DECLARATION OF MICHAEL GOTTLIEB, M.D.

I, Michael Gottlieb, M.D., declare:

1. I am a medical doctor. I am credited with the discovery of AIDS. I was actively involved in both AIDS research and the practice of medicine, treating AIDS patients throughout the 1980's, from prior to my first publications on Acquired Immune Deficiency Syndrome in 1981 through this date, and specifically including the time period 1988 through 1991 involved herein. Many of my professional accomplishments are listed in my curriculum vitae attached hereto as Exhibit "A".

2. During the time period 1988 through 1991 I served as Medical Director of the Immune Suppressed Unit at Sherman Oaks Community Hospital, as Assistant Clinical Professor of Medicine at the UCLA School of Medicine and in the private practice of medicine specializing in the treatment of HIV and AIDS patients. Between 1985 and 1991 I was a consultant to the Rand Corporation in Santa Monica and also served from 1984 through 1985 as Acting Chief of the Division of Clinical Immunology and Allergy at the University of California at Los Angeles. From 1983 through 1987 I was the Director of the UCLA AIDS Clinical Research Center and from 1980 through 1987 I was an Assistant Professor of Medicine, Division of Clinical Immunology and Allergy, Department of Medicine, University of California, Los Angeles.

3. I received my medical degree from the University of Rochester School of Medicine. I am Board Certified in Internal Medicine and in Allergy and Immunology. I took my
internship at the Strong Memorial Hospital in Rochester, New York, Assistant Residency in Surgery, at the same institution 1974 to 1975 and Residency in Medicine 1975 to 1977. A served a fellowship in Medicine (Immunology and Rheumatology) at Stanford University of Medicine in 1977 through 1979 and was a Research Associate of the Howard Hughes Medical Institute at the Stanford University School of Medicine 1979 to 1980.


8. I have served as editor of the AIDS Clinical Digest and AIDS Patient Care. I have served on the Editorial Boards of Hematologic Pathology, Physicians Journal Update, AIDS Research and Human Retroviruses and the Journal of the Acquired Immune Deficiency Syndrome. I have also served as a Reviewer for the New England Journal of Medicine, Annals of Internal Medicine, Journal of Immunology, Physicians Journal Update and the Journal of Acquired Immune Deficiency Syndromes. Some of my additional professional accomplishments are contained in my curriculum vitae attached hereto as Exhibit "A".

9. Homeopathy is not and never was an approved modality of treating HIV or AIDS patients. Its principles including those detailed in the book Valentine Birds recommended to his patients in the "Wellness Letters" are outside the sphere of Western of medicine. Homeopathy's principles that its remedies can cure symptoms by using
substances which cause the symptoms is foreign to the principles of medicine. The homeopathic principle that the medicine is more "potent" the more diluted it is, is contrary to common, pharmacologic medical understanding, and in particular contrary to the concept of "dose response," a universally accepted principle of pharmacology. The homeopathic concept that an "energy essence" or "atomic imprint" is transferred from one substance to another by "concussing" or shaking it, is without scientific basis. The bankruptcy of homeopathy is made patent by its proffered mechanism of action as articulated in the book, "Homeopathy: Medicine for the 21st Century" by Dana Ullman, quoted extensively and recommended by Valentine Birds in his "Wellness Letters":

"Homeopaths agree that solutions diluted beyond 24x or 2c (diluted 1:9 24 times) may not have any molecules of the original solution, but they assert that 'something' remains: the essence of the substance, its resonance, its energy, its pattern . . . although homeopathic remedies may be so dilute as not to have any molecules, a pattern of the substance remains . . . homeopaths call this the 'liforce' or 'vital force', which they describe as inherent, underlying, interconnective, self healing process of the organism. The bio energetic force is similar to what
the Chinese call 'chi', the Japanese call 'ki', Yogis call 'prana', Russian scientists call 'bioplasm', and Star Wars characters call 'The Force.' Homeopathy theorizes that this bioenergetic process is sensitive to the sub molecular homeopathic medicines. The resonance of the micro dose is thought to effect the resonance of the person's life force."

10. To treat AIDS patients with homeopathy is not innocuous simply because the product is inert and may cause no direct harm. HIV and AIDS patients require appropriate treatment and if they are led to use ineffective treatments to the exclusion of effective treatments, they suffer a substantial detriment to their health.

11. Such products when offered for treatment of AIDS or HIV are defined by the Food and Drug Administration, Compliance Policy Guides, Guide 7150.10 as health fraud products, and present an indirect health hazard because they result in reliance on the product, and the consumer is likely to delay or discontinue appropriate medical treatment. Exhibit "B".

12. As stated in the Food and Drug Administration Compliance Policy Guidelines governing health fraud, effective June 5, 1987 "Health fraud products are articles of unproven effectiveness that are promoted to improve health, well being or appearance . . . A health fraud product presents an indirect health hazard, if as a result of
reliance on the product, the consumer is likely to delay or discontinue appropriate medical treatment."

13. In evaluating indirect health hazard products for FDA regulatory action, the following are relevant considerations: "Whether the therapeutic claims, conditions to be treated are significant . . ."; "whether there are scientific data or specific information to support the safety or effectiveness of the product for its intended use . . ."; and "the degree of vulnerability of the prospective user group, e.g. the elderly, or persons with illness for which there is no recognized effective treatment."

14. The promotion of homeopathy as efficacious in the treatment of cancer or AIDS is illegal, in violation of Health & Safety Code Section 26463. And it is a violation of medical ethics.

15. The foregoing Food and Drug Administration amendments to Policy Guide 7150.10 - Quackery; and Health & Safety Code Section 26463 aforementioned, mirror standards of practice and ethics governing physicians treating AIDS patients in the 1989 through 1991 time period during which the plaintiffs here were treated with these health fraud products.

16. The black box with dials and wires with electrodes described by Valentine Birds, M.D. in his deposition and by the plaintiffs in their declarations, as used in the treatment of his AIDS patients, describes no legitimate medical instrument known to me for the treatment of AIDS or any other disease. It is described by some plaintiffs as used in the selection of homeopathic remedies. This Dr.
Birds denies. However, in the plaintiff Helen Mac Eachron's medical chart is a document recording "organ frequencies" and "toxin frequencies" which Dr. Birds acknowledges were "frequencies" obtained by turning the dials on one of these black boxes. Dr. Birds acknowledges that these "organ frequencies" and "toxin frequencies" were used in the selection of medical treatment for his patients. And he also acknowledges treating his patients with the black box called the "Acuscope". These black boxes were therefore used to select homeopathic remedies, used as diagnostic tools to determine medical treatment and used to treat everything from catheter infection, Declaration of James Looney, to genital herpes, Declaration of Christopher Thompson.

17. While vague in the specific manner of using his black boxes, Dr. Birds acknowledged "sometimes" applying the "electrodes" to acupuncture points. He also described two other black boxes used by his office, one a "Recreation Machine" and one other, both used in the same manner. In the deposition of Doris Deiteman, she recalls being told that the black box worked on "sin waves." She tried it out on herself and felt nothing. None of these instruments are familiar to medical science, and would also fall within the FDA Compliance Policy Guide for Quackery and Health Fraud, Guide 7150.10, Exhibit "B".

18. "Typhoid vaccine protocol" is not a "protocol" accepted by medical science. I am aware of no scientific literature which would support the use of typhoid vaccine in the treatment of HIV or AIDS patients. In the deposition of Dr. Birds, he was unable to identify any literature,
scientific or otherwise, in support of his "protocol." There
is no physician of whom I am aware who uses any such protocol
on his AIDS or HIV positive patients. While Dr. Birds
claimed that there were eighteen physicians nationwide who
had used it, he could name none, and eighteen physicians,
even if accurate, would not qualify the "protocol."

19. Furthermore, the concept for the "protocol," use of
typhoid vaccine on HIV and AIDS patients, does not suggest
any plausible mechanism of efficacy in the treatment of
either HIV or AIDS. This was also the opinion of the
Administrative Judge for the Medical Board in re the
Revocation of the Medical License of Dr. Birds.

20. Finally, *Pneumocystis carinii* pneumonia, which was
the disease I found unusually prevalent in my sampling of
homosexual patients at the turn of the prior decade, and
which led me to identify and publish the first articles on
this Acquired Immune Deficiency Syndrome, was an extremely
deadly opportunistic disease which at that time and until the
development of pneumocystis prophylaxis and treatment with
Bactrim and Pentamidine, was the primary killer of AIDS
patients. It was well understood by everyone involved in the
treatment of HIV and AIDS patients that *Pneumocystis carinii*
pneumonia was a disease which if not properly treated would
commonly result in death.

21. Both prior to 1987 and through this date it was
mandatory to conform with the standard of care that patients
with pneumocystis be treated as aforementioned. To fail to
treat hospitalized AIDS patients with pneumocystis with the
standard antibiotic treatments was clearly both in violation
of the standard of care and very dangerous.

22. The treatment by Valentine Birds of AIDS patients with pneumocystis by intravenous infusions of Vitamin C was an extraordinary departure from the standard of care, which raises very real and very serious doubts about the competency and medical judgment of a physician who would so flagrantly place into jeopardy the life and health of his patients. The use of Vitamin C in the treatment of pneumocystis is not just very dangerous, bad medicine, it is truly such a departure from justifiable medical practice that this physician's judgment should not have been entrusted with decision making affecting HIV or AIDS patients at all, or the treatment of any disease entity which could result in a risk to life or health if untreated or improperly treated. This constituted unethical medical experimentation, particularly given that the approved modalities for Pneumocystis treatment were reasonably safe and efficacious and because the use of Vitamin C for the treatment of Pneumocystis was irrational.

23. In terms of both Drs. Birds' and Herman's, the use of Viroxan, there was never any credible evidence of Viroxan's efficacy. The in vitro and pre-clinical studies do not support efficacy or safety. See FDA Response to Pre-IND, the Declaration of Stuart Krasner, the University of California, Irvine, professor who conducted some of these studies for Dr. Herman, and the correspondence of Abbott Laboratories appended hereto as Exhibits "C", "D" and "E" respectively.

24. The Food and Drug Administration reviewed the Viroxan pre-Investigational New Drug Application and
concluded there was no evidence of efficacy or safety.

Michael A. Ussery, Ph.D., the Pre-IND Team Leader, Division of Anti-Viral Drug Products, Office of Drug Enforcement II, Food & Drug Administration, and George F. Kenter, Division of Drug Labeling Compliance, Food & Drug Administration, rejected the Viroxan Pre-IND stating, inter alia:

"The non-clinical data presented and the rationale proposed for the activity of Viroxan, do not provide sufficient support for any clinical trial on HIV - infected patients at any stage of the disease. No convincing evidence for either direct or indirect anti retroviral or immunomodulatory activity is provided.

The protocol is poorly conceived and does not meet the minimal necessary criteria; no rational study design is described; the efficacy end points are not described; no provision is made for adequate safety monitoring or management of toxicity.

The previous clinical experience data presented do not constitute evidence of either safety or efficacy.

The administration of Viroxan to humans for any purpose, or supplying the drug to patients in the absence of an
IND, is a most serious violation of the New Drug Provision of the United States Food & Drug Act... What has been said concerning 'Viroxan' applies with equal force to the use of any other new drug that is not the subject of an approved application or an IND." Exhibit "C".

25. It is doubtful that Dr. Birds had sufficient knowledge or training to interpret whatever Viroxan data was presented to him, since in deposition he professed ignorance of many of the most fundamental principles of the scientific method necessary to interpret the results of human studies. He expressed ignorance of the meaning of confidence intervals and p. values, universally employed to express the statistical significance of clinical results, without an understanding of which leaves the reader unable to discern the meaningfulness of the results, its statistical significance, the criteria by which results are determined to be meaningful. He also expressed ignorance of such fundamental principles necessary for the interpretation of clinical studies as "confounding variables" and he could not state even why it would be beneficial to blind or double blind, i.e. provide for the ignorance of the experimental subjects and investigator as to which individual subjects would receive the drug and which would not.

