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Administrative Law: FDA Jurisdiction and Enforcement Discretion Regarding State-Mandated Use of Lethal Drugs for Capital Punishment

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ADMINISTRATIVE LAW: FDA JURISDICTION AND ENFORCEMENT DISCRETION REGARDING STATE-MANDATED USE OF LETHAL DRUGS FOR CAPITAL PUNISHMENT—*Chaney v. Heckler*, 718 F.2d 1174 (D.C. Cir. 1983), *cert. granted*, 104 S. Ct. 3532 (1984) (No. 83-1878).

I. INTRODUCTION

Several states have recently enacted statutes mandating the use of lethal injections for human executions.[1] Controversy regarding these statutes has surfaced, however, because the Food and Drug Administration (FDA) has not approved the use of such drugs for human execution.[2] In *Chaney v. Heckler*,[3] the United States Court of Appeals for the District of Columbia confronted this issue and determined not only that the FDA has jurisdiction over a state's use of drugs for lethal injections,[4] but also that the FDA *must* either investigate such use and take appropriate regulatory action or give clear and convincing reasons for declining to exercise its enforcement powers.[5]

Although the court's goal of ensuring that death row prisoners are not subjected to a cruel death may be admirable, the *Chaney* decision is a major departure from prior case law on both the jurisdictional and the enforcement discretion issues. This note will examine the court's rationale and its failure to satisfactorily resolve the constitutional questions concerning federalism and separation of powers involved in *Chaney v. Heckler*.

II. FACTS AND HOLDING

Eight Texas and Oklahoma prison inmates, who were sentenced to

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1. *See, e.g.*, TEX. STAT. ANN. art. 43.14 (Vernon 1979 & Supp. 1984), which provides that "[w]henever the sentence of death is pronounced against a convict, the sentence shall be executed . . . by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death and until such convict is dead."

Similarly, OKLA. STAT. ANN. tit. 22, § 1014(A) (West Supp. 1983) mandates that "[t]he punishment of death must be inflicted by continuous, intravenous administration of a lethal quantity of an ultrashort-acting barbiturate in combination with a chemical paralytic agent until death is pronounced by a licensed physician."

At least three other states have adopted similar statutes authorizing lethal injections as the method used for human executions. *See*, IDAHO CODE § 19-2716 (1979 & Supp. 1984); N.M. STAT. ANN. § 31-14-11 (Supp. 1983); WASH. REV. CODE ANN. § 10.95.180 (Supp. 1984–1985).

2. See *infra* note 22 for the procedures by which "new drugs" may be approved by the FDA.

3. 718 F.2d 1174 (D.C. Cir. 1983), *cert. granted*, 104 S. Ct. 3532 (1984) (No. 83-1878).

4. *Id.* at 1182.

5. *Id.* at 1190–91.

death by lethal injection, petitioned the FDA[6] to take investigatory and enforcement action to prevent the use of certain drugs in implementing the death penalty.[7] The inmates contended that the states' use of these drugs violated the "new drug"[8] and "misbranding"[9] provisions of the Federal Food, Drug, and Cosmetic Act[10] (FDCA). The commissioner of the FDA refused to take any action, claiming that the FDA lacked jurisdiction in this situation.[11] The commissioner further argued that, even if the FDA had jurisdiction to regulate such use, the refusal to act on the inmates' petition was within the FDA's enforcement discretion.[12]

The plaintiffs then filed an action in the United States District Court for the District of Columbia to compel the FDA to conduct evidentiary hearings for the purpose of determining whether the statutes in question[13] violated the provisions of the FDCA.[14] The district court granted summary judgment for the FDA, holding that the denial of the plaintiffs' petition was a valid exercise of the agency's discretion.[15]

The plaintiffs appealed to the United States Court of Appeals for the District of Columbia Circuit, which vacated the district court's decision and remanded the case for further proceedings.[16] In so ruling, the court held that the FDA had jurisdiction to regulate the states' use of prescription drugs for lethal injections.[17] Additionally, the court determined that the FDA abused whatever enforcement discretion it may have had by "arbitrarily and capriciously refus[ing] to exercise its reg-

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6. Citizens' petitions to the FDA are governed by 21 C.F.R. § 10.30 (1984).

