

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>KIYOSHI KUROMIYA, et al., Plaintiffs,</b>  <b>v.</b>  <b>THE UNITED STATES OF AMERICA, Defendant.</b>	<b>CIVIL ACTION NO. 98-3439</b>
------------------------------------------------------------------------------------------------------------------------------	---------------------------------

**MEMORANDUM & ORDER**

**Katz, S.J.**

**December 1, 1999**

A group of approximately 160 plaintiffs has raised an equal protection challenge to the administration of a government program by which eight individuals receive marijuana to treat various ailments. Plaintiffs contend that they are similarly situated to those individuals and that the government has acted unconstitutionally in denying them access to the same program.<sup>1</sup> The time for discovery has now concluded, and the government's motion for summary judgment is before the court. As the government had a rational basis for its decision not to supply marijuana to the plaintiffs through the compassionate use program, the court must grant the government's motion.

**I. Background**

The compassionate use program was established in 1978 to settle a civil lawsuit. Initially, only one individual, Robert Randall, received marijuana from the government for

---

<sup>1</sup>By order of March 10, 1999, the court granted in part and denied in part the government's motion to dismiss. See Kuromiya v. United States, 37 F. Supp.2d 717 (E.D. Pa. 1999). The court dismissed all of the plaintiffs' claims challenging the constitutionality of the Controlled Substance Act as applied to marijuana as well as an equal protection challenge related to the scheduling of the drug Marinol. The court, however, permitted plaintiffs' claims regarding access to the "compassionate use" program to proceed.

treatment of his glaucoma. See Def. Ex. 3 at 3 (Mem. from Assistant Secretary of Health James Mason describing program’s origin); see also Def. Ex. 5 (legal documents describing circumstances by which Randall would receive marijuana without legal consequences). The government subsequently agreed to supply medical marijuana to several other individuals through the same mechanism. See Def. Ex. 3 at 3-4.<sup>2</sup>

The beginnings of this program may be distinguished from the ordinary processes by which most drugs are approved for experimental use. The Food and Drug Administration (FDA) does provide a mechanism known as the treatment IND<sup>3</sup> by which drugs that are under clinical investigation may be distributed to patients for whom no alternative drug or therapy is available. See 21 C.F.R. § 312.34(a). However, the compassionate use program did not comply with the requirements of a treatment IND. See 21 C.F.R. § 312.34(b)(1);<sup>4</sup> Def. Ex. 1 ¶¶ 3-6 (noting

---

<sup>2</sup>Several government agencies, including the FDA, the National Institute on Drug Abuse/National Institute of Health, and the Drug Enforcement Agency were involved, directly or indirectly, in the process by which applicants were approved and ultimately received shipments of marijuana cigarettes. See Plf. Ex. 2 at 7-14 (interrogatory responses describing administration); see also id. at 31-35 (outlining application, approval, and implementation process).

<sup>3</sup>“IND” stands for “investigational new drug.” A traditional IND entails a long-term series of clinical trials aimed at establishing the safety and efficacy of the drug. See 21 U.S.C. § 355(b)-(d); 21 C.F.R. § 312.21.

<sup>4</sup>A treatment IND may be approved if:

- (i) The drug is intended to treat a serious or immediately life-threatening disease;
- (ii) There is no comparable or satisfactory alternative drug or therapy available . . . ;
- (iii) The drug is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed; and
- (iv) The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence.

distinctions between compassionate use program and treatment INDs). Rather, the marijuana program may more appropriately be described as a “single patient IND,” in which the drug was simply distributed to certain individuals. As described by the government,

Single patient INDs cannot establish the scientific efficacy of new drugs; nor are they intended to permit the widespread distribution of unapproved drugs. The INDs are not conducted in controlled clinical settings, nor are they blinded or closely monitored by FDA or the clinical investigators. Thus, reports resulting from single patient INDs are merely anecdotal, and are not designed in a manner to provide the type of scientific data necessary to establish the safety and efficacy of a new drug.

