

distribution of marijuana outside the IND process is in violation of the Act.

4. While FDA processes and allows single-patient INDs for investigational drugs to proceed, FDA does not supply the drugs. In the case of single-patient INDs 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 authority under the Public Health Service Act. Before the National Institute on Drug Abuse can supply the marijuana to the sponsoring physician for a single-patient IND, because the drug is regulated under the Controlled Substances Act, the physician must apply to and receive approval from the Drug Enforcement Administration, the Department of Justice, to receive and dispense the marijuana. When the Drug Enforcement Administration 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.

5. When a single-patient IND for marijuana is received by the Center for Drug Evaluation and Research, it is forwarded to the Pilot Drug Evaluation Staff for review. The IND is assigned to a consumer safety officer who distributes copies to the reviewing chemist, pharmacologist, and medical officer. These reviewers decide whether it is safe for the study proposed in the IND to proceed.

6. The Center for Drug Evaluation and Research received a single-patient IND for marijuana for Ladd Huffman on January 2,

1991. The IND was submitted by Patricia J. Harrison, M.D. The IND was received by the Pilot Drug Evaluation Staff on January 7, 1991. The consumer safety officer distributed the IND to the reviewers. The pharmacology review was completed on January 10, 1991, and it determined that it was safe for the IND to proceed. The chemistry review was completed on January 11, 1991, and it determined that it was safe for the IND to proceed.

7. I called the sponsoring physician, Dr. Harrison, on January 11, 1991, to discuss the requirements for the IND and to request the submission of additional information.

8. I completed the medical review of the IND for Ladd Huffman on January 16, 1991, and determined that it was safe for the IND to proceed. On January 25, 1991, I received the information I had requested from Dr. Harrison.

9. On March 8, 1991, I issued a letter to Dr. Harrison advising her that the IND for Ladd Huffman could proceed.

10. 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 for Drug Abuse would continue to supply marijuana for single-patient INDs.

11. In March 1992, the Pilot Drug Evaluation Staff was advised that the Secretary of the Department of Health and Human Services had made a decision that the National Institute on Drug Abuse would not provide marijuana for single-patient INDs except to those patient who were receiving marijuana at that time. This

group receiving marijuana included patients whose INDs FDA had already reviewed and allowed to proceed, whose physicians had received approval to receive the marijuana from the Drug Enforcement Administration and for whom the National Institute on Drug Abuse had shipped marijuana upon receipt of the Drug Enforcement Administration order form submitted by the physicians.

12. As I understand it, the March 1992 decision of the Secretary of Health and Human Services not to provide marijuana to additional single patient INDs was based on a number of considerations including the health concern of providing patients with potentially harmful substances, and the fact that existing medical evidence does not support additional research on smoked marijuana to treat disease in single patient studies. For those patients who had already received marijuana, marijuana would continue to be supplied while their physicians, with assistance from the Department of Health and Human Services, explored alternative therapies. Through attrition among this patient group, the Department of Health and Human Services would eventually achieve its ultimate goal of not supplying marijuana for any patients under single-patient INDs.

13. As I understand from the National Institute on Drug Abuse, shipments began in August 1991 for the last person to receive marijuana under a single-patient IND.

14. As I understand from the Drug Enforcement Administration, that agency received an application from Dr.

Harrison to receive and dispense marijuana for Ladd Huffman on August 19, 1991 but no registration to receive marijuana was issued. Since Dr. Harrison had not received approval to receive and dispense marijuana for Ladd Huffman from the Drug Enforcement Administration, the National Institute on Drug Abuse had not shipped any marijuana for Ladd Huffman. Therefore, under the March 1992 decision of the Secretary, the National Institute on Drug Abuse would not supply marijuana for Ladd Huffman's single-patient IND.

15. There were 27 additional single-patient INDs that FDA had allowed to proceed which had not receive marijuana. Under the Secretary's March 1992 decision, marijuana would not be supplied for these INDs by the National Institute on Drug Abuse.

16. In March 1992, as a result of the Secretary's decision, I contacted the sponsoring physicians of the INDs for Ladd Huffman and other patients who were not already receiving marijuana to advise them that the National Institute on Drug Abuse would not supply marijuana for their single-patient INDs. I 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 INDs for these individuals were cancelled.

