

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LADD HUFFMAN,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil No. 93-0237 NHJ

MEMORANDUM OF POINTS AND AUTHORITIES IN
SUPPORT OF DEFENDANT'S MOTION TO DISMISS,
OR IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

INTRODUCTION

Plaintiff filed this pro se complaint against the Food and Drug Administration (FDA), alleging that the FDA's failure to provide him with marijuana as a medical treatment for his multiple sclerosis following the FDA's alleged approval of his application for the drug under the Compassionate Investigational New Drug [IND] Program violates his right to equal protection and due process under the Constitution. Complaint, para. 11. Plaintiff also alleges that another individual, who resides in his state, applied for similar permission and was granted access to marijuana and continues to receive such treatment. Id. at paras. 9-10. To remedy these alleged wrongs, plaintiff seeks an order directing the FDA to provide him with marijuana under the Compassionate IND Program.

Plaintiff's arguments must fail for two reasons. First, plaintiff's equal protection and due process arguments fail to

state a claim because he does not allege discrimination against a class of individuals nor has he demonstrated a protected property or liberty interest at stake. Second, even if plaintiff's Complaint can be read to state such constitutional claims, the accompanying Declaration of Daniel A. Spyker [Spyker Declaration], Medical Officer in the Pilot Drug Evaluation Staff at the FDA's Center for Drug Evaluation and Research, and the Declaration of Corinne P. Moody [Moody Declaration], Consumer Safety Officer in the Pilot Drug Evaluation Staff, amply demonstrates that the circumstances surrounding the cancellation of plaintiff's application for marijuana were different than those involved in the patients receiving marijuana under an IND, and that the difference in treatment was rationally based.²

For the reasons set forth below, and those set forth in the accompanying declarations, the FDA respectfully submits that its motion to dismiss, or in the alternative, for summary judgment, should be granted.

STATUTORY AND REGULATORY SCHEME

A. Statutory Control of Marijuana

Marijuana is one of the substances regulated by the Controlled Substances Act, 21 U.S.C. §§ 801, et seq. It is classified into Schedule I, 21 U.S.C. § 812(c), Schedule I,

² Moreover, the relief sought by plaintiff -- an order directing the FDA to provide him with the requested marijuana -- is unobtainable. The FDA does not supply the marijuana in connection with the IND applications; the marijuana is provided by the National Institute on Drug Abuse. Spyker Declaration, para. 4.

(c)(10), which means that, by law, it has been determined (A) to have a high potential for abuse; (B) to have no currently accepted medical use in treatment; and (C) to lack an accepted safety for use even under medical supervision. 21 U.S.C. § 812(a)(1). Possession of a controlled substance without a valid prescription or under one of the exceptions in the statute is illegal. 21 U.S.C. § 844(a).

B. New Drug Approval Process

The Federal Food, Drug, and Cosmetic Act [the Act] provides for stringent regulation of drugs. Before a new drug may be marketed, it must be subjected to testing to establish that it is safe and effective for the conditions for which it is to be used. New drugs may not be distributed unless the FDA approves a new drug application [NDA] supported by substantial evidence of the drug's safety and efficacy. 21 U.S.C. § 355(b)-(d).³

However, the Act also directs the FDA to provide, by regulation, exemptions from the NDA requirements for drugs "intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." 21 U.S.C. § 355(i). The Food and Drug Administration's regulations relating to investigational new drug applications (IND) accomplish this purpose. See generally 21 C.F.R. Part 312. Under these regulations, a "clinical

³ The Act refers to approval of new drugs by the "Secretary" of Health and Human Services. The Secretary has delegated this authority to the Commissioner, who has redelegated the authority within the FDA. 21 C.F.R. §§ 5.80; 5.10(a)(1).

investigation" is an experiment in which "a drug is administered or dispensed to, or used involving, one or more human subjects." 21 C.F.R. § 312.2(b). If a drug sponsor submits an IND to the FDA and the agency does not put the proposed investigation on hold, the drug may then be administered to individuals enrolled in the investigation in accordance with the IND. 21 C.F.R. § 312.40, 312.42.