26. Stephen Herman's experimental protocol was described in the FDA response to the Pre-IND as "poorly conceived and does not meet the minimal necessary criteria;
no rationale study design is described; the efficacy and
points are not described; no provision is made for adequate
safety in monitoring or management of toxicity." Either Dr.
Birds failed to inquire of the protocol and methodology of
the Viroxan study in which he volunteered to participate, or
he failed to appreciate its gross lack of merit.

27. In the deposition of Stephen Herman, M.D., Dr.
Herman states unequivocally that he told Valentine Birds that
the drug was illegal and unapproved. Whether Dr. Herman is
to be believed or Dr. Birds is to be believed, given the
health consequences of their undertaking, especially to
catheterize human subjects for infusion of an experimental
drug, requires that the physician assure himself that the
drug has an approved IND or is otherwise approved for human
trials and that this modality of administration is approved.

28. Dr. Birds should have requested the experimental
protocol, the documentation in reference to the agency which
approved the trial, and should have inquired to confirm the
status of the investigation. This is particularly true since
Dr. Birds was a physician who would undertake the fiduciary
duty of a physician to his patients who would be catheterized
on his direction and this is especially so since it is not
reasonable to assume that a patient will or can make the
appropriate inquiry for himself but will most commonly rely
upon the physician's advice in the selection and use of the
modalities of his treatment.

29. Given Dr. Herman's testimony that he told Dr. Birds
that the drug was illegal and given the duty of Dr. Birds to
determine the drug's legality prior to administering the
1. drug, let alone by Hickman catheter, Valentine Birds clearly made an extreme departure from the standard of care when he agreed to administer this experimental drug and arrange to admit the patients for Hickman catheterization for infusion of the drug.

30. When the facts of Valentine Birds' conduct are considered as a whole. The use of homeopathy in the treatment of HIV and AIDS patients, the use of the black box, or the acuscope, or the Renaissance machine in the selection of homeopathic remedies, and the assessment of "organ frequencies" and "toxin frequencies" including as a diagnostic tool for use in determining the treatment to be accorded HIV and AIDS patients, the use of "typhoid vaccine protocol" in the treatment of HIV and AIDS patients, and perhaps most dangerously, the use of Vitamin C in the treatment of pneumocystis, and the use of Viroxan by Hickman Catheter, either because the foregoing was illegal or because it demonstrated a pattern of very bad judgment called health fraud by the FDA, Valentine Birds, M.D. demonstrated a wilful, intentional volitional, conscious disregard for the health and safety of his patients and violated medical ethics and both deprived his patients of proper health care to their detriment and exposed them to substantial dangers yielding septicemia, death and a variety of other adverse results as documented in the Medical Board Opinion and in the depositions and medical records of the plaintiffs herein.

31. Each of the factors set forth in the amendments to the Compliance Policy Guide 7150.10, "Quackery", Exhibit_B hereto, defining health fraud products with
indirect health hazards and health fraud products which
present direct health hazards are satisfied by Valentine
Birds' use of typhoid vaccine therapy and homeopathy in the
treatment of HIV and AIDS, and Vitamin C for the treatment of
pneumocystis.

32. Health fraud upon HIV positive and AIDS patients is
not innocuous. Treating pneumocystis with Vitamin C was an
extreme and dangerous departure from good medical judgment
and could have killed the patients if not stopped. This
extreme departure from good medical judgment, given its
potential life and death consequences was clearly despicable
as I understand the term and apply it in this medical
context. While homeopathy and black boxes may not cause
direct harm, they still fall within the definition of health
fraud products and pose a health hazard to the patient,
particularly to HIV and AIDS patients who may be led to
forego efficacious treatment necessary to prolong their
opportunistic disease free health and prolong their lives.

33. At the time period of 1988 to 1991, the only
approved drug for treatment of HIV and AIDS was AZT. AZT
delays the onset of AIDS and extends the life expectancy of
those who use it.

34. Apparently, according to both Dr. Birds' "Wellness
Letters" and his "Typhoid Vaccine Protocol" pamphlet, AZT and
Pentamidine were contra-indicated while taking the "Typhoid
Vaccine Protocol." Clearly then, the typhoid vaccine
protocol is an indirect health hazard. (This was also the
Opinion of the Administrative Law Judge for the Medical Board
who revoked the medical license of Valentine Birds, M.D.).
35. Valentine Birds, M.D. failed to do those things required by the standard of care, to wit, most importantly, AZT and pneumocystis prophylaxis and treatment. And what he did do, was AIDS fraud. HIV positive and AIDS patients are peculiarly desperate and particularly vulnerable to AIDS quackery in the same way and for many of the same reasons as cancer patients have traditionally been marked for cancer fraud. Each of the modalities, homeopathy, black boxes, typhoid vaccine, Vitamin C for pneumocystis and Viroxan, all met the FDA guidelines for quackery and health fraud.

36. Finally, since it is true that homeopathy is not a treatment for HIV or AIDS, if it is a treatment for anything, and since typhoid vaccine therapy is not a treatment for AIDS, and in fact an unapproved indication for an approved pharmaceutical whose only indication is a vaccination for typhoid, since the black boxes are patently a fraud, and of course Viroxan which was illegal human medical experimentation, leads in each case inescapably to the conclusion that Birds' recommendations of these drugs was misrepresentation and his failure to advise the patients of the unapproved status of the drugs was concealment of an important fact known to Birds, fairly obviously with the intention on his part to obtain money at the risk and in fact to the patient's injury.

37. With regard to Stephen Herman, it is apparent from a review of his 1988 patent submission that he had other than altruistic motives for developing Viroxan. In fact, the patent application lists indications for everything from bee stings, chicken pox and sunburn lotion, to venereal warts,
1 Exhibit F hereto, and subsequent documentation reveals that Herman tried to sell the product as a soap to the Japanese, Exhibit G hereto, considered submitting it for testing as a biological warfare antidote to the military, Exhibit H hereto, among any number of other claims.

38. It is also apparent that long prior to Dr. Berman's treatment of these plaintiffs with Viroxan in 1989 and 1990, he was attempting to sell the rights to Viroxan to drug companies, Exhibit I hereto, and was obtaining both a salary and expenses from a series of investors. See declaration of Stuart Krasner, Ph.D., Exhibit D, and the deposition of Stephen Herman.

39. The concept for the drug was found by the Food and Drug Administration to "provide no convincing-evidence for either direct or indirect anti retroviral or immunomodulatory activities...", Exhibit C hereto, as Herman postulated e.g. in his paper presented to a symposium on antioxidants in January 1990, entitled "Viroxan - a Novel Superoxide Generating Compound with Broad Spectrum Anti-Infecive Activity and Immunomodulatory Applications in the Clinical Management of Chronic Inflammatory Autoimmune Disease." Exhibit J hereto. Furthermore, the clinical experience which Dr. Herman tabulated in Exhibit J, supra, and as represented to his patients, e.g. declaration of James Looney, was certainly false and misleading. First, raw data are not meaningful in establishing efficacy or safety without a protocol, hypothesis, methodology, results and appropriate statistical analysis. Dr. Herman admitted in deposition having no protocol, hypothesis or methodology, and admitted
that he subjected the data to no test of statistical significance. No physician or scientist can interpret such data as presented. "The subjects were treated under no known protocol with an unapproved experimental compound. The clinical results are not interpretable as presented." FDA response to Pre-IND, Exhibit "C".

40. According to the testimony of the plaintiffs, they were provided Exhibit J, and/or its tables and graphs or in some cases selected raw data, i.e., immune panels from previous patients. None of these categories of information provided the patient any meaningful or accurate basis upon which to elect to use the drug. However, the manner in which it was presented, with lines slanting always upward purporting to record the effect on T-4 levels of Viroxan over time was misleading. It could be expected to mislead the untrained plaintiffs. Even Valentine Birds, M.D. concluded after review of Exhibit "J" that it was "very impressive."

Deposition of Valentine Birds, M.D.

41. Dr. Herman's data in addition to being uninterpretable, were also, certainly inaccurate, at least in the sense that he had many more subjects than he reported, in violation of the scientific method, and he reported only the data on those subjects whose T-4 levels went up.

42. In this equally anecdotal population of plaintiffs, all suffered declines in T-4 levels while on Viroxan. See depositions of plaintiffs and the medical records of Valentine Birds. Furthermore, according to the declaration of Stuart Krasner, Ph.D., Herman told him that he had treated hundreds of patients, and was in December 1989 treating
between forty and sixty AIDS patients. Exhibit D hereto.

And, therefore, it must certainly be true that the data presented by Herman to his patients, to the FDA in the pre-IND and in the "Viroxan - a Novel Superoxide" paper were selected from a larger population of patients with much more mixed results.

43. As one example, Timothy Johnson was treated with Viroxan from October 1989 until February 1991 and was in fact one of the subjects Herman presented to the AIDS conference in June of 1990. See declaration of Timothy Johnson, Exhibit K hereto. And yet his data Herman never reports. Nor does Herman report the data of any of the other plaintiffs with the exception of Mr. Looney.

44. The foregoing substantive misrepresentations of data are contained in the "Viroxan: A Novel Superoxide" study. The tables and graphs attached are not presented in accordance with the scientific method, they are misleading, specifically, giving a false impression that the drug has an effect when the results are not supportive of any effect, as concluded by the FDA in response to the more complete pre-IND.

45. For good reason, drugs should only be manufactured in licensed laboratories with proper sterility and quality controls. The reason for this is to assure that the product is sterile and unadulterated, particularly for intravenous administration and especially in immune deficient patients. According to Dr. Herman's testimony, and the Opinion of the Administrative Law Judge in re the Revocation of the Medical License of Valentine Birds, M.D., neither of Dr. Herman's
laboratories, neither that at his home nor that in Brea, was licensed. The sterility controls were nonexistent, and his quality control was inadequate, see, e.g., deposition of Stephen Herman, M.D., and declaration of Stuart Krasner, Ph.D., Exhibit D hereto.

46. Obviously, and as stated by the FDA in response to the Viroxan IND, "The Administration of Viroxan to humans for any purpose, or supplying the drug to patients, in the absence of the IND, is a most serious violation of the new drug provisions of the U.S. Food and Drug Act," Exhibit C hereto, and it is also very dangerous, especially in the absence of appropriate pre-clinical testing including adequate toxicology testing to determine the drug's safety, and the safety of the drug as administered, according to its proposed modalities of administration. In addition, the drug should not be administered until there is a determination, pre-clinically, of reason to believe the drug is efficacious. As acknowledged by the FDA response to the pre-IND, "the non-clinical data presented and the rationale proposed for the activity of Viroxan did not provide sufficient support for any clinical trial in HIV infected patients at any stage of the disease." Exhibit C hereto.

47. Viroxan also falls within the amendments to FDA Compliance Policy Guide 7150.10 - "Quackery", Exhibit "B", and in particular its definition of a "health fraud product." Clearly, "the therapeutic claims and conditions to be treated are significant," There were no meaningful "scientific data or specific information that can support the safety or effectiveness of the product for its intended . . . use," and
the intended recipients of the product fit the criteria "of vulnerability ... e.g., ... persons with illnesses for which there is no recognized effective treatment," at least in the sense that as yet medical science has not developed a cure for AIDS.

48. Certainly, persons with AIDS, and persons who are HIV positive, are both vulnerable and desperate to save their lives and avoid what is often a debilitating, painful and sad demise as they succumb to opportunistic diseases such as MAI, cytomegalovirus, cryptoccocal meningitis, Pneumocystis and others. They have seen their colleagues in their endeavor to live, waste to shockingly emaciated condition, kept alive by total parenteral nutrition until they finally succumb.

49. These men and women are particularly susceptible to any representation that a drug may raise their T-4 levels, because, for them that means, literally, immunity from the opportunistic diseases to which they fear they are destined to succumb otherwise.