Def. Ex 1 ¶ 5 (Aff. of Dr. Cynthia McCormick<sup>5</sup>). Moreover, the government apparently never conceded formally that marijuana was effective in treating the symptoms of those individuals who were receiving it.

This anomalous status ultimately contributed to the termination of the compassionate use program. In 1989, applications began to increase from fewer than five a year to a high of approximately forty applications following Mr. Randall’s work with advocacy organizations to expand the single patient IND. See Def. Ex. 1 ¶ 7; Def. Ex. 3 at 4; Def. Ex. 6 at 1; but see Plf. Ex. 2 at 30 (government response to interrogatory stating that a total of 63 individuals applied for single patient INDs between 1978 and the present). The government apparently attempted to dissuade Mr. Randall from these efforts and informed him of the methods by which a larger-scale IND that might lead to useful findings could be initiated. See Def. Ex. 6.

---

Id.

<sup>5</sup>Dr. McCormick is the FDA’s Division Director of Anesthetics, Critical Care and Addictive Drug Products, Center for Drug Evaluation and Research. See Def. Ex. 1 ¶ 1. Among her other duties, Dr. McCormick evaluates IND applications. See id. ¶ 2.

The government also, however, decided to reevaluate the program as a whole. As Dr. McCormick explained the situation,

[A]s I understand it, [this expansion] threatened the availability of marijuana for future single patient INDs and other research projects. In 1991, FDA sought assistance from the Department of Health and Human Service, Public Health Service, in dealing with the increasing number of single patient INDs. This led to a review of the INDs by Assistant Secretary for Health, Dr. James O. Mason.

Def. Ex. 1 ¶ 7. Dr. Louis Sullivan, the Secretary for Health & Human Services, eventually approved Dr. Mason's recommendations that the program end except for those patients already receiving marijuana. See Def. Ex. 4 at 27-28.

In the first memorandum to Dr. Sullivan, dated June 1991, Dr. Mason highlighted many of the issues that would play a part in the program's termination, including the difficulty of acquiring marijuana and the lack of useful results. See Def. Ex. 7 at 1-3. Dr. Mason stated that the "widespread use of marijuana for medical purposes, especially where alternative medications are available, is bad public policy and bad medical practice." Id. at 3. After discussing difficulties in actually bringing marijuana into the marketplace, Dr. Mason described various side effects and the lack of medical support for claims made by medicinal marijuana users. See id. at 3-4.

The second memorandum, dated January 31, 1992, includes Dr. Mason's recommendations, which were approved by Dr. Sullivan on March 4, 1992. See Def. Ex. 3 at 8. As Dr. Mason explained, his recommendations were "based on the premise that supplying marijuana to additional applicants was suspect on public health grounds, and, in the absence of a clear research protocol, raised concerns about [the government's] legal authority to distribute

marijuana for this purpose.” Id. at 1. After hinting at possible legal difficulties in continuing to supply marijuana, Dr. Mason stated that “[l]ittle or no useful data has been obtained” from the program, and “there is consensus within the Public Health Service that the single-patient IND process would not yield useful data in the future that would resolve the remaining safety and effectiveness issues.” Id. at 4. Dr. Mason then outlined the recommendations that were ultimately approved:

1. NIDA will continue to grow marijuana in amounts sufficient to fulfill the needs of PHS-approved research. New single patient INDs would not fall into this category.
2. PHS will continue to supply marijuana to the 13 patients currently receiving shipments. At the same time, PHS will aid and encourage the physicians of all patients to use alternative therapies.
3. NIH will work with its AIDS clinical trial network to design a protocol and begin a well-controlled clinical trial of Megace and Marinol, the most promising agents studied to date for HIV wasting-syndrome. The NIH study protocol is being developed and trials can begin in 3-6 months. Every effort will be made to enroll the patients of physicians with pending applications in this study as well as the ongoing Unimed study.