C. Single-patient INDs for Marijuana

Use of marijuana as an investigational new drug would require not only the FDA's acceptance of an IND submitted by a drug sponsor (with a qualified physician investigator), but also the participation of a legal supplier of marijuana, and approval by the Drug Enforcement Administration [DEA]. In the case of single-patient IND applications for marijuana, the marijuana is provided by the National Institute on Drug Abuse, Public Health Service, Department of Health and Human Services, pursuant to its research authority under Sections 301 and 302 of the Public Health Service Act. *Spyker Declaration*, para. 4. Before the National Institute on Drug Abuse can supply the marijuana, however, the applicant's physician must apply to and receive approval from the DEA to receive and dispense the drug, because marijuana is regulated under the Controlled Substances Act. When the DEA issues a registration for the physician to receive the marijuana, it provides the order form which must be presented to the National Institute on Drug Abuse for shipment of the marijuana. *Id.*

FACTUAL BACKGROUND

The Center for Drug Evaluation and Research received a single-patient IND application for marijuana for plaintiff on January 2, 1991. The IND was submitted by his physician, Patricia J. Harrison, M.D. The pharmacology review was completed on January 10, 1991, and the chemistry review was completed on January 11, 1991. Following this review, it was determined that it was safe for the IND to proceed. Spyker Declaration, para. 6. Dr. Spyker called Dr. Harrison, on January 11, 1991, to discuss the requirements for the IND application and to request the submission of additional information, which she provided on January 25, 1991. On March 8, 1991, Dr. Spyker issued a letter to Dr. Harrison advising her that plaintiff's IND application could proceed. Id. at paras. 7-9. Plaintiff's next step was for his physician to seek approval from the DEA to receive and dispense marijuana. Id. at para. 4.

In June 1991, the Pilot Drug Evaluation Staff was advised that the Assistant Secretary for Health, Department of Health and Human Services, had decided to consider whether the National Institute on Drug Abuse would continue to supply marijuana for single-patient INDs. In response to this information, the Pilot Drug Evaluation Staff stopped taking actions on single-patient IND applications for marijuana. Moody Declaration, para. 6.

On August 19, 1991, the DEA received an application from Dr. Harrison to receive and dispense marijuana for plaintiff. Spyker Declaration, para. 14. On August 21, 1991, the FDA received a

request from the DEA for information regarding the IND application submitted by plaintiff.⁴ Moody Declaration, para. 7. Since FDA action on single-patient IND applications had been discontinued following the June 1991 decision of the Assistant Secretary of Health, no response was given to the DEA regarding plaintiff's IND application. Moody Declaration, para. 7. The DEA did not issue a registration to Dr. Harrison. Spyker Declaration, para. 14.

In March 1992, the Pilot Drug Evaluation Staff was advised that the Secretary of the Department of Health and Human Services had decided that the National Institute on Drug Abuse would not provide marijuana for single-patient INDs except to those patients who were receiving marijuana at that time. This group included patients whose INDs had already been reviewed and allowed to proceed by the FDA, whose physicians had received approval to receive the marijuana from the DEA and for whom the National Institute on Drug Abuse had shipped marijuana upon receipt of the DEA order form submitted by the physicians. The rationale for this decision was the fact that the research gained through IND users of marijuana had provided little, if any, useful data, and the FDA thus did not want to increase the pool of users in light of health concerns over providing patients with

⁴ When the DEA receives an application from a sponsor for a registration to receive and dispense marijuana, the DEA would request information from the FDA regarding the status of the IND application. The DEA would issue the requested registration only if the FDA advised that the IND application had been allowed to proceed. Moody Declaration, para. 5.

a potentially harmful substance. The FDA intended to work with the patients already receiving marijuana and their doctors in exploring alternative therapies so that, through attrition among these users, the FDA could ultimately discontinue supplying marijuana to any single-patient users. Spyker Declaration, paras. 11-12. Because plaintiff's physician had not received approval from the DEA to receive and dispense marijuana, and in light of the Secretary's March 1992 decision, the National Institute on Drug Abuse would not supply marijuana for plaintiff's IND application. Id. at para. 14.

