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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LARRY LEON CHANEY, et al., :

Plaintiffs, :

v. : Civil Action No. 81-2265

RICHARD S. SCHWEIKER, :
Secretary, Department of
Health and Human Services, :

Defendant. :

MEMORANDUM OPINION

This case presents the question of whether the Secretary of the Department of Health and Human Services and his designated agent, the Commissioner of Food and Drugs, abused their discretion by declining to exercise their regulatory authority under the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. § 301 et seq. (1976 & Supp. IV 1980) (hereinafter "FDC Act" or "the Act") to prevent the states of Oklahoma, Texas, Idaho, and New Mexico from utilizing certain prescription drugs for the purpose of administering the death penalty through the medium of lethal injections. Plaintiffs are inmates at the Oklahoma State Penitentiary and the Ellis Unit of the Texas Department of Corrections and are under sentence of death by lethal injection. The gravamen of their complaint for declaratory and injunctive relief is that the Secretary and the Commissioner have ignored their statutory obligations by refusing to take specific remedial steps ostensibly designed to insure that drugs administered in state-mandated lethal injection procedures are demonstrated to be safe and effective for that particular purpose. See 21 U.S.C. § 355. In addition, plaintiffs maintain that since all of the formal requisites for the assertion of jurisdiction by the Food and Drug Administration (hereinafter "FDA") allegedly have been

satisfied here, the Commissioner is therefore required to exercise his extensive regulatory power over drugs utilized by the states to execute condemned prisoners. For the reasons stated herein, the Court has concluded that the Commissioner's decision to refrain from interfering with the implementation of state capital punishment statutes constitutes a defensible exercise of his considerable investigative and enforcement discretion under the FDC Act. There are no issues of material fact remaining in dispute, and the defendant, accordingly, is entitled to judgment as a matter of law.

Background

In recent years, the states of Oklahoma, Texas, Idaho, and New Mexico have adopted capital punishment statutes mandating the use of marketable prescription drugs for administering the death penalty by lethal injection. These statutes generally provide that prisoners sentenced to death for capital offenses shall be executed by intravenous administration of a short-acting barbiturate in combination with a chemical paralytic agent.* Although neither the statutes nor the applicable implementing regulations adopted in Idaho and New Mexico identify the drugs to be utilized by prison officials in administering the death penalty, the drugs specified in the relevant Oklahoma and Texas regulations are quite clearly manufactured for distribution and sale in

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* The Oklahoma statute is representative of these lethal injection laws in its description of the method of execution to be followed by the state:

> The 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 according to accepted standards of medical practice.

OKLA. STAT. ANN. tit. XXII, § 1014A (West Supp. 1981-1982).

interstate commerce. See 21 U.S.C. § 321(b).* Each of these drugs may be lawfully manufactured and marketed for various medical and therapeutic uses,** but none has been approved by the FDA for the non-therapeutic purpose of executions.

On December 19, 1980, plaintiffs filed a citizen petition with the Secretary of Health and Human Services (hereinafter "the Secretary") pursuant to 21 C.F.R. § 10.30 (1980), requesting that the FDA undertake specific investigatory and enforcement action to prevent the unapproved potential use of marketed prescription drugs as lethal injections to execute condemned prisoners.*** In their petition, plaintiffs asserted that the untested and unapproved use of prescription drugs to execute state prisoners violates the provisions of section 505(a) of the FDC Act, 21 U.S.C. § 355(a), which generally prohibits the

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* According to the Oklahoma Department of Corrections Policy and Procedures Memorandum No. OP-050301 (Revised), issued July 21, 1981, and the Texas Department of Corrections Procedures for the Execution of Inmates Sentenced to Death, the ultrashort-acting barbiturate to be used in all executions is sodium thiopental. The Oklahoma Memorandum also states that the chemical paralytic agent to be administered in all lethal injections is either tubocurarine, succinylcholine chloride, or potassium chloride.

Sodium thiopental is manufactured by Abbott Laboratories of North Chicago, Illinois. Tubocurarine is manufactured by Eli Lilly and Company of Indianapolis, Indiana. Succinylcholine chloride is manufactured by Squibb & Sons, Inc. of Princeton, New Jersey, and Burroughs Wellcome Co. of Research Triangle Park, North Carolina. Potassium chloride is manufactured by Invenex Laboratories of Orlando, Florida. See Physicians Desk Reference (35th ed. 1981).

