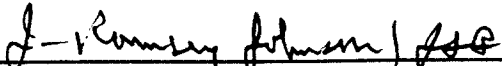
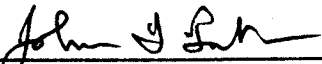


authorities. A proposed order reflecting the relief sought is also attached.

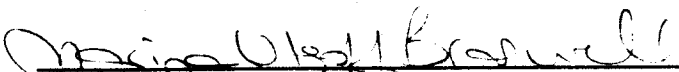
Respectfully submitted,



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2. A single-patient IND application for marijuana, an unapproved new drug under the Act, allows a physician to receive and dispense marijuana as an investigational drug for use in one specific patient. Id.

3. While the FDA processes and allows single-patient IND applications for investigational drugs to proceed, the FDA does not supply the drugs. 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. Id. at para. 4.

4. Before the National Institute on Drug Abuse can supply marijuana to the sponsoring physician for a single-patient IND application, the physician must apply to and receive approval from the DEA to receive and dispense the marijuana. Id.

5. The FDA's Center for Drug Evaluation and Research received plaintiff's single-patient IND application for marijuana, submitted by his physician, Patricia J. Harrison, on January 2, 1991. Id. at para. 6.

6. The Pilot Drug Evaluation Staff completed its pharmacology and chemistry review of plaintiff's application on January 11, 1991, and determined that it was safe for the IND application to proceed. Id.

7. Dr. Spyker called Dr. Harrison on January 11, 1991, to discuss the requirements for the IND and to request the submission of additional information, which she provided on January 25, 1991. Id. at paras. 7-8.

8. On March 8, 1991, Dr. Spyker issued a letter to Dr. Harrison advising her that plaintiff's IND application could proceed. Id. at para. 9.

9. 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. Id. at para. 10.

10. In light of this June 1991 decision, the Pilot Drug Evaluation Staff stopped taking actions on single-patient IND applications for marijuana. Declaration of Corinne P. Moody [Moody Declaration], Consumer Safety Officer in the Pilot Drug Evaluation Staff, filed on this date, para. 6.

11. The DEA received an application from Dr. Harrison to receive and dispense marijuana for plaintiff on August 19, 1991. Spyker Declaration, para. 4.

12. On August 21, 1991, the FDA received a request for information from the DEA regarding plaintiff's IND application. Moody Declaration, para. 7.

13. In light of the June 1991 decision, the FDA did not respond to the DEA's request. Id.

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 already receiving marijuana in August

1991. Spyker Declaration, paras. 11, 13.

15. This group included patients whose INDs the FDA had already reviewed and allowed to proceed, 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. Id.

16. The DEA did not issue Dr. Harrison a registration to receive marijuana on plaintiff's behalf. Id. at para. 14.

17. Since Dr. Harrison had not received approval to receive and dispense marijuana for plaintiff from the DEA, the National Institute on Drug Abuse has not shipped any marijuana to plaintiff. Id.

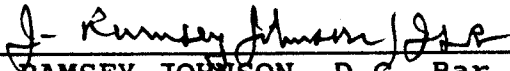
18. There were twenty-seven additional single-patient IND applicants whose applications the FDA had allowed to proceed but who did not receive marijuana following the March 1992 decision. Id. at para. 15.

19. 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 marijuana for their single-patient IND applications. 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. Id. at para. 16.

20. The single-patient IND applications for these individuals were then cancelled. Id.

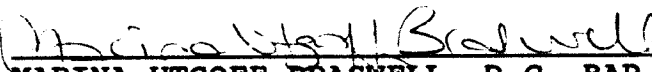
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