50. It was not within the standard of medical care and specifically not within the standard of care of physicians who would undertake to treat AIDS patients and HIV patients to sell, dispense or recommend Viroxan to the plaintiffs. And it was not within the standards of medical ethics to conceal from them the fact that this drug was illegal, unapproved, or that the experimentation was being conducted by persons who were unqualified to do so. It was not within the standard of care to represent to plaintiffs that Viroxan had any effect on HIV, AIDS, their immune systems, or their susceptibility to opportunistic disease. It is below the
standard of medical ethics to tell these HIV and AIDS patients, as stated in the "clinical summary," one of the attachments to the "Viroxan: A Novel Superoxide" study, Exhibit J hereto that:

"Clinical Summary

"Rapid improvement in clinical manifestations in AIDS and ARC patients included: Reduction of adenopathy; marked decrease in fatigue; clearing of thrush and hairy leukoplakia; weight gain; clearing of neurological symptoms; clearing of visual disturbances; clearing of diarrhea; clearing of pulmonary congestion. As immune system regeneration progresses patients become totally asymptomatic ..." Clinical Summary, Exhibit J hereto.

51. This type of illegal human medical experimentation on HIV and AIDS patients was inconsistent with medical ethics. It was a violation of the confidence of the patient in his medical care providers, the confidence expressed by the plaintiffs as their basis for enduring the experimentation. Medical ethics requires that the health care provider not only refrain from aiding or participating in this type of human medical experimentation, but requires that the health care provider affirmatively advise the patient of the dangers and the consequences of submitting to such human medical experimentation.

52. This illegal human medical experimentation was
health fraud and both Drs. Herman and Birds failed to disclose the risks while they touted false benefits, which were unsupported by any of the data marshalled in support of the pre-IND. This was misrepresentation and a violation of a patient's right to be fully informed and make an intelligent decision to participate in medical experimentation. The AIDS fraud of Birds from homeopathy and black boxes to typhoid vaccine and Vitamin C for Pneumocystis to the Viroxan AIDS fraud all constituted unapproved human medical experimentation, which was ethically untenable and demonstrated a conscious disregard for the lives and health of their patients. Dr. Herman's conduct of the illegal human Viroxan medical experiment also in my opinion constituted conscious and wilful disregard of the lives and health of his experimental subjects.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed this 6th day of October, 1992, at Los Angeles, California.

MICHAEL GOTTLIEB, M.D.
SUBJECT:  Health Fraud - Factors in Considering Regulatory Action

BACKGROUND

Health Fraud products are articles of unproven effectiveness that are promoted to improve health, well being, or appearance. They can be drugs, devices, foods or cosmetics for human or animal use.

The previous Compliance Policy Guide 7150.10, Quackery - Priorities for Initiating Legal Action, established agency priorities based on categorizing the violative articles as a "direct health hazard", "indirect health hazard", or "major economic cheat". While such descriptions served the purpose of communicating the general impact of different types of health fraud products on the public, they did not take into account a number of factors which influence the initiation of a regulatory action.

This revision of the CPG establishes practical definitions for "direct health hazard", and "indirect health hazard". Because all health fraud products are in fact economic cheats, a separate definition for major economic cheat has been eliminated. The revised CPG also describes factors the agency will consider prior to initiating regulatory actions against health fraud products.

DEFINITIONS

A health fraud product presents a direct health hazard if it is likely to cause injury, death or other serious adverse effect when used as directed or in a customary manner.

A health fraud product presents an indirect health hazard if, as a result of reliance on the product, the consumer is likely to delay or discontinue appropriate medical treatment. The health hazard is indirect when it does no direct harm to the person as a result of its use, but rather delays or interferes with effective treatment. Consumers who purchase these products are misled by exaggerated or false claims that are made for the products.
POLICY

Products that pose a direct health hazard to the user shall receive the agency's highest priority attention, regardless of whether they are health fraud products. Documented cases of such products should be expedited and referred to the appropriate center for regulatory follow-up. Health fraud products for which there is not a documented direct health hazard (i.e. indirect health hazard products) will still be considered for regulatory action but on a lower priority.

In evaluating regulatory actions against indirect health hazard products, the following factors should be considered by districts and the centers:

1. Whether the therapeutic claims, or conditions to be treated are significant as interpreted by the appropriate center;
2. Whether there are scientific data or specific information to support the safety or effectiveness of the product for its intended or customary use;
3. The degree of vulnerability of the prospective user group, e.g., the elderly, persons with illnesses for which there is no recognized effective treatment;
4. The availability of other administrative or regulatory alternatives to bring the product or firm into compliance, e.g., education, referral or cooperation with local, state or other federal agencies;
5. The amount of agency resources required and whether they are sufficient to pursue the action to its conclusion;
6. The source of the product, size of the industry distributing the same or similar products, and the impact of the action on that source and industry;
7. The cost of the product, the economic impact of this cost on the target user group, as well as the profit (per sale) realized from the sale of the product;
8. The amount (dollar and volume) of product sold, and the geographical scope of its distribution;

In most cases, the seriousness of the therapeutic claims and the nature of the indirect hazard will be obvious. We recognize that when a product with unproven therapeutic claims is first introduced, it is difficult to predict its economic impact because, whether or not a regulatory action is taken, the product may not be accepted in the marketplace. Generally, new health fraud products with undetermined economic impact and limited health significance should result in a Notice of Adverse Findings Letter to the promoter. Regulatory action should be considered for products of limited health significance when it appears there is a growing national or substantial regional market for them. The office of compliance in each center will designate a contact and a back-up person for primary consultation on health fraud action.
Foods for human use, nutritional supplements and cosmetics with therapeutic claims will generally be treated as drugs and should be referred to the Center for Drugs and Biologics, Health Fraud Staff, which will coordinate these issues with the Center for Food Safety and Applied Nutrition.

Health fraud products that are the statutory responsibility of another agency should generally be referred to that agency for follow-up. For example, a strictly mail order operation, or one which principally uses media advertising should be referred to the U.S. Postal Service or the Federal Trade Commission and assistance provided, as needed. Local and state health departments and other federal agencies should be consulted because they may be sources of possible corrective action. If the health fraud practice or operation has been legalized (or its practical equivalent) in a certain locality, it is unlikely that a referral for a regulatory action against that practice or operation would be approved in that locality unless there are compelling reasons to do so. This does not preclude action in other jurisdictions. Referral of information on fraudulent products to the appropriate home district and headquarters units should be done as a matter of course.

In general, regulatory action will continue to be deferred on products that are covered by the OTC Review, pending the publication of final monographs.
JAN 9 1991

James E. Lenick, Esq.
Consultant
Stephen Pharmaceutical
P.O. Box 3119
Seal Beach, CA 90740

Dear Mr. Lenick:

Please refer to your request for pre-IND consultation regarding the drug Viroxan and to your telephone conversation of June 25, 1990 with Ms. Toní Anthony of this division. We have completed our review of the materials provided, and would like to convey the following comments to assist you in the further development of your drug:

Chemistry, Manufacturing and Controls

We recommend that the following information be included in your IND submission:

1. Please provide a literature reference from which the term "terpane alkoxide" is derived.

2. Please provide the correct molecular weight (M.W.) for "terpane alkoxide" so that it is consistent with the empirical formula of C_{10}H_{11}O.

3. Please provide addresses of the manufacturers of the new drug substance and the finished dosage form, and submit Drug Master Files (DMF) describing these facilities.

4. Please provide an impurity profile for the drug substance.

5. Please discuss all available physico-chemical properties, including solubility profile and stability under stressed conditions, and submit more detailed information on structure elucidation, including elemental analysis and peak assignments for IR, NMR and mass spectra.

6. Please establish a reference standard, fully characterized and analyzed, and provide a description on its preparation.
7. Please include assay and purity (preferably by GC or HPLC), and a limit on residual chloroform (when used) in the specifications for the bulk drug substance.

8. Please express the dosage strength in a consistent manner, whether it is 330 mg/ml, 33% by weight, or 33% by volume.

9. Please clarify the container and fill size(s) of the drug product since different sizes have appeared in the pre-IND submission.

10. Please propose limits on purity and assay, and include pyrogenicity and sterility in the specifications for the finished dosage form.

11. Please describe in detail the analytical test methods and their validations.

12. Please expand the stability protocol to include stressed conditions, e.g. heat, light, and humidity, submit all available data, and demonstrate that the analytical method(s) used are stability-indicating.

Microbiology

We strongly suggest the following comments and recommendations be addressed prior to submitting your IND:

Information was provided in this submission concerning Viroxan activity against a variety of micro-organisms including bacteria, fungi, protozoa, and viruses. None of the studies described provided a sufficient rationale and summarized data to support use of Viroxan in AIDS patients for the treatment of Human Immunodeficiency Virus (HIV-1) infection. Furthermore, a plan clearly outlining future studies to develop these data was not included. It is suggested that the sponsor should carefully review all "Points to Consider" documents provided with respect to the kind of data required to provide a useful risk/benefit profile for a drug intended for use in the treatment of HIV infection. After reviewing the documents, the sponsor should develop a plan to evaluate these parameters in suitable experimental systems. Once the sponsor has developed suitable plans, he should then re-contact the division for further assistance. With respect to Microbiology, the information provided in this pre-IND submission has limited value in supporting safety and efficacy for Viroxan use in HIV infected patients in human clinical trials.
Pharmacology/Toxicology

We recommend that the following comments and suggestions be addressed prior to submitting your IND:

The toxicology data included in this submission are not acceptable for establishing the safety of Viroxan. It is suggested that the sponsor carefully review all "Points to Consider" documents provided with respect to the kind of data required to provide a useful risk/benefit profile for a drug intended for use in the treatment of HIV infection. After reviewing the documents, the sponsor should develop a plan to evaluate these parameters in suitable experimental systems. Once the sponsor has developed suitable plans, he should then re-contact the division for further assistance.

Plans for Clinical Development

We have the following comments and recommendations that should be addressed prior to submitting your IND:

1. The sponsor should explore the use of radio-labelled Viroxan to conduct preclinical pharmacokinetic studies in order to describe the absorption, distribution, metabolism, and excretion of the drug and its metabolites. These studies should cover the same dose range and schedule of administration as proposed for clinical use.

2. The non-clinical data presented and the rationale proposed for the activity of Viroxan do not provide sufficient support for any clinical trial in HIV-infected patients at any stage of the disease. No convincing evidence for either direct or indirect antiretroviral or immunomodulatory activity is provided. Therefore, no risk/benefit assessment can be made.

3. The proposed protocol is poorly conceived and does not meet the minimal necessary criteria: no rational study design is described; the efficacy endpoints are not described; no provision is made for adequate safety monitoring or management of toxicity.

4. The previous clinical experience data presented do not constitute evidence of either safety or efficacy. The subjects were treated under no known protocol with an unapproved experimental compound. The clinical results are not interpretable as presented.
5. If an IND were to be submitted for Viroxan, assurances would have to be made that the investigators would conduct any future studies in an ethical and safe fashion. The clinical protocol would have to address a rationale for the dosage chosen for study, provide for adequate controls, and address patient safety in an acceptable fashion.

This letter is an informal communication under 21 CFR 10.90 (b) (9) that represents the best judgement of the pre-IND consultation team at this time. Please feel free to contact Ms. Toni Anthony at (301) 443-9550 with any questions or requests for further information. She will assist you in contacting other members of the pre-IND team as needed.

In addition to the pre-IND recommendations and comments given, the FDA would like to advise you that the agency is aware of a matter now before officials of the State of California, governing Dr. Herman's use of Viroxan. In this regard, should an IND be granted, such an action would have no bearing on, nor would it interfere with the California action. A summary of this letter is being provided to the California state health authorities, since we are obligated as a law enforcement agency to coordinate our efforts with those of the State of California.

The administration of Viroxan to humans for any purpose, or supplying the drug to patients in the absence of an IND, is a most serious violation of the new drug provisions of the U.S. Food and Drug Act. Accordingly we must also advise you that there must be no further use of Viroxan for any purpose other than in vitro or animal studies until there is a valid IND on file with the FDA.

What has been said concerning "Viroxan" applies with equal force to the use of any other new drug that is not the subject of an approved application or an IND. Should you have any questions or doubts about the proper course of action, we suggest a written communication be addressed to Mr. George F. Kenter,
5600 Fisher's Lane, HFD-310, Rockville, MD 20857. Mr. Kenter can be contacted at (301) 295-8063.