** Sodium thiopental is an anesthetic and hypnotic drug commonly utilized in medical and surgical procedures to induce sleep. Tubocurarine and succinylcholine chloride are effective muscle relaxants generally utilized as adjuncts to anesthesia. Potassium chloride is widely used as a potassium supplement.

*** See Exhibit A To Plaintiffs' Memorandum In Support Of Their Motion For Summary Judgment And In Opposition To Defendant's Motion To Dismiss Or, In The Alternative, For Summary Judgment (hereinafter "Plaintiffs' Memorandum").

interstate distribution of any "new drug"* unless the Secretary has approved an application supported by substantial evidence** which demonstrates the drug's safety and effectiveness. By its express terms, section 505 requires premarketing approval for "any new drug" unless it is exempt under the grandfather provisions of the Act or intended solely for investigative use. See 21 U.S.C. §§ 321(p)(1), 355(i). Moreover, section 201(p)(1) of the Act defines the term "new drug" (which includes the majority of prescription drugs) to encompass "[a]ny drug . . . not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the

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* The term "drug" is defined in section 201(g)(1) of the Act, 21 U.S.C. § 321(g)(1), to include

> . . . (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A),(B), or (C); but does not include devices or their components, parts, or accessories.

** The term "substantial evidence" is defined in section 505(d) of the Act, 21 U.S.C. § 355(d), to mean

> . . . evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

labeling thereof . . . ."* Plaintiffs supplemented their petition with documentary evidence designed to support their position that the only available evidence concerning the safety and effectiveness of the aforementioned drugs for use in administering the death penalty strongly indicates that the lethal injection procedure is not a swift, painless, and humane medium for inducing the cessation of bodily functions. On the basis of the affidavits** and other supporting documentation appended to their petition, plaintiffs requested the Secretary to prevent these states from utilizing prescription drugs in state-mandated executions until scientifically valid tests conducted by the sponsors of those drugs firmly established their safety and effectiveness for the contemplated use.

Plaintiffs also maintained in their petition that the drugs that have been designated for use in lethal injection procedures are "misbranded" under the Act because they do not contain "adequate directions for use" in administering the

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* The Supreme Court has stated that general recognition of a drug's safety and effectiveness for intended uses requires an "expert consensus" on safety and effectiveness founded upon "substantial evidence" as defined in section 505(d) of the Act, 21 U.S.C. § 355(d). Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 629-634 (1973).

** The affidavits submitted by licensed physicians in conjunction with plaintiffs' petition indicate that there is currently no "expert consensus" derived from "adequate and well-controlled investigations" that the drugs to be administered to condemned inmates will produce loss of consciousness and death without delay or discomfort. Moreover, these physicians aver that there are no published scientific data which even address the use of these drugs as a means of executing human beings. Finally, the physicians maintain that participation by any doctor in the ordering, preparation, or administration of prescription drugs as a means of implementing the death penalty is flatly prohibited by the Hippocratic Oath, which has served as the ethical foundation of the medical profession for 2500 years. The American Medical Association and the professional medical societies of each of the four states that have adopted lethal injection statutes have endorsed or promulgated resolutions which declare that a physician, as a member of a profession dedicated to the preservation of human life, should not participate in any way in an authorized execution unless such "participation" is limited to making a determination or certificaton of death. See Affidavits of Dr. Ward Casscells, Dr. Richard S. Hodes, and Dr. Leroy David Vandam, Exhibit A To Plaintiffs' Memorandum.

death penalty, as ostensibly required by section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1), or adequate warnings that this contemplated use may be dangerous and inhumane. The FDA has interpreted this statutory provision to require that all drugs distributed through the channels of interstate commerce contain "directions under which a layman can use a drug safely and for the purpose for which it is intended";* the effect of that implementing regulation is to make it impossible for any prescription drug to comply with the statutory directive unless it qualifies for an exemption, because prescription drugs by definition can be used only under the supervision of a licensed physician. See 21 U.S.C. § 353(b)(1).

