or state proprietary activities, *see* United Transp. Union v. Long Island R.R., 455 U.S. 678, 685 (1982), the states have been required to yield. *See* Flax, *supra* note 6 at 671-82; *supra* note 6 and accompanying text.

[38] 456 U.S. 742 (1982).

[39] *Id.* at 765. In *FERC v. Mississippi*, the Court was asked to review the constitutionality of the Public Utility Regulator Policies Act of 1978 (PURPA), *id.* at 742, a system of legislation directed, in part, at state-run power facilities, *id.* at 743. PURPA requires a state regulatory authority to consider six methods of determining utility rates. 16 U.S.C. § 2621(a), (d) (1982). The state is not required to adopt these federal standards. *Id.* § 2621(a). Another challenged section requires the states to consider the adoption of federal standards concerning restrictions on the distribution of electrical service. *Id.* § 2623. The State of Mississippi challenged PURPA on both Commerce Clause and tenth amendment grounds. 456 U.S. at 752. The Court held that the power of Congress to regulate state-operated power utilities was within the ambit of the Commerce Clause, *id.* at 753, and rejected the claim that PURPA intruded on state sovereignty in violation of the tenth amendment, *id.* at 765. The Court reasoned that since Congress could totally preempt the states in regulating power utilities, *id.*, a less-intrusive system whereby the states merely were forced to consider federal standards was constitutionally permissible, *id.* at 765-66.

[40] 456 U.S. at 764 n.28. The *Mississippi* Court also had reiterated the *National League of Cities* test. *See id.*

[41] *See National League of Cities*, 426 U.S. at 856 (Blackmun, J., concurring). Justice Blackmun's concurrence in *National League of Cities* viewed the majority opinion as embodying a balancing test. *See id.* In subsequent Supreme Court decisions, this balancing of federal and state power has been cited as a separate requirement. *E.g.*, Hodel v. Virginia Surface Mining & Reclamation Ass'n, 452 U.S. 264, 288 n.29 (1981).

[42] 460 U.S. 226 (1983).

[43] *Id.* at 235.

ture integral operations.[44] Although it was not necessary to reach the issue, the Court indicated that even if the first three prongs of the *National League of Cities* test were satisfied, the balancing test would mandate state submission.[45]

Although successful tenth amendment challenges remain rare,[46] it is submitted that the Court has not retreated entirely from the spirit of *National League of Cities*. Thus, *National League of Cities* and its progeny serve as a guide in circumscribing the power of a federal agency to regulate in an area protected by the tenth amendment.[47] Therefore, it is suggested that an agency must take into account the impact of federal regulation on the ability of the states to structure their internal affairs. A subsequent judicial review of the action of the agency should weigh that consideration as an element in determining whether the decision of the agency was within the scope of its discretion.[48] Thus, it is sub-

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[44] *Id.* at 234-35.

[45] *Id.* at 235 n.17.

[46] *E.g.*, EEOC v. Wyoming, 460 U.S. 226, 236-39 (1983); FERC v. Mississippi, 456 U.S. 742, 761 (1982); Hodel v. Virginia Surface Mining & Reclamation Ass'n, 452 U.S. 264, 287-88 (1981); *see* Howard, *Judicial Federalism: The States and the Supreme Court*, in AMERICAN FEDERALISM, A NEW PARTNERSHIP FOR THE REPUBLIC 215, 221-22 (R. Hawkins, Jr. ed. 1982); *The Supreme Court, 1981 Term*, 96 HARV. L. REV. 62, 186-87 (1982).

The Supreme Court cases decided subsequent to *National League of Cities* demonstrate that a significant erosion of congressional power to legislate in areas of national importance, foreseen by some commentators, *see, e.g.*, Comment, *Redefining the* National League of Cities *State Sovereignty Doctrine*, 129 U. PA. L. REV. 1460, 1469 (1981), did not occur.

[47] *See supra* notes 30-31 and accompanying text.