Sincerely yours,

Michael A. Ussery

Michael A. Ussery, Ph.D.
Pre-IND Team Leader
Division of Antiviral Drug Products
Office of Drug Evaluation II

George F. Kenter
Division of Drug Labeling Compliance
BEBORE THE DEPARTMENT OF CONSUMER AFFAIRS OF THE STATE OF CALIFORNIA

In the matter of the investigation of: STEPHEN D. HERMAN, MD

DECLARATION OF STUART KRASSNER, Sc.D.

I, STUART KRASSNER, Sc.D., am employed as a Professor of Developmental and Cell Biology at the University of California, at Irvine and have been at the University of California, at Irvine since 1965. I hold a B.S. and Sc.D. from Brooklyn College and The Johns Hopkins University respectively. I am currently involved in research in the area of parasitology, specifically protozoan pathogens of humans.

I, STUART KRASSNER, Sc.D., declare that if called to testify I would relevantly and competently as follows:

On August 19, 1988, I was contacted by a friend from the business community named JACK BALDRIDGE, V.P. at A.I.T., and asked to meet ED MERINO and STEPHEN HERMAN, MD to discuss a possible new anti-AIDS drug, LP. On August 31, 1988, I met with ED MERINO and STEPHEN HERMAN. STEPHEN HERMAN told me that he had a drug which he was currently using to treat AIDS.

I asked STEPHEN HERMAN if he had received the appropriate U.S. Food and Drug Administration (FDA) approval to proceed with administering the drug to human AIDS patients. STEPHEN HERMAN told me that he had contacted the FDA people in California and was told that, as long as he was not advertising the drug as an AIDS remedy, not profiting from the manufacture, or offering for sale of such a drug, and using the drug for experimental purposes only, he did not require filing an "Investigational New Drug" (IND) application with the FDA. I, along with ED MERINO and JACK BALDRIDGE, questioned whether
STEPHEN HERMAN was in compliance with proper FDA IND filing procedures.

STEPHEN HERMAN was told by JACK BALDRIDGE and ED MERINO that he could be leaving himself open to FDA criminal action. STEPHEN HERMAN assured us that everything was in order since he was a medical doctor treating patients; he was not charging for the drug nor advertising it as a cure.

STEPHEN HERMAN asked me to perform in vitro activity tests with regards to Trypanosoma cruzi and Toxoplasma gondii. The latter parasite is opportunistic in nature and frequently associated with immunosuppressed patient infections while the former is a major pathogen in Latin America. My laboratory conducted these in vitro activity tests with Trypanosoma cruzi (i.e., on cells) for STEPHEN HERMAN and found that the drug was toxic for this organism. In November, 1988, subsequent to performing these initial in vitro tests, I became a consultant for STEPHEN HERMAN. I was paid for further tests by JOSEPH AIDLIN. I believe that JOSEPH AIDLIN was the primary financial sponsor for STEPHEN HERMAN, JAMES HERMAN, and research on LP (later renamed VIROXAN by STEPHEN AND JAMES HERMAN). I know that The Regents of the University of California received a total of approximately $37,000 between April, 1989 and January, 1990 from JOSEPH AIDLIN for LP studies. I also believe that STEPHEN HERMAN was paid $80,000 per year as salary for his work with LP and that James Herman received a salary as well.

Initially, I was given toxicity data conducted by North American Science Associates, Inc. (NAMSA) which indicated that the drug was non-toxic. Due to the results of toxicity tests performed in my laboratory, I questioned the validity of this conclusion and recommended further in vivo acute toxicity studies on mice, rats and rabbits to confirm this result. Tests done from December, 1988 through January, 1990 indicate that there is a toxic effect in
animals at a dose greater than 1.9 mg (107 mg/kilo), a dose ten times greater than the dose initially given patients by STEPHEN HERMAN at that time. In December, 1989, STEPHEN HERMAN indicated that he was increasing the patient dose from 600 mg/day to 3000 mg/day, because his severely acute patients were not improving as quickly as he wished. 3000 mg/day appears within the maximum tolerated intramuscular, intraperitoneal, and oral administered dose in mice and rats. However, rabbits appeared to experience adverse reactions at the injection site (i.e. subdermal swelling and severe muscle tenderness) with 1.9 mg LP. A dose greater than 1.9 mg killed all test mice and rats.

I continued to ask STEPHEN HERMAN for all relevant patient clinical data, but never received this material which caused me great concern and raised questions about STEPHEN HERMAN's results with his patients. I repeatedly told STEPHEN HERMAN of the need for patient selectivity in order to conduct a well-controlled study which would generate meaningful results. STEPHEN HERMAN told me that he did not feel the need for patient selectivity as he could treat anyone with the drug and that he felt obligated to treat all sick patients. I felt that STEPHEN HERMAN was not qualified as a scientist to properly conduct a well-controlled research study with regards to the efficacy and safety of his drug and told him of my concerns. I explained to STEPHEN HERMAN that FDA Phase I tests would have to be performed and reiterated the need for an IND approval. Both JACK BALDRIDGE and ED XERINO informed STEPHEN HERMAN of similar concerns on many occasions.

STEPHEN HERMAN maintained that he wanted to treat AIDS and that he felt it a waste of time to conduct appropriate studies because people were dying from the disease every day.

STEPHEN HERMAN spoke of the great potential for making an extraordinary amount of money with his drug on several occasions and was extremely
rubber stoppers on the vials were not airtight; laboratory personnel noted that the vials on more than one occasion leaked while in use. I believe that this indicates a potential for contamination.

On May 31, 1989 through June 1, 1989, I accompanied STEPHEN HERMAN and JAMES HERMAN to Abbott Laboratories in Chicago where they were told that tests performed at Abbott Laboratories failed to show an efficacious effect with regards to various infectious agents. Abbott Laboratories agreed to do further tests. I know that Abbott Laboratories has since informed STEPHEN HERMAN that the drug has unlikely potential for treating systemic bacterial and fungal diseases, is ineffective against Herpes simplex virus and leukemia virus in mice, and does not appear to be useful as a therapeutic agent. I also know that Lederle Laboratories also informed STEPHEN HERMAN and JAMES HERMAN that the drug failed to show an efficacious effect in their tests. During my trip, the topic of oral administration of the drug was brought up. STEPHEN HERMAN told me that a previous group of five AIDS patients receiving the drug orally died.

I was told that the early drug manufacturing procedure was performed in STEPHEN HERMAN's pool house in the back of his residence at 9341 Hazel Circle in Villa Park. I saw the pool house manufacturing site in March, 1989. I commented to STEPHEN HERMAN that the lab appeared "primitive". STEPHEN HERMAN told me that it was adequate for his purposes at the time.

In September/October, 1989, I was told by ED MERINO and JAMES HERMAN that they now had a laboratory facility. The following address:

2781 Saturn Street
Suite F
Brea, CA  (714) 996-4489
was given to me by STEPHEN BERMAN in January, 1990. I have never been to the lab in Brea nor have I ever seen any form of batch records for formal drug manufacture. I was told that equipment had been purchased for the lab.

I understand that STEPHEN BERMAN was arrested on January 11, 1990 by Medical Board and Food and Drug Investigators. I was unaware that STEPHEN BERMAN was charging his patients for the drug. I had no knowledge that STEPHEN BERMAN was allowing his patients to self-administer the drug. I was disappointed that STEPHEN BERMAN and JAMES HERMAN had misled me into believing that everything was in order.

Two or three days after STEPHEN BERMAN's arrest, my lab was contacted by JAMES HERMAN and asked when the next delivery of drug for continuing research should be delivered. My lab informed JAMES HERMAN that all research on their drug was ended on January 11, 1990 and would not be continued. JAMES HERMAN contacted me again to inquire about the final report. I told him that the final report would be sent to JOSEPH AIDLIN.

Prior to October/November, 1989, I was told by either STEPHEN BERMAN or JAMES HERMAN that there was an associate involved with them named VALENTINE BIRDS, MD. I was told that VALENTINE BIRDS treated a lot of AIDS patients, that he referred patients to STEPHEN BERMAN, and was involved in implanting catheters in AIDS patients for easier intravenous administration of the drug.

In October/November, 1989, I spoke with JOSEPH AIDLIN with regards to the intravenous catheters and VALENTINE BIRDS. JOSEPH AIDLIN told me that he was aware of a relationship between VALENTINE BIRDS and STEPHEN BERMAN.

In addition to treating AIDS patients, I was told by STEPHEN BERMAN that the drug was also used to treat cancer in at least one other patient (a female with Hodgkin's Disease) and himself (for a lymphoma). I am also aware that STEPHEN BERMAN used the drug to treat at least one patient with
arthritis. In December, 1989, JAMES HERMAN told me that STEPHEN HERMAN was
treating approximately 40-60 AIDS patients. During the sixteen months that I
was associated with STEPHEN AND JAMES HERMAN, they claimed to have treated
hundreds of patients.

I declare under penalty of perjury that the foregoing is true and
correct of my personal knowledge.

Executed this 7th day of May, 1990 at

Irvine, California.

Stuart Krassner, M.D.
Declarant
From: Jacob J. Clement, Ph.D.  
Dept. 47F -Bldg. AP9A  Ed. 7-4417  
Date: August 31, 1989

To: Donna M. Sauer  O431, AP9A

cc: Jacob J. Platner  O466, AP9A

RE: LP-1

The Anti-Infectives area has completed in vitro and in vivo biological testing of LP-1. Under our in vitro test conditions, the agent had no significant activity against bacteria, fungi, or virus including HIV. LP-1 was also tested in two test systems. These systems included LP-1 against P388 murine leukemia; topical LP-1 against HSV-1 dermatitis, and parenteral LP-1 against systemic bacteria: E. coli, S. aureus, and L. monocytogenes; and infections. In view of these results I can not recommend additional consideration of this agent as an anti-infective.

LP-1 has been submitted for testing in the lipopolysaccharide screen. Results of these tests will not yet been received but will be forwarded to you as soon as they are available.

Please contact me if you have any questions.
CONFIDENTIAL

Charles W. Stiefel
Executive Vice President
and General Counsel
Stiefel Laboratories, Inc.
2801 Ponce de Leon Boulevard
Coral Gables, Florida 33134

Re: Stephen Herman Patent Application
Our File No. HERMA.01A

Dear Charlie:

As promised, I am enclosing a copy of our draft patent claims and a structural formula of linalool ozonide, which is currently our preferred compound. If you have any questions, please give me a call.

Very truly yours,

Ned A. Israelsen

Enclosures (2)
cc: Stephen Herman, M.D.
nai-5066
1. A method of medical treatment, comprising the topical application of compounds resulting from the ozonization of a terpene.

2. The method of Claim 1, wherein said terpene is linalool.

3. A method of medical treatment, comprising systemic injection of compounds resulting from the ozonization of a terpene.


6. Pharmaceutical compositions, comprising pharmaceutically effective amounts of a composition of matter comprising an ozonide of a hemi-terpene, mono-terpene, sesqui-terpene, di-terpene, ses-terpene, tri-terpene, or tetra-terpene in a pharmaceutically acceptable topical or injectible carrier.

7. The ozonide of geraniol.

8. The ozonide of linalool.

9. The ozonide of limonene.

10. The ozonide of alpha-pinene.

11. The ozonide of camphor.

12. The ozonide of iridodial.

13. The ozonide of loganin.

14. The ozonide of cymene.

15. The ozonide of a farnesane.

16. The ozonide of a eudesmane.

17. The ozonide of an acocane.

18. The ozonide of a cedrane.

19. The ozonide of a chamigrane.
IN THE IOWA DISTRICT COURT, IN AND FOR JOHNSON COUNTY

STATE OF IOWA,

Plaintiff,

vs.

VICTOR HERBERT,

Defendant.

The above-entitled matter was presented to the Court pursuant to Rule 54 of the Iowa Rules of Criminal Procedure. The Court has reviewed the brief submitted by the defendant and the brief submitted by the State and the record made by the hearing magistrate.

Rule 54 of the Iowa Rules of Criminal Procedure state that findings of fact in the original action shall be binding on the judge deciding the appeal if they are supported by substantial evidence.

The magistrate, in his conclusions of law, did indicate the manner in which the defendant approached the victim would place the victim in fear of immediate physical contact which would be injurious or insulting or offensive. Further, the magistrate found that the victim was touched in such a way that it was offensive and that the defendant had the ability to execute the assault.