Id. at 4-5. The same memorandum explains that those individuals with pending applications would not receive marijuana. See id. at 8; see also Def. Ex. 8 (March 18, 1992, memorandum from Mason describing implementation of those steps); Def. Ex. 9 (March 20, 1992, memorandum from Mason describing final decision).

As the foregoing suggests, the question before the government was what to do with the individuals who were then receiving marijuana. At the time the program stopped accepting new applicants in March 1992, there were thirteen participants; presently, eight remain. See Def. Ex. 1 ¶ 11. The government’s submissions reveal that it decided to permit those currently in the program to continue receiving marijuana (although they would be encouraged to utilize

alternative therapies) and to terminate the program as those patients died or left the program voluntarily. See id. ¶ 9. As Dr. Mason explained, this decision would “in effect, extricate PHS from supplying marijuana through single-patient INDs by attrition[.]” Def. Ex. 3 at 6; see also Def. Ex. 9 at 1 (March 20, 1992, memorandum from Mason to FDA, NIH, and Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), stating that government would continue to provide marijuana to those currently receiving it in an effort to balance interests).

## II. Discussion<sup>6</sup>

The government’s submissions suggest at least four bases for the termination of the compassionate use program: bad public policy, bad medicine, a lack of marijuana for the remaining patients, and the existence of alternative treatments. The government explains its decision to continue providing marijuana only to the remaining individuals in the program as a means of balancing the government’s desire to avoid distributing marijuana to increasing numbers of individuals with the interests of those who had already relied upon the drug. These

---

<sup>6</sup>Summary judgment is appropriate “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). The moving party has the burden of demonstrating the absence of any genuine issue of material fact. See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). When ruling on a summary judgment motion, the court must construe the evidence and any reasonable inferences drawn therefrom in favor of the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). In other words, if the evidence presented by the parties conflicts, the court must accept as true the allegations of the non-moving party. See id. However, Rule 56 “mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” See Celotex Corp., 477 U.S. at 323.

justifications provide a rational basis for the government's decisions.<sup>7</sup>

As the court discussed previously, the classification in this case does not “burden[] a fundamental right” or “target[] a suspect class.” Kuromiya, 37 F. Supp.2d at 727 (citations omitted). A classification that does not affect a fundamental right or a suspect class

cannot run afoul of the Equal Protection Clause if there is a rational relationship between the disparity of treatment and some legitimate governmental purpose. Further, a legislature that creates these categories need not actually articulate at any time the purpose or rationale supporting its classification. Instead a classification must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis for the classification.

Heller v. Doe, 509 U.S. 312, 320 (1993) (citations, internal punctuation omitted); see also Romer v. Evans, 517 U.S. 620, 631 (1996) (stating that reviewing court must uphold classification “so long as it bears a rational relation to some legitimate end”).<sup>8</sup> Courts may not use the rational

---

<sup>7</sup>The fact that this constitutional challenge occurs in the context of an agency action does not fundamentally alter the court's approach. See, e.g., Smith v. Shalala, 954 F. Supp. 1, 4 (D.D.C. 1996) (applying rational review to FDA's refusal to permit plaintiff to participate in an IND). In contrast, plaintiffs' action could not proceed if they were simply challenging the FDA's refusal to permit the distribution of marijuana for medical purposes, see, e.g., Carnohan v. United States, 616 F.2d 1120, 1121 (9th Cir. 1980); Garlic v. FDA, 783 F. Supp. 4 (D.D.C. 1992), or if they were attacking a particular regulation. See, e.g., Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936, 939 (D.C. Cir. 1991). However, the court does not interpret plaintiffs' claims as advancing either of those theories. Rather, before the court is only the very narrow question of whether equal protection principles were violated by the fact that, when the government decided to end the compassionate use program, plaintiffs were excluded when others were allowed to remain in the program.