7. Chaney v. Heckler, 718 F.2d 1174, 1177 (D.C. Cir. 1983), *cert. granted*, 104 S. Ct. 3532 (1984) (No. 83-1878). The inmates specifically requested that the FDA take action to: (1) place warnings on the boxes of drugs involved, stating that such drugs had not been approved for use as a means of human execution; (2) send similar notice to the manufacturers of those drugs and the state prison systems involved; (3) place a similar warning in the Drug Bulletin; (4) set up procedures whereby drugs earmarked for use in lethal injections would be seized and condemned by the FDA; and (5) recommend prosecution of those parties who knowingly sell or buy such drugs for use as lethal injections. *Id.* at 1178.

8. *See infra* note 21.

9. *See infra* note 24.

10. 21 U.S.C. §§ 301–392 (1982).

11. *Chaney*, 718 F.2d at 1177.

12. *Id.*

13. See *supra* note 1 for the pertinent text of the Texas and Oklahoma statutes at issue.

14. Chaney v. Schweiker, [1982–1983 Transfer Binder] FOOD DRUG COSM. L. REP. (CCH) ¶ 38,184, at 39,031 (D.D.C. Aug. 30, 1982), *vacated*, 718 F.2d 1174 (D.C. Cir. 1983), *cert. granted*, 104 S. Ct. 3532 (1984).

15. *Chaney*, [1982–1983 Transfer Binder] FOOD DRUG COSM. L. REP. (CCH) ¶ 38,184, at 39,037. In so holding, the district court noted that "decisions of . . . agencies to *refrain* from instituting investigative and enforcement proceedings are essentially unreviewable by the courts." *Id.* at 39,035 (citations omitted) (emphasis in original). Because this holding was dispositive of the case, the trial court declined to review the jurisdictional issue. *Id.* at 39,035–36.

16. *Chaney*, 718 F.2d at 1192.

17. *Id.* at 1182.

ulatory jurisdiction."[18]

III. ANALYSIS

A. *FDA Jurisdiction*

The Federal Food, Drug, and Cosmetic Act[19] gives the secretary of Health and Human Services and the commissioner of the Food and Drug Administration[20] the responsibility to ensure that "new drugs"[21] are safe and adequately labeled.[22] Additionally, section 331(k) of the act[23] provides criminal penalties for actions resulting in the misbranding or adulteration of a drug, if such actions are taken while the drug is "held for sale . . . after shipment in interstate commerce."[24] Section 331(k) was designed to expand the scope of the FDCA to reach those situations in which a seller misbrands a drug that is neither received nor sold by him or her in interstate commerce.[25]

One exception to the FDCA's coverage, however, is the so-called "practice of medicine" exemption which allows licensed physicians to use drugs in ways not specifically approved by the FDA without violating the FDCA's new drug or misbranding provisions.[26] The scope of this exemption was the first issue decided by the court in *Chaney v. Heckler*.[27]

In *Chaney*, the FDA argued that a state's use of lethal injections fell within the "practice of medicine" exception.[28] The FDA contended

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18. *Id.* at 1177.

19. 21 U.S.C. §§ 301–392 (1982).

20. 21 C.F.R. § 5.10 (1983) provides the secretary of Health and Human Services with the authority to delegate implementation of the FDCA to the commissioner of Food and Drugs.

21. In general, a "new drug" is one that "is not generally recognized, among experts . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. . . ." 21 U.S.C. § 321p(1) (1982).

22. *See* 21 U.S.C. § 355 (1982) (setting out procedures whereby "new drugs" may be approved by the FDA).

23. 21 U.S.C. § 331(k) (1982).