Pursuant to 21 C.F.R. § 201.100 (1982), the FDA has exempted prescription drugs from the restrictions imposed by section 502(f)1 of the Act, as long as availability of each drug is conditioned upon a) a prescription from a licensed medical practitioner, and b) a label bearing appropriate cautionary language and a detailed description for pharmacists and physicians designed to insure that the drug is properly prescribed, dispensed, and administered. In addition, the FDA requires that any "new drug" subject to section 505 of the Act bear a label that has been authorized by the FDA through an approved new drug application (NDA). Id. Plaintiffs have pressed the argument that the absence of FDA approval of a NDA which would permit the marketing of the prescription drugs at issue here for use in state-mandated lethal injections renders the prescription drug exception set forth in 21 C.F.R. § 201.100 inapplicable and compels the conclusion that those drugs are "misbranded" under the

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* 21 C.F.R. § 201.5 (1982) (emphasis supplied). The "intended use" of a drug refers to "the objective intent of the persons legally responsible for the labeling of drugs," such as manufacturers, wholesalers, or retailers. 21 C.F.R. § 201.128.

Act.* In other words, plaintiffs submit that because state prison systems which have obtained the drugs at issue through the channels of interstate commerce intend to use the drugs for the purpose of executing human beings, FDA regulations require those prisons to provide "adequate directions for use" within the meaning of 21 C.F.R. § 201.5.** Finally, plaintiffs asserted that these allegedly misbranded drugs are "held for sale [by the states] after shipment in interstate commerce," and are thus fully subject to the prohibitory language of 21 U.S.C. § 331(k).***

At the conclusion of their petition, plaintiffs requested the Secretary to take the following specific enforcement steps to prevent the states from using prescription drugs in administering the death penalty:

1) Affix a boxed warning to the labels of the drugs designated by statute or prison policy for use in state-supervised lethal injection procedures, declaring that those drugs are not approved for use as a means of execution, are not considered safe and effective for that use, and should not be so employed by any state;

2) Notify the manufacturers of the drugs and appropriate prison officials in Oklahoma, Texas, Idaho, and New Mexico that the drugs designated by statute or prison policy for use in administering the death penalty by lethal

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* Misbranded drugs, no less than unapproved new drugs, may not be lawfully introduced into interstate commerce. See 21 U.S.C. § 331(a).

** Plaintiffs do not and indeed cannot suggest that these prescription drugs were developed and marketed by their manufacturers for the purpose of executing condemned prisoners. To reiterate, each of these drugs has been formally approved by the FDA and/or lawfully marketed and labeled for specific medical and therapeutic uses.

*** That subsection prohibits "the doing of any . . . act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale . . . after shipment in interstate commerce and results in such article being adulterated or misbranded."

injection are not approved for use as a means of execution, are not considered safe and effective for that use, and should not be so employed by those states;

3) Place in the Drug Bulletin an article advising that the drugs specified for use in state-supervised lethal injection procedures are not approved for use as a means of execution, are not considered safe and effective for that use, and should not be so employed;

4) Adopt and implement a policy for the seizure and condemnation from state prisons or departments of corrections of drugs which are destined or held for use as a means of execution;

5) Recommend the prosecution of manufacturers, wholesalers, retailers and pharmacists who knowingly sell drugs for the unapproved use of administering lethal injections, and of prison officials who knowingly buy, possess, or use drugs for that unapproved purpose. Plaintiffs' Memorandum, at 6-7 n.4. Finally, plaintiffs requested the Secretary to provide them with a hearing on any controlling issue of fact raised by their petition.

On July 7, 1981, the Commissioner of Food and Drugs denied plaintiffs' petition without addressing the merits of plaintiffs' "new drug" and "misbranding" theories of statutory violations. In his response to the petition, the Commissioner noted general agreement with plaintiffs' position that the FDA has the authority and responsibility to prevent the promotion and use of certain drug products for purposes not included in the labeling of those drugs. Nevertheless, the Commissioner's review of the statute, the implementing regulations, and applicable precedent ultimately led him to conclude that the FDA's jurisdictional authority did not extend to the state-sanctioned use of prescription drugs in administering the death penalty by lethal injection. Alternatively, the Commissioner concluded that even if the FDA did have jurisdiction as a statutory matter to grant

plaintiffs the extensive relief that they had requested, he would nonetheless decline as a matter of inherent enforcement discretion to pursue wide-ranging investigative and enforcement action which would effectively preclude four states from implementing duly authorized capital punishment statutes enacted in furtherance of proper state functions.

