FOIA Number: 2018-0756-F

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Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member: Kristine Gebbie

Subseries:

OA/ID Number: 8300

FolderID:

Folder Title:
[Sanctuary Task Force] [loose]

Stack:	Row:	Section:	Shelf:	Position:
S	66	5	1	3

THE WHITE HOUSE
OFFICE OF DOMESTIC POLICY FEB 22

CAROL H. RASCO
Assistant to the President for Domestic Policy

To: _____ _____

_____ _____

Draft response for POTUS
and forward to CHR by: _____

Draft response for CHR by: _____

Please reply directly to the writer
(copy to CHR) by: _____ To Paul/Terry

Please advise by: _____ rush reply

Let's discuss: _____

For your information: _____

Reply using ~~form code~~: Email

File: _____

Send copy to (original to CHR): _____

Schedule ? : ☐ Accept ☐ Pending ☐ Regret

Designee to attend: _____

Remarks: _____

_____

_____

_____

_____

THE WHITE HOUSE

WASHINGTON

February 22, 1994

TO: Kristine Gebbie

FROM: Carol H. Rasco CHR by ram

SUBJECT: Sanctuary Task Force

I have been asked by White House staff if the administration has a position on this issue. I have enclosed a copy of materials forwarded to me on the issue. Do you have any guidance?

Thank you.

Sanctuary Task Force

1-800-Sanctuary

"There is no greater good than to relieve the suffering of another man"

The FDA's mission is to protect the public against harmful drug toxicities. Since the thalidomide scare of the '60's, the FDA has developed stringent guidelines and regulations for drug approval. It currently costs in excess of $190 million and takes four to ten years to bring a single drug to the marketplace. As a result of the high costs and the lengthy approval process, many potentially beneficial drugs are being tested overseas or are never seeing the light of day. In fact, some of the drugs being tested in Europe were developed at the National Institutes of Health at U.S. taxpayers' expense.

We are 13 years into the AIDS epidemic and have only three FDA-approved HIV therapies, all of which have limited benefit. Patients with late-stage, life-threatening diseases are often excluded from U.S. drug trials, and are desperate for treatment now. Physicians and their patients have been frustrated in their attempts to gain access to promising therapies, and should have access to experimental drugs. Protecting the general public against harmful side effects is necessary, but we need to adopt a different standard for life-threatening diseases. There is no side effect worse than death.

The Sanctuary Drug Act offers a solution. By establishing a Sanctuary Board as a separate arm of the FDA, composed of prominent researchers and HIV-treating physicians, potentially beneficial, non-FDA approved drugs warranting scientific investigation will be identified and evaluated. Those agents deemed to be within the range of acceptable risk will be selected for study inclusion. Study participants will be limited to patients with less than one year to live. Sanctuary will supply and closely monitor the safety and efficacy of therapeutic agents in a structured, uniform study, wherein data will be collected, interpreted and disseminated to physicians via electronic data transmission. This structure will expedite our ability to recognize treatments with the potential for cure, allow alternative therapies to be scientifically evaluated, reduce exploitation by charlatans who prey upon the desperately ill with quack cures, and greatly reduce drug development costs. The expanded national access to drugs and information will also eliminate duplication of research on ineffective agents.

In dealing with the AIDS crisis, and with all incurable diseases, we must take bold and determined steps. In response to this, a group of HIV-treating physicians, AIDS activists, and HIV-infected and affected persons have recently formed the Sanctuary task force. Sanctuary will offer *hope* to the terminally ill -- an opportunity to improve their chances for survival and quality of life, and the opportunity to participate in the search for a cure.