[48] *See* Bowman Transp., Inc. v. Arkansas-Best Freight Sys., 419 U.S. 281, 285 (1974); Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 401, 416 (1971); Wong Wing Hang v. INS, 360 F.2d 715, 718 (2d Cir. 1966). *See generally* L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE ACTION 180-83 (1965) (review of discretion mandates analysis of factors considered by the agency).

Discretion has been defined as the "power to make a choice within a class of actions." *Id.* at 359. A refinement of this definition describes discretion as "an individualized application of administrative judgment which allows a variable response and solution to problems evolving from changing conditions." E. FOLLICK, THE ELEMENT OF DISCRETION INHERENT IN ADMINISTRATIVE ADJUDICATION 3 (1967). The element of discretion vested in an administrator has been the subject of scholarly scrutiny. *See, e.g.*, K. DAVIS, DISCRETIONARY JUSTICE: A PRELIMINARY INQUIRY (1969); Note, *Judicial Review of Administrative Inaction*, 83 COLUM. L. REV. 627 (1983).

Section 10(e) of the APA directs a reviewing court to set aside agency action that is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) (1982). Section 10(a) of the APA, however, provides that judicial review is unavailable to the extent that "agency action is committed to agency discretion by law." *Id.* § 701(a)(2). Agency action is defined as "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to

mitted that the task of the court should be limited to a determination of whether, on the facts of a given case, the tenth amendment was a legitimate factor for the agency to consider. If the court determines that the decision of the agency to exercise its discretion based upon tenth amendment concerns was not arbitrary and capricious, the decision should be upheld.[49] Under this analysis, *National League of Cities* can remain a vital factor in structuring federal-state relations by preventing federal agency regulation in areas properly left to the states.

Consideration of the Tenth Amendment in Chaney v. Heckler

In *Chaney*, there was an indication that concern for interference with traditional state functions was a factor in the decision of the Agency to decline to regulate the drugs in issue.[50] In her initial letter to the plaintiffs, the Commissioner referred to the use of lethal injections as " 'duly authorized statutory enactments [that furthered] . . . proper state functions.' "[51] The *Chaney* majority interpreted this statement as an assertion by the FDA that it lacked jurisdiction in any area licensed by the state.[52] To counter this argument, the *Chaney* court cited several state-licensed activities within the jurisdictional reach of the FDA.[53] Thus, the court dis-

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act." *Id.* § 551(13). There is no legal distinction between inaction and action in the enforcement discretion context. Note, *supra*, at 633-34. Although the conciliation of § 10(e) with § 10(a) has prompted much scholarly debate, New York Racing Ass'n v. NLRB, 708 F.2d 46, 50 (2d Cir.), *cert. denied*, 104 S. Ct. 276 (1983), the suggestion that "agencies have untrammeled authority to act in areas committed to agency discretion reflect[s] a position that has been increasingly restricted, if not nullified" by courts considering the provisions of the APA authorizing judicial review, Suwannee S.S. Co. v. United States, 354 F. Supp. 1361, 1368 (Cust. Ct. 1973).

In *Chaney*, the majority properly reviewed the exercise of discretion by the FDA, searching for the relevant factors considered by the agency. *See Chaney*, 718 F.2d at 1189 n.38.

[49] *See supra* note 44 and accompanying text.

[50] *See Chaney*, 718 F.2d at 1178. The original letter in response to the prisoners' petition stated that the Agency would not take action if the alleged risk of harm to the public health resulted from state enactment of lethal injection laws. *Id.*

[51] *Id.*

[52] *See id.* at 1179-80.