In March 1992, as a result of the Secretary's decision, Dr. Spyker contacted the sponsoring physicians of the IND applications for plaintiff and other patients who were not already receiving marijuana to advise them that the National Institute on Drug Abuse would not supply them marijuana. He also advised the sponsoring physicians of other treatment options for their patients' conditions and the availability of referrals to experts at the National Institutes of Health, Public Health Service, Department of Health and Human Services. The single-patient IND applications for these individuals were then cancelled. Spyker Declaration, para. 16.

ARGUMENT

I. Plaintiff's Complaint Fails To State A Claim For A Constitutional Violation

The gravamen of plaintiff's Complaint is that his application for an IND for marijuana for multiple sclerosis was denied while a similar application by another individual from his

state was granted. While the FDA cannot disclose information regarding patients receiving marijuana under single-patient IND applications without such patients' consent, Spyker Declaration, para. 17, 5 U.S.C. § 552a, even if plaintiff's allegations are taken as true his Complaint fails to state a cognizable claim.

The Equal Protection Clause protects from "disparity in treatment by a state [or federal government] between classes of individuals whose situations are arguably indistinguishable." Ross v. Moffitt, 417 U.S. 606, 600 (1979) (emphasis added). Thus, to bring an action under the Equal Protection Clause, plaintiff must show "intentional discrimination against him because of his membership in a particular class, not merely that he was treated unfairly as an individual." Huebschen v. Dept. of Health and Social Services, 716 F.2d 1167, 1171 (7th Cir. 1983) (emphasis added). This discriminating purpose implies that the decisionmaker "selected or reaffirmed a particular cause of action at least in part 'because of,' not merely 'in spite of,' its adverse effect upon an identifiable group." Personnel Administrator of Massachusetts v. Feeney, 442 U.S. 256, 279 (1979) (emphasis added).

Plaintiff's Equal Protection claim stems from the FDA's alleged failure to treat him similarly to another patient he claims is receiving marijuana under the same program for the treatment of multiple sclerosis. Complaint, paras. 9-11. This individualized treatment is not governed by the Equal Protection Clause. Plaintiff's failure to identify any class to which he

belongs that has been subject to different treatment warrants dismissal of this claim.

Plaintiff's due process claim is similarly defective. In order to establish a claim alleging a violation of due process, a plaintiff must first show that he or she possess a property or liberty interest protected by the Fifth Amendment. See, e.g., Cleveland Bd. of Education v. Loudermill, 470 U.S. 532, 538-41 (1985); Reeve Aleutian Airways, Inc. v. United States of America, 982 F.2d 594, 598 (D.C. Cir. 1993); Doe v. Casey, 796 F.2d 1508 (D.C. Cir. 1986), aff'd in relevant part sub nom. Webster v. Doe, 108 S. Ct. 2047 (1988). Then the plaintiff must show that the state or federal government deprived him or her of the liberty or property interest in violation of due process or equal protection guarantees. Doe v. Casey, 796 F.2d at 1510.

Plaintiff clearly has no liberty interest at stake here. In order to state a claim for a violation of a liberty interest under the Constitution, a plaintiff must allege that the government "altered his status in a tangible way and that an imposition of stigma or injury to reputation accompanied this change in status." United States Information Agency v. Krc, 905 F.2d 389, 397 (D.C. Cir. 1990). Plaintiff makes no such allegations in his Complaint.