With regard to the theft, the magistrate found that the defendant, while taking the property, did intend to return the property less the audio recordings on the tape. Those facts are supported by the record as shown by the magistrate's notes of the testimony.
Section 714.1 states: "A person commits theft when the person . . . (1) takes possession or control of the property of another, or property in the possession of another, with the intent to deprive the other thereof." The property in this case which the defendant attempted to deprive the victim thereof was the tape recording of the words of the defendant.

The defendant, through his presentation of evidence put in issue the ownership of the spoken words both by his contention that it was a copyright item and, further, that the speech was not to be recorded except by the University under the written authorization of the defendant.

The defendant, through his presentation of evidence put in issue the ownership of the spoken words both by his contention that it was a copyright item and, further, that the speech was not to be recorded except by the University under the written authorization of the defendant.

In this case, because of its unusual circumstances, the burden was upon the State to show beyond a reasonable doubt that the property involved was not that of the defendant's. Any evidence presented in court would have clearly put that at issue and the responsibility of the State upon rebuttal evidence would have been to show beyond a reasonable doubt that the spoken words issued by the defendant were not still his property at the time that they were captured upon the cassette tape in the possession of the victim. A person cannot be found guilty of stealing his own property.

The magistrate court made no determination as to whether the recordings were still the property of the defendant. nor would the evidence in the notes support such a finding. Since the burden is on the State beyond a reasonable doubt to show that the
property was not that of the defendant's, the defendant should have been found not guilty of the theft charge.

Section 708.1 of the Code of Iowa defines assault, "a person commits an assault when, without justification, the person does any of the following: (1) Any act which is intended to cause pain or injury or which is intended to result in physical contact which will be insulting or offensive to another, coupled with the apparent ability to execute the act. (2) Any act which is intended to place another in fear of immediate physical contact which will be painful, injurious, insulting or offensive, coupled with the apparent ability to execute the act."

The facts as determined by the magistrate in this matter indicates that an assault did take place. The intended part of this particular crime means being done consciously and not accidental or inadvertently. However, the assault is subject to a justification, which in Section 704.4 of the Code of Iowa refers to defense of property, and that "a person is justified in the use of reasonable force to prevent or terminate criminal interference with the person's possession or the right in property."

The burden is then upon the State to prove beyond a reasonable doubt that the defendant was not acting with justification. Section 704.6 of the Code of Iowa defines certain instances in which such justification is not available. Section 701.6 of the Code of Iowa speaks to ignorance or mistake of fact and is relevant to this case because of the ownership of the words on the audio tape. Whether the words on the tape were the property of the defendant, because of copyright laws, or whether they were not his property, it is clear from the testimony that the defendant considered the words to be his.
property and the actions taken were then in defense of that
property. Because of the defendant's defense of property, and
the defense was available to him because none of the provisions
of Section 704.6 would make it unavailable, the defendant was
then acting with justification and because of that the defendant
should be found not guilty.

The decision of the magistrate is reversed with regard to
each count. The defendant is found not guilty on each count and
the charges are dismissed with the costs to be assessed against
the State.

DATED this 27 day of October, 1987.

JOHN R. SLADEK
District Associate Judge
20. The ozonide of a caryophyllane.
21. The ozonide of a illudane.
22. The ozonide of a humulene.
23. The ozonide of a himachalene.
24. The ozonide of a longifolane.
25. The ozonide of a pethydropalene.
26. The ozonide of a quaiane.
27. The ozonide of a quaianolide.
28. The ozonide of a germacran.
29. The ozonide of a gibberellin.
30. The ozonide of vitamin A.
31. The ozonide of a labdene.
32. The ozonide of a clerodane.
33. The ozonide of abietic acid.
34. The ozonide of a phyllocladene.
35. The ozonide of a opiolobolin.
36. The ozonide of retigaranic acid.
37. The ozonide of gassgadic acid.
38. The ozonide of a carotene.
39. The ozonide of alpha-carotene.
40. The ozonide of beta-carotene.
41. The ozonide of squalene.
42. The ozonide of lanosterol.
43. The ozonide of euphol.
44. The ozonide of oleane.
45. The ozonide of ursane.
46. The ozonide of lupeol.
47. The ozonide of hydroxyhopanone.
48. The ozonide of a lupane.
49. The ozonide of a hopane.
50. A method of treating vaginal infections by intravaginally administering an effective amount of a compound of any one of Claims ___.___.
51. A method of treating herpes lesions by topically administering an effective amount of a compound of any one of Claims ___.___.

-12-
52. A method of treating chicken pox lesions by topically administering an effective amount of a compound of any one of Claims ___.

53. A method of treating fungal infections of the skin or nails by topically administering an effective amount of a compound of any one of Claims ___.

54. A method of treating indolent neoplasms by administering an effective amount of a compound of any one of Claims ___.

55. A method of treating sunburn by topically administering an effective amount of a compound of any one of Claims ___.

56. A method of treating acne by topically administering an effective amount of a compound of any one of Claims ___.

57. A method of treating sexually transmitted diseases by topically administering an effective amount of a compound of any one of Claims ___.

58. A method of treating insect bites by topically administering an effective amount of a compound of any one of Claims ___.

59. A method of treating bee stings by topically administering an effective amount of a compound of any one of Claims ___.

60. A method of treating dermatitis resulting from exposure to poisonous plants by topically administering an effective amount of a compound of any one of Claims ___.

61. A method of preventing transmission of sexually transmitted diseases by administering a compound of any one of Claims ___ in conjunction with use of a condom.

62. A method of treating nonspecific dermatoses by topically administering an effective amount of a compound of any one of Claims ___.

63. A method of treating swollen joints by injection of an emulsion containing an effective amount of a compound of any one of Claims ___.
STRUCTURAL FORMULA OF LINALOOL OXONIDE

\[
\begin{align*}
\text{CH}_3 & \quad \text{O} \\
\text{CH} - \text{CH}_2 - \text{CH}_2 - \text{C} - \text{CH} & \quad \text{O} \\
\text{CH}_3 & \quad \text{OH} \\
\text{H}_2\text{O}_2 & \\
\text{H}_2\text{O} \\
\text{CH}_3 & \quad \text{O} \\
\text{C} - \text{CH}_2 - \text{CH}_2 - \text{C} - \text{CH}_3 & \quad \text{OH} \\
\text{C}_6\text{H}_5 & \quad \text{O} \\
\end{align*}
\]
REPORT OF TEST RESULTS
(English translation)

Foundational Juridical Person
Food, Chemicals (Drugs) Safety Center
HATANO LABORATORY

EXHIBIT G
TEST RESULTS

No. 91-248
March 25, 1992

M/S Maruzen Mates Co., Ltd.

Foundational Juridical Person
Foods, Chemicals (Drugs) Safety Center
Hatano Laboratory

The results of test requested on March 11 are as follows:

1. Name of Test: Test of sterilizing power
2. Name of Material for Test: Nurse's Soap
3. Bacterium Prepared for Test: As per attached paper - 6 kinds
4. Way of Test: As per paper attached, I & II
5. Test Results: As per paper attached, III
Dear Sir:

Though delayed, enclosed please find the photos in question.

In regards to the results of the test, according to the comments of Mr. Takashima, Chief of the Laboratory, the Nurse's Soap is fairly good for sterilization (power) among the soap, but not antidote (disinfectant). In other words, the Nurse's Soap is so effective in comparison with ordinary soap.

This is, however, just our private comments.

It is necessary to do the test of "Carbonic Literal Coefficient Measurement" to compare with other things.

Understanding the above, if you use our comments somehow, it is our pleasure.

Thank you for your desire for the test using our Laboratory.

Yours truly,

March 27, 1992
TEST RESULTS

No. 91-248
March 25, 1992

M/S Maruzen Mates Co., Ltd.

Foundational Juridical Person
Foods, Chemicals (Drugs) Safety Center
Hatano Laboratory

The results of test requested on March 11 are as follows:

1. Name of Test: Test of sterilizing power
2. Name of Material for Test: Nurse's Soap
3. Bacterium Prepared for Test: As per attached paper - 6 kinds
4. Way of Test: As per paper attached, I & II
5. Test Results: As per paper attached, III
Paper 1

Bacterium prepared for test

Real Bacillus
1. Aspergillus niger ATCC 16404
2. Candida albicans ATCC 10231

Four Kinds of Bacterium
3. Escherichia coli ATCC 8739
4. Pseudomonas aeruginosa ATCC 9027
5. Staphylococcus aureus ATCC 6538
6. Bacillus subtilis IAM 1213

1. Test Method - "Pre-growing"

- As to Aspergillus niger, we grew Potato Deoxytroche Agar-agar (PDA) at 29°C for 7 days on the slope, and made spore liquid with physical salt water added by 0.05% Tween 80. By this liquid, we adjust spore number as $1.3 \times 10^6$ pcs/ml.

- About Candida albicans, we grew it with Glucose Peptone (GP) broth at 35°C for 18 hours and we adjust spore number as $1.7 \times 10^6$ pcs/ml by physical salt water added 0.05% Tween 80.

- Regarding the above four Bacteria, we grew them with Soybean Casein Digest (SCD) broth at $37^\circ$ C for 18 hours. After the growing, the numbers of Bacterium per broth one and are as follows:
  - Escherichia coli $8.1 \times 10^7$ pcs
  - Pseudomonas aeruginosa $3.6 \times 10^8$ pcs
  - Staphylococcus aureus $7.5 \times 10^8$ pcs
  - Bacillus subtilis $4.0 \times 10^7$ pcs
II. "Actual Test"

In the glass bottle (20 ml) sterilized with stirrer magnet, we prepared object to be tested by 10 ml. And to test one kind of Bacterium per bottle, we prepared further five bottles and put the object by 10 ml per bottle.

Before the actual test, we agitated those bottles by stirrer not rising in bubbles.

After this process, we applied Bacterium liquid by 0.1 ml and 10 seconds later, 30 seconds later, 60 seconds later and 3 minutes later, each time we picked up the object by 30 ml.

As to the real Bacillus, we put it on PDA plate and for (about) Bacteriums, we put it on the standard agar-agar plate.
Paper 2

III. "After growing"

We grew PDA plate at 29°C for four days. We grew standard agar-agar plate at 37°C for 24 hours.

Results of Test

"Sign"

†, ††, ††† = Growing of Bacillus or Bacterium was confirmed

"-" = Growing of Bacillus or Bacterium was not confirmed

<table>
<thead>
<tr>
<th>Time</th>
<th>10 sec</th>
<th>30 sec</th>
<th>1 min</th>
<th>3 min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspergillus niger</td>
<td>††</td>
<td>†</td>
<td>†</td>
<td>†</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>†††</td>
<td>††</td>
<td>†</td>
<td></td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>†††</td>
<td>†</td>
<td>†</td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacillus subtilis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Due to the less Bacillus or Bacterium, it is difficult to make the decision, but according to the results of test, we think the Nurse's Soap has the following features:

- As to the mildew (mold), it is difficult to sterilize completely after three minutes.

- Against the yeast (ferment) and gram positive bacterium, Nurse's Soap has enough sterilization.