[53] *Id.* at 1180. The *Chaney* majority pointed to the regulation of drugs by the FDA in prison clinical investigations and veterinary practices. *Id.*; *see* United States v. Beauthanasia-D. Regular, [1979 Transfer Binder] FOOD DRUG COSM. L. REP. (CCH) D 38,265 (D. Neb. 1979) (regulation of veterinarians' use of drugs); 21 C.F.R. § 50.44 (1984) (regulation of prison clinical investigations). It is submitted that the court's discussion of state-licensed activities is inapposite since the administration of state prison facilities is more than merely licensed by the state. These activities are an integral state function, subject to federal inter-

missed the letter as a mere "glib statement."[54] It is submitted, however, that an alternative interpretation of the Commissioner's statement is feasible. The letter could have been read as a finding by the FDA that the regulation of drugs used in state executions would be an unwarranted interference with state activities protected by the tenth amendment.[55] Under the facts of *Chaney*, it is submitted, the tenth amendment was a legitimate factor to consider, and, therefore, the action of the FDA should have been upheld as within its discretionary power.

There is no direct federal legislation or agency regulation governing the use of lethal injections by the states as a means of capital punishment; thus, there is no issue of federal preemption.[56] Pervasive regulation by the FDA in this area, it is submitted, would satisfy the first three prongs of the *National League of Cities* test. That is, it is the state alone that is responsible for the administration of capital punishment for violation of state law.[57] Any regulation of this function, therefore, would necessarily regu-

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ference only in extraordinary circumstances. *See* Johnson v. Avery, 393 U.S. 483, 486 (1969); *infra* note 53 and accompanying text.

[54] *Chaney*, 718 F.2d at 1191. The *Chaney* majority focused on the arguments that the FDA offered on appeal. *Id.* at 1179. Rather than focusing on the subsequent arguments offered by counsel, the court should have focused its examination on the Commissioner's letter in response to the prisoners' request. *See* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., ___ U.S. ___, 103 S. Ct. 2856, 2870 (1983) (agency action must be upheld on basis articulated by agency, not *post hoc* rationalizations of counsel); Burlington Truck Lines v. United States, 371 U.S. 156, 168-69 (1962) (*post hoc* rationalizations inadequate for review); *cf.* Rockford League of Women Voters v. United States Nuclear Regulatory Comm'n, 679 F.2d 1218, 1220 (7th Cir. 1982) (informal action that does not compile formal record adequate for review may necessitate reconstruction of informal record). *See generally* K. DAVIS, ADMINISTRATIVE LAW TEXT § 16.09 (3d ed. 1972) (discussing findings and reasons requirement).

[55] *See supra* text accompanying note 46.

[56] *See Chaney*, 718 F.2d at 1181 n.18. If a conflict exists between federal and state law, the Supremacy Clause of the Constitution ensures that the federal law will prevail. U.S. CONST. art. VI, cl. 2. *See generally* W. LOCKHART, Y. KAMISAR & J. CHOPER, THE AMERICAN CONSTITUTION: CASES AND MATERIALS 239-47 (5th ed. 1981) (discussing preemption). Congressional intent to preempt state law, however, is not lightly inferred. *See* Maurer v. Hamilton, 309 U.S. 598, 615-17 (1940). Thus, an effort is made to construe seemingly conflicting legislation in harmonious manner. However, since the FDCA has been given a broad construction by the Supreme Court, it is likely that conflicting state legislation would be deemed preempted. *See* United States v. Sullivan, 332 U.S. 689, 693 (1948).

[57] *See* Johnson v. Avery, 393 U.S. 483, 486 (1969); Jackson v. Taylor, 539 F. Supp. 593, 595 (D.D.C. 1982), *aff'd*, 713 F.2d 865 (D.C. Cir. 1983); Jordan v. Mills, 473 F. Supp. 13, 18 (E.D. Mich. 1979); *cf.* Perez v. United States, 402 U.S. 146, 158 (1971) (Stewart, J., dissenting) (definition and prosecution of state criminal acts is beyond scope of congressional power and is reserved to the states by ninth and tenth amendments.).