17. FDA cannot disclose information regarding patients receiving marijuana under single-patient INDs without such patients' consent.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that, to the best of my knowledge and belief, the foregoing is true and correct.

Executed on: June 16, 1993 at Rockville, MD.

Daniel A. Spyker
Daniel A. Spyker, PhD, M.D.
Medical Officer
Pilot Drug Evaluation Staff
Center for Drug Evaluation
and Research
United States Food and Drug
Administration

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LADD HUFFMAN,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil No. 93-0237 NMJ

DECLARATION OF CORINNE P. MOODY

I, Corinne P. Moody, do hereby declare the following:

1. I am a Consumer Safety Officer in the Pilot Drug Evaluation Staff, Center for Drug Evaluation and Research, United States Food and Drug Administration (FDA). I have held this position since June 1989. Prior to this, I held several other positions in FDA regional and headquarters offices since 1977.

2. In my position as a Consumer Safety Officer, I am a regulatory specialist on a multidisciplinary team that reviews investigational new drug applications (INDs) and new drug applications (NDAs) submitted under the Federal Food, Drug, and Cosmetic Act. I manage the review process for drugs that are abused as well as drugs used to treat drug abuse. In my position, I have been responsible for the review process for single-patient INDs for therapeutic use of marijuana.

3. Under a single-patient IND, a sponsor, usually a physician, submits an IND for one patient to be treated with an unapproved drug that is under investigation. The contents of the single-patient IND includes the sponsor's name and curriculum

vitae, the patient's name, the disease being treated, the patient's medical history and the protocol for the study.

4. With regard to single-patient INDs for marijuana, three separate agencies, FDA, the Drug Enforcement Administration, and the National Institute on Drug Abuse, are involved. The sponsor of the IND submits it to FDA which in turn reviews the IND and determines if it is safe for the study under the IND to proceed. The sponsor also applies to the Drug Enforcement Administration for a Schedule I license to receive and dispense the marijuana to the patient. The National Institute on Drug Abuse supplies the marijuana for use under the single-patient INDs.

5. When the Drug Enforcement Administration receives an application from a sponsor for a Schedule I license to receive and dispense marijuana under a single-patient IND, that agency would request information from FDA regarding the status of the IND. The Drug Enforcement Administration would issue a Schedule I license only if FDA advised that the IND had been allowed to proceed.

6. 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 marijuana would continue to be supplied by the National Institute on Drug Abuse for single-patient INDs. In response to this decision, the Pilot Drug Evaluation Staff stopped taking actions on single-patient INDs for marijuana.

7. On August 21, 1991, FDA received a request from the Drug Enforcement Administration for information regarding the IND submitted for Ladd Huffman. As stated in paragraph 6, since the Pilot Drug Evaluation Staff had discontinued actions on single-patient INDs in light of the June 1991 decision of the Assistant Secretary for Health, I did not provide a response to the Drug Enforcement Administration's request for information on the IND for Ladd Huffman.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that, to the best of my knowledge and belief, the foregoing is true and correct.

Executed on: 6-16-93

327

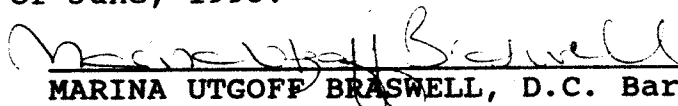
Corinne P. Moody
Corinne P. Moody
Consumer Safety Officer
Pilot Drug Evaluation Staff
Center for Drug Evaluation and
Research
United States Food and Drug
Administration

CERTIFICATE OF SERVICE

I certify that the accompanying Defendant's Motion To Dismiss, Or In The Alternative, For Summary Judgment, with declarations and proposed order, was served upon plaintiff pro se by depositing a copy of it in the U.S. mail, first class postage prepaid, addressed to:

Mr. Ladd Huffman
Post Office Box 201
Calumet, Iowa 51009

on this 17th day of June, 1993.


MARINA UTGOFF BRASWELL, D.C. Bar #416587
Assistant United States Attorney
555 - 4th Street, Room 4824
Washington, DC 20001
(202) 514-7226