- To the gram negative bacterium, it is necessary to take more than one minute to sterilize them.
1. *Apergillus niger*  
   (曼科：VBI)

2. *Candida albicans*  
   (曼科：肠内)
試験成績書

財団法人 食品薬品安全センター
秦野研究所
試験成績告

食塩700乾発31配糖248号
平成4年3月25日

丸常メイツ株式会社

平成4年3月11日付で困ってご承認のあった検体について行った
試験成績は次のとおりです。

1. 試験の名称 殻質試験
2. 検体の名称 Nurse's Soap
3. 供試瓶体 別紙1に記載の6個体
4. 試験法 別紙1〜2に記載
5. 試験成績 別紙2に記載
[試験菌]

<table>
<thead>
<tr>
<th>菌属</th>
<th>菌名</th>
<th>ATCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>革 面</td>
<td>Aspergillus niger</td>
<td>16404</td>
</tr>
<tr>
<td></td>
<td>Candida albicans</td>
<td>10231</td>
</tr>
<tr>
<td>革 面</td>
<td>Escherichia coli</td>
<td>8739</td>
</tr>
<tr>
<td></td>
<td>Pseudomonas aeruginosa</td>
<td>9027</td>
</tr>
<tr>
<td></td>
<td>Staphylococcus aureus</td>
<td>6538</td>
</tr>
<tr>
<td></td>
<td>Bacillus subtilis</td>
<td>1213</td>
</tr>
</tbody>
</table>

[試験法]

(1) 前培養

Aspergillus nigerについてはビオチナ・デキストロース栄天（PDA）斜面
結晶で29℃、7日間培養し、0.05% Tween 80 添加生理食塩水で菌子作
製し、同様で菌子数を1.3×10^6個/ml に調整した。

Candida albicansについてはグルコース・ベプトン（G P）プロスで35℃、
18時間培養し、0.05% Tween 80 添加生理食塩水で細胞数を1.7×10^6個/ml に
調整した。

上記4種の菌種についてはソイビーン・カゼイン・ダイジェスト（S C D）
プロスで37℃、18時間培養した。培養後、プロス1 ml中の細胞数はそれぞれ
以下のとおりであった。

<table>
<thead>
<tr>
<th>菌名</th>
<th>細胞数</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escherichia coli</td>
<td>8.1×10^7 個</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>3.6×10^6 個</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>1.5×10^6 個</td>
</tr>
<tr>
<td>Bacillus subtilis</td>
<td>4.0×10^7 個</td>
</tr>
</tbody>
</table>

(2) 本試験

スターラー・マグネットを入れて試験を施したガラスビン（容積20 ml）に
検体を10 ml分取した。1本に付いた1個試の試験を行うため、同様にさらに5
本のガラスビンに検体を分取した。

本試験直前に検体の入ったガラスビンをスターラーに掛け、泡が立たないよ
うに振摺した。

スターラーに掛けた試験を室温で0.1 ml注入し、10秒後、30秒後、1分後、
および3分後に1回目（約30 ml）を採り、2回目についてはPDA平板、2回
については標準換天平板1枚ずつに塗抹した。

...
(3) 影響

PDA平板は29℃で4日間培養、CAース天平板は37℃で24時間培養を施し、
菌の生育の有無を判定した。

【試験結果】以下の如く表示した。

菌の生育が認められたものを＋ーを、認められなかったものを－で示した。

<table>
<thead>
<tr>
<th>菌株</th>
<th>10秒</th>
<th>30秒</th>
<th>1分</th>
<th>3分</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspergillus niger</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bacillus subtilis</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

供試した菌株が少ないため断定はできないが、得られた結果から破壊は次の様な
傾向を有するのではないかと推察された。

・カビに対しては3分間の作用時間でも完全に殺菌することが難しい。
・酵母、およびグラム陽性菌に対しては充分な殺菌力がある。
・グラム陰性菌菌に対しては該当のために1分間以上の作用時間が必要である。

以上
Foundational Juridical Person
Food, Chemicals (Drugs) Safety Center
No. 12, 1-15 Toranomon, Minato-Ku, Tokyo 105
Tel: 03-3503-0491

HATANO LABORATORY
No. 5, 729 Ochiai, Katano-City, Kanagawa-Ken 257
Tel: 0463-82-4751
February 24, 1991

Dr. James Brodsky
Stephens Pharmaceuticals Group
1700 W. Katella, #300
Orange, CA 92867

Dear Jim:

It was good to have you and Chris here last week. I feel we accomplished a good deal, and I hope you feel your visit was worthwhile.

I am enclosing several items of interest. Note especially the materials on toxogon.

When I visit you during my trip we can discuss these areas in more detail. I will be in Southern California during March 6-13. It will be good to see you and Chris again.

Hope you can communicate your experiences here with your associates at Stephens Pharmaceuticals Group.

I met with Charles Singleton on February 24, and he and I will present to Stephens Pharmaceuticals Group very soon... I feel the plan will present to Stephens's interests, eliminate the squabbling, and yet enable Viroxen to get under way in a proper scientific and professional manner to evaluate it in treating AIDS, cancer, as a spermicide, and as an antidote for biological/chemical warfare. As you have seen, I am in a position to do all of this.

Please keep me informed on the response you are getting at Stephens Pharmaceuticals Group.

Sincerely,

[Signature]

CA: Schlesinger, Ph.D.
Dr. Idaho

CS:el
Enclosures
Dear Dr. Herman:

This letter will serve to outline the framework of a proposed business relationship between you ("Dr. Herman") and Genelabs Incorporated ("Genelabs") regarding the development of a class of chemical compounds ("Compound") for pharmaceutical applications.

Dr. Herman will license all rights to the Compound to Genelabs. Genelabs will offer Dr. Herman $6,000 in cash upon signing this letter of intent. After completing its internal review, including but not limited to biological testing and patent review, Genelabs will offer Dr. Herman 10,000 warrants to purchase Genelabs common stock at the current fair market price. Genelabs will also start to make monthly payments to Dr. Herman, based on a workplan to be prepared by Dr. Herman to further the research and development of the Compound, in an amount not to exceed $10,000 per month.

Upon regulatory approval of the first IND, the monthly payment will be increased to 150% of the amount prior to such event; 20% of the warrants (2,000) will be vested at this time. Upon regulatory approval of the first NDA, the monthly payment will be increased to 150% of the amount prior to such event. 80% (8,000 warrants) will be vested at this time.

Upon market launch, Dr. Herman will earn a royalty of 5% on net sales in lieu of the above monthly payment but under no circumstance will the amount be less than the monthly payment made to Dr. Herman prior to this event.

The terms proposed in this letter are subject to the approval of the Board of Directors of Genelabs. If you are in agreement, please sign at the end of this letter and return one copy to me.

Genelabs Incorporated

Accepted and Agreed to:

Frank Kang, Ph.D.

Stephen D. Herman, M.D., D.A.B.R.
VIROXAN - A Novel Superoxide Generating Compound With Broad Spectrum Anti-Infective Activity and Immunomodulatory Applications In The Clinical Management Of Chronic, Inflammatory, Autoimmune Disease.

STEPHEN D. HERMAN, M.D. and JAMES A. HERMAN, B.S., STEPHENS PHARMACEUTICALS GROUP, INC.; and JEFFREY H. REINHARDT, M.Sc., MARIN CLINIC OF PREVENTIVE MEDICINE AND HEALTH EDUCATION.

ABSTRACT

A wide spectrum of chronic, degenerative diseases involve immune dysregulation associated with chronic inflammatory foci or infections which may be of bacterial, fungal, parasitic, or viral etiology.

VIROXAN, a new, minimally toxic, pharmaceutical agent, hydrolyzes in aqueous solutions to produce large amounts of superoxide($O_2^-$) which is microbiocidal and potentially immunomodulatory.

In vitro assays of minimal inhibitory concentrations(MIC's) yielded results as follows: Staphylococcus aureus ATCC 6536F, 3.1 ug/ml; Streptococcus pyogenes KK 351, 6.2 ug/ml; Klebsiella pneumoniae ATCC 8045, 6.2 ug/ml; Pseudomonas aeruginosa A5005, 6.2 ug/ml; Bacteroides fragilis 784, 0.1 ug/ml; Clostridium difficile ATCC 17457, 0.1 ug/ml; Clostridium perfringens 755, 0.1 ug/ml; Candida albicans ATCC 10232, 1.56 ug/ml; Cryptococcus albidos ATCC 36140, 0.2 ug/ml; and Trypanosoma cruzi, Epimastigotes, 10 ug/ml.


Subsequent in vitro studies of VIROXAN'S antiviral activity in the presence of cultured human lymphocytes infected with Human Immuno-Deficiency Virus(HIV), demonstrated virucidal activity at 0.3 μM(79.5 ug/ml).

Preliminary clinical evaluation with intravenous(IV) VIROXAN in a limited number of patients has produced positive clinical responses in both polyarthritic patients and acquired immunodeficiency(AIDS) patients. Clinical progress and laboratory data will be presented to summarize these findings; quantitative-structure-activity relationships predict the utility of VIROXAN as a broad-spectrum, therapeutic agent which crosses the blood-brain barrier and will be useful in the treatment of infectious diseases, inflammatory diseases, and immune dysfunction diseases.
### Table 1. In Vitro activity of LP-1

**EXPERIMENT DATE:** 01/25/89  **ABBOTT NUMBER:** A-GM7  **LOT NUMBER:** XXXX  
**PROJECT NAME:** GM SCREEN  **PRIMARY MEDIUM:** BBIB  **SOLVENT:** P-GLYCOL  
**POTENCY:** 1.00  **STANDARD:** CIPROFLOXACIN  **CHEM. CODE:** LP-1

<table>
<thead>
<tr>
<th>ORGANISM</th>
<th>MIC (ug/ml)</th>
<th>SMIC (ug/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAPHYLOCOCCUS AUREUS</td>
<td>ATCC 6536F</td>
<td>3.1</td>
</tr>
<tr>
<td>ENTEROCOCCUS FARCUM</td>
<td>ATCC 2043</td>
<td>12.5</td>
</tr>
<tr>
<td>STREPTOCOCCUS PYOGENES</td>
<td>KK351</td>
<td>6.2</td>
</tr>
<tr>
<td>ESHERICHIA COLI JUBL</td>
<td></td>
<td>6.2</td>
</tr>
<tr>
<td>ESHERICHIA COLI SS</td>
<td></td>
<td>1.56</td>
</tr>
<tr>
<td>KLEBSIELLA PNEUMOBLITE</td>
<td>ATCC 8045</td>
<td>6.2</td>
</tr>
<tr>
<td>PSEUDOMONAS AERUGINOSA</td>
<td>A5007</td>
<td>6.2</td>
</tr>
</tbody>
</table>

**EXPERIMENT DATE:** 01/31/89  **ABBOTT NUMBER:** A-GM7  **LOT NUMBER:** XXXX  
**PROJECT NAME:** G.M. SCREEN  **MEDIUM:** PBS+G  **SOLVENT:** P-GLYCOL  
**POTENCY:** 1.00  **STANDARD:** AMPHOTERICIN B  **CHEM. CODE:** LP-1

<table>
<thead>
<tr>
<th>ORGANISM</th>
<th>MIC (ug/ml)</th>
<th>SMIC (ug/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CANDIDA ALBICANS ATCC 10232</td>
<td>1.56</td>
<td>0.39</td>
</tr>
<tr>
<td>CANDIDA ALBICANS 579 A</td>
<td>1.56</td>
<td>0.39</td>
</tr>
<tr>
<td>CANDIDA ALBICANS CCM 443</td>
<td>1.56</td>
<td>0.39</td>
</tr>
<tr>
<td>CANDIDA ALBICANS CCM 274</td>
<td>0.78</td>
<td>0.39</td>
</tr>
<tr>
<td>CANDIDA ALBICANS ATCC 38247</td>
<td>1.56</td>
<td>25.</td>
</tr>
<tr>
<td>CANDIDA TROPICALIS EBRL-1-112</td>
<td>0.78</td>
<td>0.39</td>
</tr>
<tr>
<td>TORULOIDSIS GLABRATA ATCC 15545</td>
<td>1.55</td>
<td>0.78</td>
</tr>
<tr>
<td>CRYPTOCOCCUS ALBIDUS ATCC 36140</td>
<td>0.2</td>
<td>0.39</td>
</tr>
<tr>
<td>ASPERGILLUS NIGER ATCC 16404</td>
<td>3.14</td>
<td>0.76</td>
</tr>
</tbody>
</table>

**EXPERIMENT DATE:** 02/07/89  **ABBOTT NUMBER:** A-GM7  **LOT NUMBER:** XXXX  
**PROJECT NAME:** G.M. SCREEN  **MEDIUM:** NBCROTH  **SOLVENT:** P-GLYCOL  
**POTENCY:** 1.00  **STANDARD:** CLINDAMYCIN  **CHEM. CODE:** LP-1