<sup>8</sup>As noted previously, it is not clear whether the plaintiffs intend to raise claims on behalf of all individuals who would like to use medical marijuana and are not permitted to do so or whether the appropriate comparison is between those individuals who were accepted into the program but denied marijuana because their applications were “pending” at the time of the decision. See Kuromiya, 37 F. Supp.2d at 729 n.13. As the result would be the same regardless of which classification is at issue, the court does not attempt to discern plaintiffs' intent.

basis standard as an excuse to judge the wisdom of policy choices. See, e.g., Heller, 509 U.S. at 319-20; see also FCC v. Beach Comm., Inc., 508 U.S. 307, 314 (1993) (noting that rational review is a “paradigm of judicial restraint”).

Plaintiffs thus bear a very heavy burden in challenging a government decision under rational basis review. Although, in this case, the government produced materials explaining the bases for its decisions, it has no burden to produce evidence demonstrating the objective rationality of the actions in question; even “rational speculation unsupported by evidence or empirical data” is enough to uphold the classification at issue. Heller, 509 U.S. at 320 (citations, punctuation omitted). The burden is on the plaintiffs, as the party challenging the classification, “to negative every conceivable basis which might support it, whether or not the basis has a foundation in the record[.]” Id. at 320-21 (citations, internal punctuation omitted); see also Beach Comm., Inc., 508 U.S. at 313 (stating that classification must be upheld if there are “plausible reasons” for it). Even illogical and unscientific actions do not necessarily violate the rational basis test so long as the assumptions made are “arguable.” Heller, 509 U.S. at 321, 333.

Plaintiffs have not met their burden, and the classification at issue here passes muster under rational basis review. As described previously, the single patient marijuana IND was never designed to derive scientifically valid results, particularly as it was initiated as part of a settlement rather than as a traditional IND. The government consistently expressed skepticism about the single patient IND format and the efficacy of using marijuana. See Def. Ex. 3 at 4 (“Little if any useful data has been obtained over the years and there is consensus within the Public Health Service that the single-patient IND process would not yield useful data in the future that would resolve the remaining safety and effectiveness issues.”); Def. Ex. 10 at 1 (letter

from Assistant Secretary of Health noting limits of single patient IND); Def. Ex. 11 at 4-5 (May 21, 1999, memorandum describing new research proposals for marijuana and stressing problems with single patient IND format). Both Dr. Mason's memoranda and Dr. McCormick's affidavit indicate that the program ended because the government did not wish to expand it in the wake of the increased applications, particularly as the government believed that alternative treatments were safer and more effective. The government was also uncomfortable with distributing marijuana as a medication to increasingly large numbers of patients given that marijuana was and is a controversial and currently illegal drug.

Given these considerations, the fact that some individuals continued to receive marijuana after the termination of the program as a whole does not constitute an equal protection violation. The government emphasized that these individuals had relied on the government-supplied marijuana for many years and that it did not wish to harm those individuals by abruptly cutting off their supply. The government's efforts to persuade these patients and their doctors to utilize alternative treatments is also consistent with its overall goal of limiting its role in distributing marijuana. While there is obviously tension between the government's repeated statements that marijuana has not been proven to provide any beneficial results and its decision to continue supplying it to eight individuals for medical needs, the government has argued that there is a difference between individuals who have used government-supplied marijuana for many years, in some cases, and those who have not.

As discussed in the previous order, the government may approach a problem piecemeal and treat different aspects of a problem differently. See Kuromiya, 37 F. Supp.2d at 728; see also New Orleans v. Dukes, 427 U.S. 297, 303 (1976) (the government may "adopt[] regulations that

only partially ameliorate a perceived evil”); see also Smith v. Shalala, 954 F. Supp. 1, 4 (D.D.C. 1996) (holding that there was no equal protection violation in refusing to admit plaintiff to IND); United States v. Cannabis Cultivator’s Club, 1999 WL 111893, at \*3-4 (N.D. Cal. Feb. 25, 1999) (stressing that the selection of a particular treatment is properly regulated by the government, including the FDA, as “an exercise of Congressional authority to limit the patient’s choice of medication” (citations omitted)); Kramer-Katz v. United States Pub. Health Serv., 872 F. Supp. 1235, 1240-41 (S.D.N.Y. 1994) (indicating that in some circumstances those already participating in an IND may have a vested interest in its continuation).<sup>9</sup> While there is certainly a disparity in treatment in this case, that disparity is neither “invidious nor irrational.” Tustin v. Heckler, 749 F.2d 1055, 1063-64 (3d Cir. 1984) (citations omitted). In short, a decision to discontinue a controversial program by “attrition” was not an infringement of equal protection principles.