OUTLINE FOR PROPOSED SANCTUARY DRUG ACT

I. PATIENT QUALIFICATIONS
- A. Life-threatening, incurable disease
- B. Expected to have less than six months to live
- C. Informed consent waivers, liability waivers
- D. Mentally competent
- E. Physician's verification of A through D

II. PHYSICIAN REQUIREMENTS
- A. Agrees to report to Sanctuary board on regular basis on patient status
- B. Pays nominal fee for Sanctuary drugs
- C. Limited to 100 patients/Sanctuary drug/year
- D. Provide Sanctuary drugs to patients at cost

III. SANCTUARY DRUG/AGENT REQUIREMENTS
- A. Meets Sanctuary toxicity standards based on animal studies
- B. Are not deemed dangerous or ineffective by the Sanctuary board
- C. Are supplied to the Sanctuary at no cost by manufacturers
- D. Removal from Sanctuary
  1. No marked improvement in patients, as compared with the natural progression of the disease, has been reported by physicians
  2. Shown to be dangerous
  3. More than 50,000 requests have been received by Sanctuary

IV. SANCTUARY BOARD
- A. Researchers, physicians, community activists
- B. Maintain an acceptable standard of toxicity
- C. Add to and remove from the Sanctuary medications/devices
- D. Maintenance and dissemination of anecdotal results from participating physicians
- E. Allowing/disallowing physician participation in program based on physicians' compliance with reporting requirements
- F. Transmit toxicological summary data to physicians
- G. Use funds collected from participating physicians to pursue the study of the toxicology of agents chosen by the committee for inclusion in Sanctuary that do not have drug company sponsorship or prior toxicological data (i.e., natural compounds or compounds showing promise in cell culture studies, but unattractive to drug companies for patent or profit reasons)

V. DRUG MANUFACTURERS
- A. May submit agents to Sanctuary without liability or loss of rights to compounds
- B. May simultaneously pursue phase one, two, or three protocols as recognized by the FDA

VI. BENEFITS
- A. Speed in recognizing agents with great potential for cure
- B. Agents without great profit potential would be evaluated/utilized
- C. Alternative therapies scientifically evaluated
- D. Drug development costs could be greatly reduced
- E. Purity and dosageof agents would be standardized, assuring:
  1. Patient safety
  2. A level playing field for comparison of agents
- F. Charlatanism reduced
- G. Tens of thousands of productive lives might be salvaged

EXPANDED SANCTUARY DRUG ACT OUTLINE

I. PATIENT QUALIFICATIONS
- A. Life-threatening, incurable illness
- B. Expected to have less than 6 months to live
  1. As determined by actuarial tables
  2. Certified by treating/requesting physician
- C. Mentally competent - see Section I/B/2
- D. Informed consent , liability waivers
  1. Discussion between patient and treating physician detailing all risks and unknowns, Sanctuary function, rules for both patient and physician
  2. Patient agrees to hold harmless all parties involved in the production, administration, distribution, and involvement in the Sanctuary
  3. Discussion and patient's agreement are video taped, and consent and liability forms are signed by patient

II. SANCTUARY BOARD MEMBER QUALIFICATIONS
- A. Has been a primary care physician for 500+ HIV patients or practice has been devoted to HIV primary care for two or more years
- B. Agrees to report to Sanctuary board on a regular basis on patient status in a format designed by Sanctuary board
  1. Monthly meetings of participating physicians via teleconference or ISDN video phone. Equipment will be provided by the Sanctuary and remain the property of the Sanctuary.
  2. All meetings will be recorded and made available to the public.
- C. Physicians will not receive any compensation for serving on the Sanctuary, but will be indemnified against tort actions by the State.
- D. Physicians will be limited as to the number of patients allowed into the Sanctuary annually.
- E. Will provide Sanctuary agents to Sanctuary patients at cost.
- F. Physicians' charges to Sanctuary patients for other services will be at the physician's discretion.
- G. Term of membership to be two years
  1. Year One of Sanctuary - 10 member physicians
  2. Year Two of Sanctuary - 20 member physicians
- H. Appointment to Sanctuary membership by Sanctuary board/*governor/president.*

III. SANCTUARY BOARD AND STAFF
- A. Board appointed by governor/president
- B. Staff (minimal) hired by Board to manage data