<table>
<thead>
<tr>
<th>ORGANISM</th>
<th>MIC (ug/ml)</th>
<th>SMIC (ug/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BACTEROIDES FRAGILIS</td>
<td>105AT25285</td>
<td>0.2</td>
</tr>
<tr>
<td>BACTEROIDES FRAGILIS</td>
<td>784</td>
<td>0.1</td>
</tr>
<tr>
<td>BACTEROIDES THETAHOTAOMICRON ATCC29741</td>
<td>.1</td>
<td>2</td>
</tr>
<tr>
<td>FUSORACETUM MOCLEATUM ATCC 25386</td>
<td>0.2</td>
<td>0.12</td>
</tr>
<tr>
<td>CLOSTRIDIUM PERFRINGENS 104AT13124</td>
<td>0.2</td>
<td>0.12</td>
</tr>
<tr>
<td>CLOSTRIDIUM PERFRINGENS 755</td>
<td>0.1</td>
<td>0.06</td>
</tr>
<tr>
<td>CLOSTRIDIUM DIFFICILE ATCC 9689</td>
<td>0.1</td>
<td>4</td>
</tr>
<tr>
<td>CLOSTRIDIUM DIFFICILE ATCC 17457</td>
<td>0.1</td>
<td>2</td>
</tr>
</tbody>
</table>
### TABLE I

**Effect of Drug Concentration on In Vitro Growth of *Trypanosoma Cruzi* Epimastigotes**

<table>
<thead>
<tr>
<th>Test Material</th>
<th>Time of Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>24 Hours</td>
</tr>
<tr>
<td>Control (propylene glycol)</td>
<td>Good Growth</td>
</tr>
<tr>
<td>100 mg Test Drug</td>
<td>No Growth</td>
</tr>
<tr>
<td>10 mg Test Drug</td>
<td>No Growth</td>
</tr>
<tr>
<td>1 mg Test Drug</td>
<td>No Growth</td>
</tr>
<tr>
<td>100 ug Test Drug</td>
<td>No Growth</td>
</tr>
<tr>
<td>10 ug Test Drug</td>
<td>No Growth</td>
</tr>
<tr>
<td>1 ug Test Drug</td>
<td>Moderate Growth</td>
</tr>
<tr>
<td>500 ng Test Drug</td>
<td>Good Growth</td>
</tr>
</tbody>
</table>
**PATIENT 1**

<table>
<thead>
<tr>
<th></th>
<th>0 MONTH</th>
<th>3rd MONTH</th>
<th>6th MONTH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHITE BLOOD CELLS</strong></td>
<td>3700</td>
<td>4900</td>
<td>5000</td>
</tr>
<tr>
<td><strong>TOTAL LYMPHOCYTES</strong></td>
<td>1005</td>
<td>1633</td>
<td>2250</td>
</tr>
<tr>
<td><strong>T LYMPHOCYTES</strong></td>
<td>834</td>
<td>1486</td>
<td>1740</td>
</tr>
<tr>
<td><strong>T-8 SUPPRESSOR CELLS</strong></td>
<td>381</td>
<td>702</td>
<td>1058</td>
</tr>
<tr>
<td><strong>T-4 HELPER CELLS</strong></td>
<td>392</td>
<td>702</td>
<td>945</td>
</tr>
<tr>
<td><strong>HELPER/SUPPRESSOR RATIO</strong></td>
<td>1.02</td>
<td>1.0</td>
<td>0.9</td>
</tr>
</tbody>
</table>
## PATIENT 2

<table>
<thead>
<tr>
<th></th>
<th>0 MONTH</th>
<th>3rd MONTH</th>
<th>6th MONTH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHITE BLOOD CELLS</strong></td>
<td>5200</td>
<td>8000</td>
<td>8000</td>
</tr>
<tr>
<td><strong>TOTAL LYMPHOCYTES</strong></td>
<td>992</td>
<td>2400</td>
<td>2500</td>
</tr>
<tr>
<td><strong>T LYMPHOCYTES</strong></td>
<td>892</td>
<td>1992</td>
<td>1875</td>
</tr>
<tr>
<td><strong>T-8 SUPPRESSOR CELLS</strong></td>
<td>505</td>
<td>936</td>
<td>825</td>
</tr>
<tr>
<td><strong>T-4 HELPER CELLS</strong></td>
<td>337</td>
<td>864</td>
<td>875</td>
</tr>
<tr>
<td><strong>HELPER/SUPPRESSOR RATIO</strong></td>
<td>0.67</td>
<td>0.92</td>
<td>1.06</td>
</tr>
</tbody>
</table>
# PATIENT 3

<table>
<thead>
<tr>
<th></th>
<th>0 MONTH</th>
<th>3rd MONTH</th>
<th>6th MONTH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHITE BLOOD CELLS</strong></td>
<td>5000</td>
<td>5000</td>
<td>4500</td>
</tr>
<tr>
<td><strong>TOTAL LYMPHOCYTES</strong></td>
<td>2200</td>
<td>1900</td>
<td>2300</td>
</tr>
<tr>
<td><strong>T LYMPHOCYTES</strong></td>
<td>1914</td>
<td>1691</td>
<td>2047</td>
</tr>
<tr>
<td><strong>T-8 SUPPRESSOR CELLS</strong></td>
<td>1276</td>
<td>836</td>
<td>966</td>
</tr>
<tr>
<td><strong>T-4 HELPER CELLS</strong></td>
<td>638</td>
<td>722</td>
<td>1012</td>
</tr>
<tr>
<td><strong>HELPER/SUPPRESSOR RATIO</strong></td>
<td>0.50</td>
<td>0.86</td>
<td>1.05</td>
</tr>
</tbody>
</table>
PATIENT 4

<table>
<thead>
<tr>
<th></th>
<th>0 MONTH</th>
<th>3rd MONTH</th>
<th>6th MONTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHITE BLOOD CELLS</td>
<td>3300</td>
<td>3900</td>
<td>3500</td>
</tr>
<tr>
<td>TOTAL LYMPHOCYTES</td>
<td>1000</td>
<td>1900</td>
<td>1600</td>
</tr>
<tr>
<td>T LYMPHOCYTES</td>
<td>790</td>
<td>1786</td>
<td>1264</td>
</tr>
<tr>
<td>T-8 SUPPRESSOR CELLS</td>
<td>640</td>
<td>1102</td>
<td>688</td>
</tr>
<tr>
<td>T-4 HELPER CELLS</td>
<td>150</td>
<td>418</td>
<td>368</td>
</tr>
<tr>
<td>HELPER/SUPPRESSOR RATIO</td>
<td>0.23</td>
<td>0.38</td>
<td>0.53</td>
</tr>
</tbody>
</table>
PATIENT 5

<table>
<thead>
<tr>
<th></th>
<th>0 MONTH</th>
<th>3RD MONTH</th>
<th>6TH MONTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHITE BLOOD CELLS</td>
<td>5900</td>
<td>5500</td>
<td>5000</td>
</tr>
<tr>
<td>TOTAL LYMPHOCYTES</td>
<td>2100</td>
<td>1815</td>
<td>1850</td>
</tr>
<tr>
<td>T LYMPHOCYTES</td>
<td>1932</td>
<td>1455</td>
<td>1468</td>
</tr>
<tr>
<td>T-8 SUPPRESSOR CELLS</td>
<td>1218</td>
<td>847</td>
<td>802</td>
</tr>
<tr>
<td>T-4 HELPER CELLS</td>
<td>425</td>
<td>495</td>
<td>500</td>
</tr>
<tr>
<td>HELPER/SUPPRESSOR RATIO</td>
<td>0.43</td>
<td>0.6</td>
<td>0.6</td>
</tr>
</tbody>
</table>
### PATIENT 6

<table>
<thead>
<tr>
<th></th>
<th>0 Month</th>
<th>2nd Month</th>
<th>3rd Month</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>White Blood Cells</strong></td>
<td>6900</td>
<td>7300</td>
<td>7000</td>
</tr>
<tr>
<td><strong>Total Lymphocytes</strong></td>
<td>1380</td>
<td>1168</td>
<td>1540</td>
</tr>
<tr>
<td><strong>T Lymphocytes</strong></td>
<td>1173</td>
<td>864</td>
<td>1247</td>
</tr>
<tr>
<td><strong>T-8 Suppressor Cells</strong></td>
<td>787</td>
<td>537</td>
<td>909</td>
</tr>
<tr>
<td><strong>T-4 Helper Cells</strong></td>
<td>207</td>
<td>210</td>
<td>277</td>
</tr>
<tr>
<td><strong>Helper/Suppressor Ratio</strong></td>
<td>0.3</td>
<td>0.4</td>
<td>0.3</td>
</tr>
</tbody>
</table>
## PATIENT 7

<table>
<thead>
<tr>
<th></th>
<th>0 Month</th>
<th>2nd Month</th>
<th>3rd Month</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>White Blood Cells</strong></td>
<td>4950</td>
<td>6000</td>
<td>7500</td>
</tr>
<tr>
<td><strong>Total Lymphocytes</strong></td>
<td>1148</td>
<td>1200</td>
<td>2025</td>
</tr>
<tr>
<td><strong>T Lymphocytes</strong></td>
<td>959</td>
<td>1020</td>
<td>1802</td>
</tr>
<tr>
<td><strong>T-8 Suppressor Cells</strong></td>
<td>719</td>
<td>732</td>
<td>1296</td>
</tr>
<tr>
<td><strong>T-4 Helper Cells</strong></td>
<td>208</td>
<td>228</td>
<td>344</td>
</tr>
<tr>
<td><strong>Helper/Suppressor Ratio</strong></td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>
### PATIENT 8

<table>
<thead>
<tr>
<th></th>
<th>0 MONTH</th>
<th>2ND MONTH</th>
<th>3RD MONTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHITE BLOOD CELLS</td>
<td>7900</td>
<td>5100</td>
<td></td>
</tr>
<tr>
<td>TOTAL LYMPHOCYTES</td>
<td>1264</td>
<td>2601</td>
<td></td>
</tr>
<tr>
<td>T LYMPHOCYTES</td>
<td>1011</td>
<td>1872</td>
<td></td>
</tr>
<tr>
<td>T-8 SUPPRESSOR CELLS</td>
<td>670</td>
<td>1457</td>
<td></td>
</tr>
<tr>
<td>T-4 HELPER CELLS</td>
<td>164</td>
<td>416</td>
<td></td>
</tr>
<tr>
<td>HELPER/SUPPRESSOR RATIO</td>
<td>0.24</td>
<td>0.3</td>
<td></td>
</tr>
</tbody>
</table>
PATIENT 9

<table>
<thead>
<tr>
<th></th>
<th>0 MONTH</th>
<th>2ND MONTH</th>
<th>3RD MONTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHITE BLOOD CELLS</td>
<td>7700</td>
<td>4400</td>
<td></td>
</tr>
<tr>
<td>TOTAL LYMPHOCYTES</td>
<td>1617</td>
<td>836</td>
<td></td>
</tr>
<tr>
<td>T LYMPHOCYTES</td>
<td>1294</td>
<td>761</td>
<td></td>
</tr>
<tr>
<td>T-8 SUPPRESSOR CELLS</td>
<td>889</td>
<td>502</td>
<td></td>
</tr>
<tr>
<td>T-4 HELPER CELLS</td>
<td>175</td>
<td>184</td>
<td></td>
</tr>
<tr>
<td>HELPER/SUPPRESSOR RATIO</td>
<td>0.19</td>
<td>0.37</td>
<td></td>
</tr>
</tbody>
</table>
PATIENT 10

<table>
<thead>
<tr>
<th></th>
<th>0 MONTH</th>
<th>2ND MONTH</th>
<th>3RD MONTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHITE BLOOD CELLS</td>
<td>3790</td>
<td>5120</td>
<td></td>
</tr>
<tr>
<td>TOTAL LYMPHOCYTES</td>
<td>1508</td>
<td>1500</td>
<td></td>
</tr>
<tr>
<td>T LYMPHOCYTES</td>
<td>1253</td>
<td>1320</td>
<td></td>
</tr>
<tr>
<td>T-8 SUPPRESSOR CELLS</td>
<td>845</td>
<td>885</td>
<td></td>
</tr>
<tr>
<td>T-4 HELPER CELLS</td>
<td>359</td>
<td>431</td>
<td></td>
</tr>
<tr>
<td>HELPER/SUPPRESSOR RATIO</td>
<td>0.42</td>
<td>0.49</td>
<td></td>
</tr>
</tbody>
</table>
Bibliography

Tissue Destruction by Human Neutrophils pt.1
S.J. Weis

Tissue Destruction by Human Neutrophils pt.2
S.J. Weis

Immunological Detection of Myeloperoxidase in Synovial Fluid from Patients with Rheumatoid Arthritis
Biochem J 1988;250:81-85
S.W. Edwards

Superoxide Modulates the Activity of Myeloperoxidase and Optimizes the Production of Hypochlorous Acid
A. Kettle
Biochem J 1988;252:529-536

Degradation of Human Glomerular Basement Membrane by Stimulated Neutrophils
S.V. Shah
J Clinical Invest 1987;79:25-31

Monocyte and Granulocyte Tumor Cell Destruction
S.J. Weis
J Clinical Invest 1982;69:255-262

Oxygen Dependent Microbicidal Killing by Phagocytes pt.1
B.M. Babior

Oxygen Dependent Microbicidal Killing by Phagocytes pt.2
B.M. Babior

Catalase, Superoxide Dismutase, and Virulence of Staphlococcus Aureus
B. Mandell
J Clinical Invest 1975;55:561-569

Oxygen Metabolites in Lactobacillus Plantarum
E. Gregory
J Bacteriology 1974;117:166-172
SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

TIMOTHY JOHNSON,

Plaintiff,

vs.