Plaintiff also has failed to state a claim for a deprivation of a property interest. Plaintiff does not allege that he has a statutory right under the Federal Food, Drug and Cosmetic Act to receive marijuana, nor does the statute in fact confer any such

right. Plaintiff also does not state that he has any constitutional right to receive an unapproved medication. Indeed, the law is clear that he has no such right. See Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980); Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980) (on remand) ("premarketing [approval] requirement of the Act, 21 U.S.C. § 355, is an exercise of Congressional authority to limit the patient's choice of medication"). As the Ninth Circuit Court of Appeals held in Carnohan, a case involving a request for the use of laetrile in a nutritional program for the prevention of cancer, constitutional rights of privacy and personal liberty do not give individuals the right to obtain an unauthorized drug free of the lawful exercise of the legitimate governmental power to protect the public health. 616 F.2d at 1122.

Thus, because plaintiff has no property or liberty interest in his receipt of marijuana under the Compassionate IND Program, plaintiff has failed to state a claim for the denial of due process in connection with the cancellation of his IND application.

II. Even If Plaintiff Had Stated A Constitutional Claim, He Was Not Denied Equal Protection Or Due Process In This Case

Even if plaintiff has stated a claim under the Equal Protection Clause, the FDA is entitled to summary judgment on that claim because plaintiff was not treated differently than other similarly situated individuals. As the Spyker Declaration points out, plaintiff was not alone in having his IND application

cancelled after it was initially allowed to proceed by the FDA. There were twenty-seven additional single-patient IND applications that FDA had allowed to proceed which were ultimately cancelled after the Secretary's March 1992 decision. Id. at para. 15. The only individuals who received marijuana based on an IND application were those who had received FDA and DEA approval, and who had begun to receive marijuana prior to the March 1992 decision. The last person to receive marijuana under a single patient IND began in August 1991, the month plaintiff's physician applied for the necessary DEA registration. Id. at paras. 11-14.

Thus, plaintiff was treated no differently than any other individual who had failed to complete the entire application process, including receipt of a registration from the DEA and receipt of marijuana from the National Institute on Drug Abuse, prior to the Secretary's March 1992 decision. Because plaintiff was clearly not treated differently from similarly situated individuals, the FDA is entitled to summary judgment on this issue.

However, to the extent that plaintiff was treated differently than patients who had completed the IND application process and begun receipt of marijuana prior to the March 1992 decision, such difference in treatment was rationally based. The decision not to provide marijuana for single-patient INDs was based on the fact that the research gained through IND users of marijuana had provided little, if any, useful data. Based on the

questionable value of the data received, and concerns over the negative public health aspects of marijuana use, the FDA reasonably concluded that it did not wish to expand the pool of marijuana users. Spyker Declaration, para. 12. In fact, the FDA intended, by working with the patient users and their doctors in exploring alternative treatment, to eventually eliminate the pool of marijuana users altogether. Id. It would have been irrational for the FDA to continue to accept IND applications for the receipt of marijuana while it was actively trying to eliminate patient users of the drug.

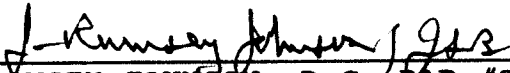
Therefore, the FDA's decision to stop accepting IND applications for marijuana is clearly reasonably related "to the legitimate state purpose of protecting the public health." Carnohan v. United States, 616 F.2d at 1122. Accordingly, plaintiff cannot demonstrate that he was denied equal protection in this case.

Finally, plaintiff cannot demonstrate any violation of due process in connection with his IND application. He was permitted to file the application and it proceeded through the FDA's review process in a manner no different from other IND applicants. See Spyker Declaration, paras. 5-9. Not only has plaintiff failed to allege a deprivation of any process to which he was due, but the FDA is unaware of any such deprivation. Consequently, the FDA is entitled to summary judgment on plaintiff's due process claim as well.


CONCLUSION

For the reasons given above, defendant FDA's motion to dismiss or, in the alternative, for summary judgment, should be granted.

Respectfully submitted,



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