24. *Id.* 21 U.S.C. § 352 (1982) sets out the conditions under which a drug may be deemed "misbranded." The particular subsection at issue here was § 352(f) which states that a drug is "misbranded" unless its label contains "adequate directions for use," including such warnings "as are necessary for the protection of users." *See* Chaney v. Heckler, 718 F.2d 1174, 1176 (D.C. Cir. 1983), *cert. granted*, 104 S. Ct. 3532 (1984) (No. 83-1878).

25. *See* H.R. REP. No. 2139, 75th Cong., 3d Sess. 3 (1938). *See also infra* notes 45–50 and accompanying text.

26. *See Chaney*, 718 F.2d at 1179–80; United States v. Evers, 643 F.2d 1043, 1044 (5th Cir. 1981). While there is little legislative history on the subject, it is nevertheless generally recognized that Congress never intended the FDCA to interfere with a physician's treatment of his or her patients. *See, e.g., Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration*, 37 Fed. Reg. 16,503, 16,503 (August 15, 1972) [hereinafter cited as *Policy Statement*].

27. 718 F.2d 1174 (D.C. Cir. 1983), *cert. granted*, 104 S. Ct. 3532 (1984) (No. 83-1878).

28. *Id.* at 1179.

that the FDCA was not intended to regulate a doctor's treatment of his or her patients because doctors are licensed by the states.[29] Likewise, according to the FDA, its jurisdiction did not extend to a state's use of lethal injections because state prisons are also state-licensed.[30] The court, however, rejected this argument, noting that a doctor's treatment of patients is not exempted from FDCA regulation merely because physicians are state-licensed. According to the court, Congress provided the exemption because it recognized that imposing the act's restrictions on the practice of medicine would unreasonably limit a doctor's treatment alternatives.[31] Thus, the court concluded that the licensure factor was irrelevant.[32]

The court then turned to the FDA's alternate jurisdictional argument—that 21 U.S.C. § 331(k)[33] was inapplicable to the state's use in this case.[34] The specific portion of this section that the FDA deemed to be inapplicable[35] was the "held for sale" provision.[36] The FDA argued that, even though the "held for sale" provision had been broadly interpreted in prior cases,[37] some type of sale was still required to bring an act of misbranding within the provisions of section 331(k).[38]

The court, however, eschewed this "plain meaning" argument.[39] Instead, it cited the legislative history of section 331(k) to show that the section was meant "to 'extend the protection of consumers . . . to the full extent constitutionally permissible.' "[40] The court concluded, therefore, that section 331(k) was intended to be broad enough to extend FDCA protection not only to the "ultimate *purchaser*" [here, the state prison officials], but also to the "ultimate consumer . . . [—] the last person to *consume* the drug."[41]

A major flaw exists, however, in the court's rationale. While it cor-

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29. *Id.*

30. *Id.* at 1179–80.

31. *Id.*

32. The dissent also agreed that the FDA's "state action" argument was without merit. *Id.* at 1198 (Scalia, J., dissenting).

33. *See supra* text accompanying notes 23–24.

34. *Chaney*, 718 F.2d at 1181.

35. Actually, Judge Scalia, in his dissent, advanced this argument much more vigorously than did the FDA. *Id.* at 1198–1200 (Scalia, J., dissenting).

36. *Id.* at 1181.

37. *See, e.g.*, United States v. Sene X Eleemosynary Corp., 479 F. Supp. 970, 981 (S.D. Fla. 1979) ("The 'held for sale' standard of . . . [21 U.S.C. § 331(k)] has long been afforded a liberal reading . . . ."); United States v. 10 Cartons, Labeled in Part "Hoxsey," 152 F. Supp. 360, 365 (W.D. Pa. 1957) ("It is not the holding for sale in a technical legal sense which gives rise to the federal jurisdiction . . . but the fact that the channels of commerce have been used.").

38. *See Chaney*, 718 F.2d at 1198–1200 (Scalia, J., dissenting).

39. *Id.* at 1181.