Plaintiffs’ responses do not provide any evidence that the government’s actions were irrational. The plaintiffs first submitted an affidavit by Kiyoshi Kuromiya, who recounts the success he has had in using marijuana to combat the wasting caused by AIDS and the serious limitations of virtually all other drugs. See Kuromiya Aff. ¶¶ 23-24, 34-35. He also describes his work with individuals attempting to gain approval for marijuana research protocols, see id. ¶¶ 36-40, and the scientific basis for claiming that smoked marijuana is medically beneficial and, indeed, crucial. See id. ¶¶ 42-45. This affidavit does not, however, counter the legitimate bases articulated by the government for giving marijuana to some individuals but not others,

---

<sup>9</sup>This holding also suggests that the plaintiffs are not similarly situated to those already in the program, which constitutes an independent reason to reject plaintiffs’ equal protection claim.

particularly in light of the rational decision to end the program as a whole. While Mr. Kuromiya suggests that some individuals with power over the program expressed homophobic beliefs, see id. ¶¶ 31-33, there is no evidence indicating that any such motivation played a role in the decision to continue providing marijuana to those patients remaining in the program or even that those officials accused of such statements relied on such a malicious motivation in deciding to end the program as a whole.<sup>10</sup>

Similarly, the plaintiffs' memorandum and supporting materials do not cast doubt on the rational basis of the government's decision to provide marijuana only to the eight remaining individuals in the program. While the memorandum of law reiterates plaintiffs' claim that the distinction is arbitrary, there is no evidence or analysis in support of this assertion. In fact, most of the material submitted discusses the efficacy of marijuana as a treatment rather than addressing the equal protection implications of the government's decision to terminate the program. Those documents that do directly address the compassionate use program do not suggest that there was any irrational or otherwise impermissible basis for the government's decision. If anything, these documents reinforce the government's own submissions by tending to demonstrate that the government consistently attempted to dissuade individuals from using smoked marijuana because of its belief that alternative therapies existed and that its decision to continue supplying marijuana to those already receiving it was based on consideration of the

---

<sup>10</sup>In paragraph 53, Mr. Kuromiya also suggests that the defendant has violated the Americans with Disabilities Act by singling out individuals with AIDS for special disfavor. No such claims were advanced in the complaint or in response to the motion to dismiss, and the court does not consider plaintiffs to have articulated any claim based on this cause of action at such a late date.

different interests they had.<sup>11</sup> While these documents do suggest that the increasing number of applications from individuals suffering from AIDS played a role in the decision to terminate the program, they also indicate that the concern stemmed from the increasing numbers and expansion of the program rather than any animus towards AIDS sufferers. See, e.g., Plf. Vol. I Ex. 30 (March 29, 1991 internal memorandum at HHS expressing concern that new applications had increased in number and extended “into a new indication”).<sup>12</sup>

The court also notes that the government has submitted documentation of the processes by which it will now make research grade marijuana available to sponsors interested in conducting research on the medical benefits of marijuana. See Def. Ex. 11 (Mem. of May 21, 1999); see also Kuromiya Aff. ¶ 39 (acknowledging new guidelines). The government emphasizes that these trials will be directed “toward multi-patient clinical studies” because of concerns that the single patient format cannot produce useful scientific data. Def. Ex. 11 at 5. These regulations seemingly indicate an increased willingness to consider new research protocols