STEPHEN D. HERMAN, M.D., STEPHENS PHARMACEUTICALS GROUP, INC., JAMES A. HERMAN, B.S., JAMES BRODSKY, VILLA PARK PHARMACY, VALENTINE BIRDS, M.D., RAJINDRA SETHI, M.D., HOWARD SINGER, M.D., HOWARD SINGER M.D., INC., MEDICAL CENTER OF NORTH HOLLYWOOD, and DOES 1 through 100, inclusive,

Defendants.

CASE BC 044 726

DECLARATION OF TIMOTHY JOHNSON, IN SUPPORT OF OPPOSITION OF MOTION FOR SUMMARY JUDGMENT

DATE: 10/21/92
TIME: 8:30 A.M.
DEPT: 41
DECLARATION OF TIMOTHY JOHNSON

I, Timothy Johnson, declare:

1. I am a plaintiff in this action. I graduated from high school, I took two years of music training. I have no education, training or experience in medicine.

2. In May of 1989 I was diagnosed with HIV. I subsequently came under the care of Anthony Scarsella, M.D. who treated me with ART up until the fall of 1989 when I came under the care of Dr. Valentine Birds and Stephen Herman, M.D. Dr. Birds initially recommended typhoid vaccine therapy which I rejected. He then told me about an exciting new trial which was available involving the drug Viroxan. He described these spectacular results he and the principal investigator, Dr. Herman, were having with the drug. Dr. Birds was very enthusiastic about the drug, the results his patients were having on the drug, and strongly recommended the trial.

3. On Dr. Birds' recommendation, I first called and then met with Dr. Herman. Dr. Herman also described the rises in the immune panels from those who had received Viroxan previously, as did his prior trial subjects including Robert Metcalf who, I would later learn, was Dr. Herman's distributor. I was subsequently mailed the document, Exhibit P, and its graphs and charts, all very persuasive in the results which reported huge increases in T-4 levels from the use of Viroxan as well as the clearing of all AIDS symptomatology. One patient described went from about 300 to 1,200 T-4 cells per cubic millimeter in a matter of only a few weeks. All of the information showed positive results. Everyone's T-4 levels
4. Dr. Herman described and Dr. Birds confirmed a collaboration between them in which Birds would monitor my health while on the drug and Dr. Herman would check my T-4 levels while on the study. I received the drug itself from Dr. Birds, Dr. Herman and Robert Metcalf.

5. At no time did anyone ever tell that the trial was illegal, that the drug was unapproved for clinical trials. I was specifically told by Dr. Herman that the experiment was a "Phase I Clinical Trial." I was told that the pre-clinical work, the in vitro and animal studies, had been completed. I was also shown results demonstrating that these tests documented the drug to be non-toxic or minimally toxic. It was my understanding that the drug was no approved in the sense that it was available in pharmacies, but that it was approved for Phase I Clinical Trials, a term I and every other AIDS patient is very familiar with since every legitimate AIDS drug goes through this Phase I process, followed by Phase II and Phase III before it is available in the pharmacies. This was the case, for example, with AZT.

6. To be allowed to join a trial of a drug like this beginning with the first Phase seemed to be an extraordinary opportunity. I knew others who had tried many times to enter clinical trials, and were not admitted. The number of patients who may enter, to my recollection, was often very limited, at least in the early phases. And it was even more true in 1989 than now that the HIV positive patient feared that his death was eminent and that science was always on the verge of
breakthrough. The cure, or at least a drug that would raise
and keep the immune system healthy, i.e. T-4 levels above that
which would leave us susceptible to opportunistic disease,
seemed less distant, less far away than today. And all that
any of us was access to that drug in time to save our lives.

7. Then and now, the way HIV and AIDS patients
distinguish the legitimate from the illegitimate by the
identity of the participants and sponsors of the drug, the
evidence that the drug has been through the animal phase and is
proven safe and the evidence of the drug's effectiveness, in
this instance the raising of T-4 levels. The primary
criterion, however, is the identity of the participants.

8. The participants in the Viroxan experiment were a
medical doctor/scientist, Stephen Herman, M.D., a medical
doctor with a large AIDS practice, Valentine Birds, a medical
center, Medical Center of North Hollywood, and a surgeon,
Rajendra Sethi, M.D. I was aware of Medical Center of North
Hollywood's involvement from the "Wellness Letters," a monthly
news letter sent to me by Valentine Birds, which would
advertise his monthly meetings at Medical Center of North
Hollywood, and colored paper fliers advertising Valentine
Birds' "Open Forum Discussions" at Medical Center of North
Hollywood.

9. In addition, I was provided a document entitled "The
Approximate Costs for Hickman Catheter Insertion", Exhibit
A, which set forth that both Medical Center of North
Hollywood and the surgeon were cooperating to provide Viroxan
patients special reduced charges to permit us to obtain the
catheters which we needed for continued participation in the experiment at a significantly reduced rate to cash paying patients. While I was fully insured and expected my insurance to fully cover the cost of the catheterization, I was very impressed by the willingness of the Medical Center of North Hollywood to co-sponsor this part of our trial.

10. In the same way the Compound Q, a Chinese root derivative, I believe, is a clinical trial that is highly desirable, only because it is conducted under the auspices of San Francisco General Hospital, so too was the Viroxan Phase I Clinical Trial. I considered the trial of Viroxan to be an extraordinary opportunity for me, in large part because it involved three highly qualified medical doctors and an apparently reputable medical center.

11. There was never anything said by Dr. Herman or Dr. Birds, by Dr. Sethi, or by anyone at the Medical Center of North Hollywood ever to lead me to believe that the study was not approved by FDA or NIH, or some other governmental body capable of approving initial clinical trials.

12. There was also no one who ever stated that Viroxan was ineffective or unsafe. Dr. Herman described it as safe and efficacious as stated above. Dr. Birds claimed also that the drug was safe and effective. Dr. Sethi told me on the first day I met him, on the date of the catheter operation, that he had heard of the very positive results from Viroxan and told me it looked very promising.

13. My prior treating physician, Dr. Scarsella, whom I would still go to for my immune panels was very disappointed
that I had quit AZT. He felt that AZT was the best drug available and that it was proven. It was a fully approved drug which had passed through all of the phases of clinical trials and could be purchased by prescription. It was in the Physician's Desk Reference and was no longer considered experimental. No one, however, claimed that it was a cure, not even the manufacture. Dr. Sarcely admitted he did not know anything about Viroxan trials or the drug and stated that he just wished I would take AZT along with it.

14. I felt that I knew a good deal about Viroxan. I had spoken with the investigators, Drs. Herman and Birds, and Herman had sent me the materials. Both Dr. Herman and Dr. Birds were adamant that AZT would kill me very quickly and that it would also interfere with Viroxan. Dr. Birds referred to AZT as poison and told me that it would destroy my organs. Dr. Herman also told me that AZT would kill me and it would interfere with Viroxan's ability to raise my T-4 levels.

15. It was based upon the advice of Dr. Birds and Dr. Herman shortly after starting taking Viroxan I discontinued AZT and remained off AZT and on Viroxan from October 1989 to February of 1991. I was catheterized in October 1989 at Medical Center of North Hollywood and infused the drug by catheter from October of 1989 through the spring of 1990 when I broke one of the tubes of the catheter by applying too much pressure, and then later because of the movement of my chest around the catheter, I had worked it loose and it was irritated somewhat sore and red. At the same time Dr. Herman had developed a new formulation of Viroxan which was less painful
to inject intra-muscularly. Based on Dr. Herman's advice, I discontinued the catheter at that time, but continued with the intra-muscular injections and continued with periodic intravenous injections in Dr. Birds' office.

16. In the middle of summer of 1990 I develop flu-like symptoms and Dr. Birds diagnosed the flu. When I found it was a common pneumonia occurring in AIDS patients, "pneumocystis," I was annoyed that my other physician found it instead of Dr. Birds. The pneumonia responded very well to treatment and I was recovered within two weeks. Although I felt that Dr. Birds could have looked better for the cause of my symptoms, I did not think he did anything wrong, as I stated in my deposition.

No doctor criticized Dr. Birds, despite the fact that I was seeing doctors whom I would have expected to state the criticism if they had had one. No one said anything critical. After all, as far as I knew I already had pneumonia before I ever complained to Dr. Birds about the flu symptoms. Although I did feel that he might have neglected to do a test to determine my condition, I did not know what that test would be and my doctors made no comments critical of Dr. Birds' having failed to test, let alone that he was negligent in the sense of legal suits. At no time did I contemplate a lawsuit over the pneumocystis. As I far as I knew, there had been no harm, and no doctor had told me that there had been any harm, and there could have been nothing to sue over, therefore even if I had thought of it.

17. Obviously, my faith and respect for Dr. Birds and Dr. Herman were unshaken. I continued taking viroxen intra-
mucosally under the care of Dr. Birds and Dr. Herman until February of 1991. I discontinued Viroxan upon my second opportunistic infection, cryptococcal meningitis, in late January or early February 1991. I took Viroxan one or two times after returning home from the hospital, but after speaking to Dr. Berman, I discontinued the Viroxan because of my conclusion that the drug was not preventing opportunistic infections as Dr. Herman said it would.

18. I still, however, did not conclude that Viroxan or the doctors and hospital involved were frauds or even negligent. In fact, on March 29, 1991, I wrote for Dr. Herman a letter attached hereto as Exhibit A, in which I expressed my positive feelings about the drug and those involved. It was not until the summer of 1991, that for the first time did I learn that I had been exploited in a very cynical, illegal, human medical experiment, that I had been lied to, that I had lost a year and one-half my precious time, endured the catheter and painful shots which I have now learned for the first time caused mummification-like damages from formaldehyde. I felt humiliated, exploited, mistreated and betrayed. I felt angry and depressed. I felt they had taken my life. I had been so diligent and conscientious in doing everything they told me and everything I thought would allow me the best chance for a cure. I did so because I wanted to live and I was trying to be conscientious in my endeavor to live. So many appointments, so much pain I endured. I understood so many daily cleanings of the catheter, always fearful of infection from this open portal to the life-blood of my immune deficient body.
19. Dr. Birds and Dr. Herman were charlatans. They were frauds. The drug was a fraud. I felt like the poor child crippled by Mengale, for no reason but idle medical curiosity, perhaps an attempt to make money. I didn't understand why they had done it, I just knew they had, and I wasn't going to be victimized again. It was then and not before that I conceived to seek and take action. Until then I had no suspicion. It would never have occurred to me that Birds and Herman motive to so betray my trust and lie to me to induce me to use a drug I was not paying for or that was not tested to be safe and efficacious.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on 10-6-92 at Morro Bay, California.

TIMOTHY JOHNSON