40. *Id.* (quoting H.R. REP. No. 2139, 75th Cong., 3d Sess. 3 (1938)).

41. *Id.* at 1182.

rectly concluded that prior case law supported a very broad reading of the "held for sale" provision,[42] the court virtually ignored the fact that the commerce clause limits congressional power (and therefore FDA jurisdiction) in this area.[43] Even assuming that the prisoners in *Chaney* were "consumers" for whose protection section 331(k) was designed, the protection is available only "to the extent constitutionally permissible."[44] By holding that the FDA has jurisdiction to regulate a state's use of drugs when administering lethal injections, the *Chaney* court effectively expanded congressional jurisdiction under the commerce clause beyond any previous interpretation of that power.

The extent of Congress' power to regulate drugs was decided in *United States v. Sullivan.*[45] In that case, a druggist who had misbranded items which were neither received nor sold by him in direct interstate transactions, challenged the constitutionality of section 331(k).[46] In affirming the druggist's conviction for violating section 331(k), the Supreme Court reasoned that section 331(k) was designed to protect consumers from the evils of "misbranded" drugs.[47] The Court also noted that the purpose of the FDCA would be easily frustrated if its coverage did not extend to consumers who purchased drugs in purely local transactions.[48] The *Sullivan* Court, however, acknowledged that section 331(k)'s coverage is limited to "the branding of articles that have completed an interstate shipment *and are being held for future sales* in purely local or intrastate commerce."[49] Therefore, it appears that Congress and the FDA can only regulate drug misbranding if it occurs before the last *commercial* transaction involving that drug.

Cases decided after *Sullivan* support this conclusion. As Judge Scalia pointed out in his dissent to *Chaney,* all of the cases cited by the majority in support of its broad interpretation of section 331(k) involved situations in which the misbranded item was still "in the stream of commerce."[50] Moreover, Congress' choice of the words "held for

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42. *See supra* note 37.

43. U.S. CONST. art. I, § 8 ("The Congress shall have Power . . . [t]o regulate Commerce . . . among the several States . . . .").

The court's only reference to congressional power in this area was the conclusory statement that "[t]he drugs that states use have moved through the channels of interstate commerce . . . and Congress thus is well within its constitutional powers when it seeks to regulate the use to which these drugs are put." *Chaney,* 718 F.2d at 1181. *See id.* at 1181 n.18.

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

45. 332 U.S. 689 (1948).

46. *Id.*

47. *Id.* at 696–97.

48. *Id.* at 695–96.

49. *Id.* at 698 (emphasis added).

50. *Chaney,* 718 F.2d at 1199 (Scalia, J., dissenting). *See, e.g., Sene X Eleemosynary Corp.,* 479 F. Supp. 970 (a drug is "held for sale" when it is mixed with another drug for sale); *10*

sale" seems to be an acknowledgment of its own limitations under the commerce clause. As Judge Scalia's dissent implied, if Congress had thought it could constitutionally regulate the misbranding of drugs outside the "stream of commerce," it could have eliminated the "held for sale" language entirely.[51]

Therefore, since any possible misbranding in *Chaney* occurred after the final commercial transaction, the court apparently overstepped its bounds in holding that the FDA had jurisdiction over the drugs involved. What is even more disturbing, however, is that the court reached its decision without even discussing the limitations placed upon Congress and the FDA by the commerce clause.[52]

B. Agency Enforcement Discretion

After deciding that the FDA had jurisdiction to investigate the plaintiffs' claim,[53] the *Chaney* court had to determine whether the FDA's decision not to investigate was reviewable.[54] Agency action is generally subject to judicial review pursuant to 5 U.S.C. §§ 701–706.[55] There are, however, two relevant exceptions to review of agency action: (1) to the extent that "statutes preclude judicial review;"[56] and (2) to the extent that "agency action is committed to agency discretion by law."[57]

The case law suggests that there is a presumption in favor of judicial review of agency action.[58] Accordingly, the "precluded by statute" and "committed to agency discretion" exceptions have been narrowly construed.[59] A problem arises, however, because the APA defines

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Cartons, Labeled in Part "Hoxsey," 152 F. Supp. 360 (drugs that were part of a treatment for which physicians charged patients $400 were "held for sale").