---

<sup>11</sup>See, e.g., Plf. Vol. 1 Ex. 44 (information sent to physicians on the use of marijuana cigarettes stressing side effects and encouraging physicians to consider alternative treatments); id. Ex. 45 (1991 memorandum noting potential limits on marijuana supplies); id. Ex. 54 (1991 memorandum from Office of National Drug Control Policy recounting HHS reservations about single patient marijuana IND); Plf. Vol. 2 Ex. 8 (February 25, 1992, memorandum describing HHS’s efforts to provide alternative therapies for patients with pending applications who would not receive marijuana); Plf. Vol. 3 Ex. 2 (portion of redacted 1993 memorandum describing decision to terminate program because of lack of research, political inconsistency, and existence of alternative medication).

<sup>12</sup>Plaintiffs also argue that the documents supporting the government’s motion and memorandum do not comply with the requirements of Federal Rule of Civil Procedure 56. Aside from the fact that the government is under no obligation to provide any justification for its actions under the rational review standard, the government has provided two affidavits, one from Dr. McCormick recounting personal knowledge, see Def. Ex. 1, and one from Karen Wagner, an attorney, see Def. Ex. 2, attesting to the fact that the documents submitted are true and correct copies of Health and Human Services documents made in the regular course of business.

that are intended, from their inception, to lead to meaningful results.<sup>13</sup>

### III. Conclusion

The issue is not whether the government's position is correct but whether it is rational. We have learned a lesson from history that courts' substituting their own judgments for the law often involves significant risk, and, in this case, the court simply cannot say that the government acted irrationally.

Providing marijuana to eight people without legal consequence is somewhat strange. Even odder is the government's having provided marijuana to a small group of people over the years in the compassionate use program without having obtained a single useful clinical result as to the utility or safety of marijuana as a medicine to alleviate the symptoms of illness. If morphine were thus dispensed, the absurdity would be even more apparent. The government has finally instituted a program to make its supply of marijuana available to serious researchers to determine the utility of the substance as medicine based on scientific empiricism rather than shibboleth. In time, knowledge sometimes has a chance to prevail over ignorance.

Given the recent changes in government policy and the flawed development of the compassionate use program, it is not beyond the bounds of rational policy to limit provision of marijuana as the government has done. One hopes that both the advocates and opponents of

---

<sup>13</sup>As a final note, the court does not construe this claim as a challenge under the Administrative Procedures Act, 5 U.S.C. § 702, but, even if it did, the government's actions would be upheld. Under these statutory provisions, a private party may bring an action in the district courts if he or she is adversely affected by a final agency action that is contrary to law, but a court may only reverse administrative action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "contrary to constitutional right." 5 U.S.C. § 706(2). As described above, the agency's actions were supported by rational considerations and could not be considered arbitrary or capricious.

medical marijuana will allow science to substitute for slogans.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>KIYOSHI KUROMIYA, et al., Plaintiffs,</b>  <b>v.</b>  <b>THE UNITED STATES OF AMERICA, Defendant.</b>	<b>CIVIL ACTION NO. 98-3439</b>
------------------------------------------------------------------------------------------------------------------------------	---------------------------------

**ORDER**

**AND NOW**, this 1st day of December, 2003, upon consideration of Defendant's Motion for Summary Judgment, the response thereto, and the Defendant's reply brief, it is hereby **ORDERED** that the Motion is **GRANTED**. This case is dismissed, and the clerk shall mark this action **CLOSED**.

**BY THE COURT:**

\_\_\_\_\_  
**MARVIN KATZ, S.J.**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<p><b>KIYOSHI KUROMIYA, et al., Plaintiffs,</b></p> <p style="text-align:center"><b>v.</b></p> <p><b>THE UNITED STATES OF AMERICA, Defendant.</b></p>	<p><b>CIVIL ACTION NO. 98-3439</b></p>
---------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------

**J U D G M E N T**

**AND NOW**, this 1st day of December, 1999, judgment is entered in favor of the defendant and against the plaintiffs.

**BY THE COURT:**

\_\_\_\_\_  
**MARVIN KATZ, S.J.**