Plaintiffs thereupon filed the instant action pursuant to 28 U.S.C. §§ 1331, 1361 (1976 & Supp. IV 1980), seeking declaratory, injunctive, and mandamus relief to compel the Secretary and his agent, the Commissioner of Food and Drugs, to immediately hold evidentiary hearings designed to ascertain whether the lethal injection procedure authorized by the states of Oklahoma, Texas, Idaho, and New Mexico conforms to the requirements of the FDC Act. In addition, plaintiffs seek an order requiring the Secretary and the Commissioner to carefully consider whether any of the enforcement steps originally requested by plaintiffs in their petition may be necessary to remedy alleged violations of the Act.

Discussion

At the outset, it is important to recognize what is not at issue in this lawsuit. First and foremost, this case does not present constitutional issues concerning the appropriateness of either the death penalty in general or the lethal injection procedure in particular. Second, the Court has not been asked to evaluate the ultimate merits of the "new drug" and "misbranding" theories that plaintiffs have advanced as a legal justification for regulatory action by the FDA. The sole issue for decision is whether the Secretary and the Commissioner have a ministerial duty under the FDC Act to exercise their considerable investigatory and enforcement powers to insure that prescription drugs utilized by prison officials to administer a lethal injection death penalty are

safe and effective for that purpose. In confronting that issue, the Court declines to review the Comissioner's determination that the FDA lacked jurisdiction to interfere with the state-sanctioned use of marketed prescription drugs in lethal injection procedures. Instead, the Court simply holds that the putative availability of a jurisdictional foothold for providing plaintiffs with the relief that they requested does not impose upon the Commissioner a mandatory duty to institute desired regulatory action. Accordingly, the Court will uphold the Commissioner's legitimate exercise of enforcement discretion without reviewing the bona fides of his interpretation of the Act's jurisdictional span.

The principal difficulty with plaintiffs' position in this litigaton stems from their apparent assumption that the absence of any express or implied exemption in the FDC Act for the state-sanctioned procedure of administering death by lethal injection somehow compels the Commissioner to assert jurisdiction over this particular unapproved use of prescription drugs. Having constructed a somewhat attenuated analytical framework to justify subjecting lethal injections to the strictures of the Act's "new drug" and "misbranding" provisions, plaintiffs now maintain that the Commissioner has no discretion to decline to initiate requested investigative and enforcement proceedings when confronted with a citizen petition alleging statutory violations. Plaintiffs also assert that the Commissioner abused his discretion by refusing to provide them with an evidentiary hearing as a prelude to desired regulatory action. The Court cannot accept either of these arguments.

It is by now well-established that decisions of executive departments and agencies to refrain from instituting investigative and enforcement proceedings are essentially unreviewable by the courts. See, e.g., National Labor Relations Board v. Sears, Roebuck & Co., 421 U.S. 132, 138 (1975); Vaca v. Sipes, 386 U.S. 171, 182 (1967) (noting

unreviewability of decisions by the General Counsel of the NLRB not to issue an unfair labor practice complaint); Moog Industries, Inc. v. Federal Trade Commission, 355 U.S. 411, 413-414 (1958) (refusing to review FTC decision not to institute "cease and desist" proceedings pursuant to section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45); Kixmiller v. Securities and Exchange Commission, 160 U.S. App. D.C. 375, 492 F.2d 641 (1974) (judicial forum not available to review SEC staff decision not to recommend investigation or enforcement action); Newman v. United States, 127 U.S. App. D.C. 263, 382 F.2d 479 (1967) (refusing to interfere with prosecutorial discretion of the United States Attorney); Securities and Exchange Commission v. Tiffany Industries, Inc., 535 F. Supp. 1167 (E.D. Mo. 1982) (SEC refusal to join company in an enforcement proceeding not subject to judicial review). The United States Court of Appeals for the Eighth Circuit has recently confirmed that this principle of investigative and enforcement discretion is fully applicable to decisions by the Commissioner of Food and Drugs to refrain from exercising his regulatory powers in the face of petitions alleging violations of the FDC Act. See National Milk Producers Federation v. Harris, 653 F.2d 339 (8th Cir. 1981). In rejecting an effort by representatives of certain dairy producers to obtain mandatory judicial relief compelling the FDA to initiate enforcement proceedings against the manufacturers of allegedly misbranded cheese substitutes,* the court reaffirmed that the executive branch and its departments "enjoy a discretion in the initiation of investigative, enforcement, and prosecutorial actions limited only by constitutional strictures and relevant statutory directives." Id. at 343 (citations omitted). After reviewing the FDC Act, the court concluded

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* Alternatively, the plaintiffs sought declaratory relief establishing the illegality of the FDA's action in allegedly sanctioning the sale in interstate commerce of misbranded cheese substitutes.

that there was "no provision which narrows or limits the discretion of the FDA to investigate, enforce, or prosecute alleged violations of the Act or its regulations." Id. at 344. The Court of Appeals accordingly held that the complaint seeking mandatory declaratory and injunctive relief against the FDA for its refusal to initiate investigative, enforcement, or prosecutorial proceedings had been properly dismissed by the District Court for failure to state a claim upon which relief could have been granted.