51. *Chaney*, 718 F.2d at 1199 (Scalia, J., dissenting). It should be noted that Congress' power to regulate under the commerce clause is not strictly limited to commercial transactions. *See, e.g.*, Wickard v. Filburn, 317 U.S. 111 (1942) (Congress has the power to regulate a farmer's growing of wheat for personal consumption because it supplied the needs of the grower which would otherwise have to be satisfied by purchases in the open market). However, such regulation of noncommercial activities is within Congress' commerce clause power only if the activities in some way affect interstate commerce. *See* Perez v. United States, 402 U.S. 146, 150–52 (1971). It seems obvious that there is no way Congress could rationally conclude that a state's use of drugs for lethal injections would have any effect on interstate commerce in those drugs.

52. *See supra* note 43.

53. *Chaney*, 718 F.2d at 1182.

54. *Id.* at 1188–89.

55. 5 U.S.C. §§ 701–706 (1982).

56. *Id.* § 701(a)(1).

57. *Id.* § 701(a)(2).

58. *See, e.g.*, Abbott Laboratories v. Gardner, 387 U.S. 136, 140 (1967) (The APA "embodies the basic presumption of judicial review to one 'suffering legal wrong because of agency action.' ") (quoting 5 U.S.C. § 702).

59. *See, e.g.*, Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 410 (1971).

"agency action" to include a "failure to act."[60] It is unclear whether such agency *inaction* in the area of enforcement is "committed to agency discretion."[61]

The *Chaney* court determined not only that the FDA's decision not to investigate *was* reviewable,[62] but also that the FDA's decision had been made "arbitrarily, capriciously, and without authority of law."[63] In making that determination, the court cited several cases in which the United States Supreme Court and the Court of Appeals for the District of Columbia Circuit had indicated that, in general, there exists a strong presumption of judicial reviewability of agency actions.[64] Judge Scalia, however, pointed out in his dissent[65] that all of the cases cited by the majority involved either interpretations of the "precluded by statute" exception or interpretations of the reviewability of an agency's exercise of discretion in areas other than enforcement.[66]

Furthermore, the court's reliance upon one commentator's opinion as support for the proposition that " 'the case law . . . [is now] strongly on the side of reviewability' "[67] was misplaced. As Judge Scalia noted, the quoted statement, when read in its proper context, more accurately reflects a recognition that *criminal prosecutorial discretion* is no longer being considered by the courts as *absolutely* unreviewable.[68] Indeed, the author of that statement had previously conceded, in the same treatise, that "the discretionary power not to enforce is almost always immune to judicial review."[69] Thus, it appears that, in the area of agency decisions declining to taken enforcement action, " 'reluctance to review remains entrenched.' "[70]

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60. 5 U.S.C. § 551(13) (1982).

61. The scope of the "committed to agency discretion" exception has been hotly debated by legal commentators. *See, e.g.*, Berger, *Administrative Arbitrariness: A Synthesis*, 78 YALE L.J. 965 (1969); Berger, *Administrative Arbitrariness: A Sequel*, 51 MINN. L. REV. 601 (1967); Davis, *Administrative Arbitrariness Is Not Always Reviewable*, 51 MINN. L. REV. 643 (1967); Saferstein, *Nonreviewability: A Functional Analysis of "Committed to Agency Discretion,"* 82 HARV. L. REV. 367 (1968).

62. *Chaney*, 718 F.2d at 1188.

63. *Id.* at 1190.

64. *Id.* at 1183.

65. *Id.* at 1193–95 (Scalia, J., dissenting).

66. *See, e.g., Overton Park*, 401 U.S. 402 (involving reviewability of the secretary of Transportation's decision to authorize federal funds for highway construction through a state park without first obtaining formal findings of fact on the highway's impact on the environment); *Abbott Laboratories*, 387 U.S. 136 (dealing with judicial review of agency rulemaking).