late the states as states.[58] In addition, federal regulation of the administration of state criminal justice systems would encroach on areas of traditional state functions,[59] and, consequently, undue regulation in this area would seriously impair the ability of the state to structure prison operations.[60] Although it is conceivable that certain regulations would not impair the ability of the states to structure integral operations, the court should limit its focus to the propriety of the consideration of the tenth amendment by the Agency.[61] The alternative interpretation of the Commissioner's letter proposed by this Comment demonstrates that the possibility of interference with state sovereignty was taken into account by the Agency.[62] The decision of the FDA could have been found to be within its discretionary powers and, therefore, should have been

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[58] *See* Hodel v. Virginia Surface Mining & Reclamation Ass'n, 452 U.S. 264, 287-88 (1981); National League of Cities v. Usery, 426 U.S. 833, 845 (1976); Jordan v. Mills, 473 F. Supp. 13, 18 (E.D. Mich. 1979). Any regulation controlling state use of drugs would be distinguished from a situation where, as in *Hodel*, the regulation was primarily directed at individual citizens. 452 U.S. at 287-88. It is submitted that a regulation directed at the method of capital punishment would have to address the states as states, since they are the entities that run the state penal systems. *See* Jackson v. Taylor, 539 F. Supp. 593, 595 (D.D.C. 1982) (administration of state prison is a "primary governmental function"), *aff'd*, 713 F.2d 865 (D.C. Cir. 1983).

[59] *See* Jordan v. Mills, 473 F. Supp. 13, 14-18 (E.D. Mich. 1979). In *Jordan v. Mills*, a state prison inmate charged the administrators of a state prison with federal antitrust violations. *Id.* at 14. Recognizing the traditional state function involved, the court employed the *National League of Cities* rationale to find that the prison administrators were immune from suit. *Id.* at 17-19. The district court considered the relationship of *National League of Cities* to the federal antitrust laws. *Id.* The court noted that the antitrust laws, as such, were not explicitly directed at the states. *See id.* at 18. The states and their subsidiaries may be subject to the antitrust laws, *id.* (citing City of Lafayette v. Louisiana Power & Light Co., 435 U.S. 389, 394-97 (1978)), although a "state action" exemption has been articulated by the judiciary, *see, e.g.*, Parker v. Brown, 317 U.S. 341, 350-51 (1943). The *Jordan* court held that if the exemption is inapplicable, a *National League of Cities* analysis should follow. 473 F. Supp. at 18. Although the challenged action in *Jordan* was directed at the prices in a prison store, it was found to be connected to an integral state function. *Id.* The court held, therefore, that the prisoner's action could not be maintained. *Id.* at 19. It is submitted that *Jordan* implies that all aspects of prison administration, although otherwise categorized as a proprietary activity, are so bound up in traditional governmental functions as to make them unreachable by federal statute. *Id.* at 18-19; *see also* Jackson v. Taylor, 539 F. Supp. 593, 595 (D.D.C. 1982) (wide latitude should be given to state prison administrators), *aff'd*, 713 F.2d 865 (D.C. Cir. 1983).

[60] *See* Jordan v. Mills, 473 F. Supp. 13, 18-19 (E.D. Mich. 1979).

[61] *See supra* note 44. It is not inconceivable that a mere advisory warning affixed to the label, analogous to the forced contemplation of standards upheld in FERC v. Mississippi, 456 U.S. 742, 765 (1982), would not unduly interfere with administration of the prison, and, therefore, would be upheld as a permissible regulation.

[62] *See supra* notes 46-47 and accompanying text.

affirmed.[63]

CONCLUSION

The issue considered in *Chaney v. Heckler* presented an opportunity for the FDA to infringe upon the rights of the states protected by the tenth amendment. Implicitly recognizing this potential, the FDA declined to exercise jurisdiction over the subject matter involved. By failing to recognize the implication of tenth amendment concerns, the *Chaney* court has effectively required the FDA to trespass upon a traditional state function.

Michael C. DeLisa

[63] *See supra* notes 54-59 and accompanying text.