The refusal to interfere with FDA policies of enforcement prioritization and resource allocation which underlies the National Milk Producers opinion is consistent with an earlier decision in this court, Cutler v. Kennedy, 475 F. Supp. 838 (D.D.C. 1979), which declined to order the Commissioner to take affirmative steps to remove certain over-the counter drugs from the market in spite of a finding that he had exceeded his statutory authority by permitting those drugs to be marketed. In its opinion, the court expressed sympathy with the plaintiffs' frustration over the FDA's dilatory enforcement of the Drug Amendments of 1962, but noted that "plaintiffs have not attempted to demonstrate that the Commissioner has a duty to seek enforcement action against every unlawfully marketed drug. Certainly, the statutory scheme and traditional notions of prosecutorial discretion would suggest just the opposite."* Id. at 856.

The Court can find no justification for either departing from the reasoning advanced in National Milk Producers and Cutler or fashioning an exception to that encompassing rationale out of statutory whole cloth to fit

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* It should be emphasized that ultimate enforcement authority to initiate prosecutions for alleged violations of the FDC Act resides in the Department of Justice and not the FDA. See 21 U.S.C. §§ 335-337. Even if the Commission had recommended enforcement action in this case, the final decision would have been left to the unfettered discretion of the Attorney General and his designated agents.

the circumstances of this case. The record indicates that plaintiffs' petition was accorded careful consideration by the Commissioner, and his reasons for declining to initiate investigative and enforcement action were fully explained in a memorandum accompanying the denial of the petition. Whether the Commissioner might have reached a different decision in light of the political, scientific, and ethical controversy surrounding the use of prescription drugs to cause death by lethal injection is of no moment; the salient point is that under established authority the decision was his to make. The Court is not prepared to dictate FDA enforcement priorities or otherwise interfere with the Commissioner's performance of his discretionary investigative

...ons* on the basis of extraneous case law arising under the national labor relations statutes.** Neither is the Court prepared to hold, as plaintiffs insist, that United States v. Articles of Drug . . . Beuthanasia - D Regular, [1979 Transfer Binder] FOOD DRUG COSM L. REP. (CCH) ¶ 38,265 (D. Neb. Aug. 1, 1979) somehow compels the Commissioner to take regulatory action against those states which utilize marketed prescription drugs to execute condemned prisoners. Beuthanasia stands for the singularly unremarkable proposition that a substance manufactured and distributed through the channels of interstate commerce for the sole

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* Plaintiffs now contend that the Commissioner's refusal to afford them an evidentiary hearing on any "controlling issue of fact" provides an appropriate basis for judicial intervention. However, it is axiomatic that a judicial order compelling the Commissioner to investigate plaintiffs' allegations through the medium of a comprehensive evidentiary hearing would have no purpose apart from serving as a prelude to the pursuit of the very enforcement steps that plaintiffs demanded in their administrative petition. Moreover, at the risk of redundancy the Court reiterates that there is no support for the proposition that the Commissioner must take specific investigative and/or enforcement steps in response to every citizen petition alleging that statutory violations have occurred. In light of the Commissioner's decision to refrain from initiating enforcement action in this case, he is not required to hold evidentiary hearings devoted to ascertaining whether these prescription drugs are safe and effective for the purpose of administering the death penalty by lethal injection.