67. *Chaney*, 718 F.2d at 1187–88 (quoting 2 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 9:6 at 239–40 (2d ed. 1979)).

68. *See Chaney*, 718 F.2d at 1195–96 (Scalia, J., dissenting).

69. 2 K. DAVIS, *supra* note 66, § 9:1 at 218.

70. *Chaney*, 718 F.2d at 1195 (Scalia, J., dissenting) (quoting Note, *Judicial Review of Administrative Inactions*, 83 YALE L. REV. 627, 658 (1983)).

Nevertheless, the *Chaney* court decided that the "committed to agency discretion" exception to judicial review of agency decisions applies "only in those rare instances where the governing statute is 'drawn in such broad terms that in a given case there is no law to apply.' "[71] The court then found that, in this case, the FDA's decision was subject to judicial review because the court had "more than enough law to apply."[72]

In addition to its reliance on prior case law,[73] the *Chaney* court found "law to apply" in a "policy statement" that had previously been promulgated by the FDA.[74] In this "policy statement," the FDA seemed to commit itself to taking action against all unapproved uses of approved drugs.[75] However, as Judge Scalia noted, this "policy statement" was of extremely limited utility as "law to apply" in this case.[76] In the first place, the "policy statement" is full of broad, ambiguous terms, thereby leaving considerable leeway in its interpretation.[77] In addition, it was promulgated in connection with a rule that was proposed but never adopted.[78] Thus, it would seem that the majority's reliance on this "policy statement," like its reliance on prior case law, was woefully misplaced.

It is unfortunate that the *Chaney* court sought to justify its decision in this manner. While it is clear that a growing number of legal scholars favor a more active role for the judiciary in regard to agency enforcement decisions,[79] it is equally clear that courts cannot fulfill such a role through the type of tenuous reasoning exhibited by the *Chaney* court. Such distortion of precedent can only serve to undermine a court's dignity and credibility.

IV. CONCLUSION

The court's decision in *Chaney v. Heckler*[80] is a major departure from prior case law in two ways. First, it expands the jurisdiction of the FDA beyond any previous interpretation of that agency's authority.[81] The FDA's jurisdiction is subject to limitations placed on congressional

71. *Chaney*, 718 F.2d at 1184 (quoting *Overton Park*, 401 U.S. at 410 (quoting S. REP. No. 752, 79th Cong., 1st Sess. 26 (1945))).
72. *Chaney*, 718 F.2d at 1186.
73. *See supra* note 64 and accompanying text.
74. *Chaney*, 718 F.2d at 1186 (quoting *Policy Statement*, *supra* note 26, at 16,504).
75. *See Policy Statement*, *supra* note 26, at 16,504.
76. *Chaney*, 718 F.2d at 1196 (Scalia, J., dissenting).
77. *Id.*
78. *Id.*
79. *See supra* note 61.
80. 718 F.2d 1174 (D.C. Cir. 1983), *cert. granted*, 104 S. Ct. 3532 (1984) (No. 83-1878).
81. *See supra* notes 45-50 and accompanying text.

power by the commerce clause, and that power does not extend to non-commercial activities that have no effect on interstate commerce.[82] Therefore, the *Chaney* decision raises serious constitutional questions, yet the court evidently did not deem these considerations of sufficient importance to warrant discussion.

Similarly, the court's treatment of the issue of agency enforcement discretion goes against the weight of prior authority.[83] The debate concerning whether the judiciary should play a more active role in reviewing agency decisions continues.[84] However, it would seem that the proper way to achieve such a role is through a well-reasoned balancing of the policy issues involved. Instead, the *Chaney* court chose to misapply precedent in order to support what was obviously its desired result, thereby blunting the precedential force of its own decision.

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82. *See supra* note 51 and accompanying text.

83. *See supra* notes 65–70 and accompanying text.

84. *See supra* note 69.