Finally, the Court notes parenthetically that the Commissioner has been afforded considerable latitude to deny requests for hearings in spite of seemingly mandatory language to the contrary in the Act itself. See, e.g., Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 619-621 (1972) (affirming Commissioner's summary withdrawal of FDA approval of a NDA despite statutory requirement in 21 U.S.C. § 355(e) of "due notice and opportunity for hearing to the applicant"); Pineapple Growers Ass'n v. Food & Drug Administration, 673 F.2d 1083 (9th Cir. 1982) (affirming Commissioner's denial of a hearing to party objecting to a revised final rule, despite requirement in 21 U.S.C. § 371(e)(3) that Commissioner "hold . . . a public hearing for the purpose of receiving evidence relevant and material to the issues raised by [the] objections"); Cooper Laboratories, Inc. v. Commissioner, Fed. F.D.A., 163 U.S. App.D.C. 212, 501 F.2d 772 (1974) (affirming summary withdrawal procedure per Hynson, supra). Here, by contrast, the statute is devoid of any language even intimating that the filing of a citizen petition ipso facto entitles the petitioner(s) to an exploratory evidentiary hearing. In fact, the pertinent regulation plainly leaves the provision of a hearing to the discretion of the Commissioner. 21 C.F.R. §10.30(h)(2). The Court therefore disagrees with plaintiffs' suggestion that the Commissioner has "abandon[ed] his statutory duties" by declining their request for a comprehensive hearing. See Plaintiffs' Memorandum, at 31.

** See Plaintiffs' Memorandum, at 16-17.

purpose of causing humane death in animals is a "drug"* which may be regulated by the FDA pursuant to its authority under 21 U.S.C. § 360b. The case provides no support whatsoever for plaintiffs' view of the Commissioner's statutory "obligation" to provide them with a public forum for airing their medical and philosophical grievances over the lethal injection procedure authorized by state laws.

Finally, plaintiffs' assertion that "Congress provided no exemptions for State-mandated actions"** when it enacted the FDC Act is decidedly irrelevant to the legal issues presented in this lawsuit. The Court has carefully examined the letter of explanation that accompanied the Commissioner's denial of plaintiffs' petition, and does not believe that the Commissioner's decision to decline to exercise jurisdiction over an unapproved use of certain lawfully marketed prescription drugs can fairly be viewed as a blanket abdication by the FDA of its authority over all state-supervised procedures that may conflict with the specific requirements or underlying norms of the Act.*** To restate a familiar refrain, the absence of a statutory exemption for state-mandated activity does not logically compel or even suggest the proffered conclusion that the Commissioner has no discretion to refrain from initiating requested investigative and/or enforcement proceedings under circumstances that would effectively preclude the implementation of duly enacted capital punishment statutes in Oklahoma, Texas, Idaho, and New Mexico.

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* See supra p. 4, note *.

** Plaintiffs' Memorandum, at 15.

*** Neither can the Commissioner's decision be viewed as a policy statement that the Act does not afford any protection to individuals incarcerated in state penitentiaries. For example, the FDA has already taken affirmative steps to regulate clinical investigations involving prisoners as subjects. 21 C.F.R. § 50.40 (1982); see also 46 Fed. Reg. 61666 (Dec. 18, 1981).

Conclusion

To summarize, the Court is unable to perceive any "constitutional strictures" or "statutory directives" which would require the Commissioner to pursue the investigative or enforcement action that plaintiffs requested in their petition. Having determined that the Commissioner properly exercised his discretion in denying plaintiffs' petition for relief, the Court will not proceed to recast the discretionary contours of the Federal Food, Drug and Cosmetic Act *in arbitrium judicis* to conform to personal conceptions of enlightened humanism. The defendant's motion for summary judgment will be granted, and an Order consistent with this Memorandum Opinion will be issued on this date.

Norma Holloway Johnson

NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE

DATED: August 30, 1982

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LARRY LEON CHANEY, et al., :

Plaintiffs, :

v. : Civil Action No. 81-2265

RICHARD S. SCHWEIKER,
Secretary, Department of
Health and Human Services, :

Defendant. :

FILED

AUG 30 1982

JAMES F. DAVEY, Clerk

ORDER

Upon consideration of defendant's motion to dismiss or, in the alternative, for summary judgment, and plaintiffs' motion for summary judgment, the memoranda of points and authorities in support of and in opposition thereto, the affidavits, exhibits, and other supporting documentation filed by the parties, and the entire record herein, it is by the Court this 30th day of August, 1982,

ORDERED that defendant's motion in the alternative for summary judgment be, and hereby is, granted, pursuant to Fed. R. Civ. P. 56(c); and it is further

ORDERED that plaintiffs' motion for summary judgment be, and hereby is, denied; and it is further

ORDERED that this action be, and hereby is, dismissed with prejudice.

Norma Holloway Johnson

NORMA HOLLOWAY JOHNSON
UNITED STATES DISTRICT JUDGE