C. Responsibilities of Board
   1. Monitor Sanctuary physician compliance
   2. Selection of agents for addition to Sanctuary
   3. Review Sanctuary physician reports of toxicology/efficacy of Sanctuary agents
   4. Contract with a cell culture lab (NIH, university) for initial toxicological studies on untested agents
   5. Act as liaison with pharmaceutical companies to insure cooperation with Sanctuary agenda
   6. Manage funds generated by Sanctuary agent fees and government funding or donations
   7. Prepare and make available to the public results of Sanctuary agents, good or bad.
   8. Establish the parameters of Sanctuary dissolution
   9. Choose physicians, patients, and agents for participation in Sanctuary

D. Will receive no compensation for serving on the board, but will be indemnified against tort actions by the State

IV. PHARMACEUTICAL COMPANIES
   A. May submit agents to Sanctuary without liability or loss of rights to compounds
   B. May simultaneously pursue phase one, two or three protocols as recognized by the FDA.

V. SANCTUARY AGENTS
   A. Agent becomes known to Sanctuary board through
      1. Reading
      2. Anecdotal experience
   B. Agent under consideration is subjected to the following qualifying questions:
      1. Is the agent currently available to physicians via the compassionate use program? If so, exclude the agent from further consideration.
      2. Is the agent available in another country? (The patient can obtain the agent through a prescription.) If so, exclude the agent from further consideration.
      3. Is there evidence of effect against HIV in non-tumor human cell culture systems (e.g., PBMC's)? If there is no evidence of effect, the agent is excluded until data showing effect become available. Developing such data may be a function of the Sanctuary.
      4. Is the therapeutic to toxic ratio in human non-tumor cell culture less than 2^1? If so, the agent is excluded from further consideration. (Note: All agents are toxic if given in large enough amounts. Digoxin, with a therapeutic to toxic ratio of approximately 2^1, is the currently acceptedtreatment for congestive heart failure, which has an average survival of around six months to one year. A therapeutic to toxic ratio of 2^1 means that twice the treatment dose can kill you.)

C. The agent is subjected to the following questions in order to accelerate placement in the Sanctuary:

1. Has the agent ever been or is it currently being used in humans for another purpose? In either case, toxicity is known and the agent may go directly to Sanctuary unless it has been excluded in Section V/B.
2. Testing
   a. Assuming no animal toxicity is found, and the agent has never been used in humans for any purpose, the agent being considered for Sanctuary status must have at minimum the LD_{50} status (the dosage necessary to kill 50% of the test animals) in mice prior to being placed in Sanctuary. If no LD_{50} exists (some medications are so harmless, you can't really kill a test animal with any reasonable amount of the agent), then the agent must be shown to be tolerated at a dose at least 30 times greater than that expected to be used in humans as estimated on a mg/kg dosing schedule, and as derived from cell culture calculations using a volume of distribution of total body water (for example, let us say that 1 microgram/ml of compound Y is shown to kill all HIV infected cells in cell culture, has no cell culture toxicity on healthy cells up to 2 times this dose, and further, no LD_{50} could be found in mice at doses 30 times greater that estimated to be used in humans on a mg per Kg basis. Then the mice should tolerate .6 x the body mass in Kg= total body water in liters. [total body water in mls] x [1 microgram/ml] x 30 = the dose needed to be tolerated by the mouse.).
   b. Animals will be maintained for one month post-exposure to assess more long-term pathological effects, and will be studied via necropsy to look for organ damage prior to placement of the agent into Sanctuary. If organ damage is found, the compound is excluded.
3. Once the agent of interest has cleared the prior hurdles, it will be placed in Sanctuary
   a. Initially, the drug will be released to ten physicians for use by ten patients, for one month.
   b. The drug will be placed on provisional status for an additional month while data on original patients is being reviewed.
   c. At this point, the Board will either approve continued use, or remove the agent from Sanctuary if an obvious pattern of toxicity is apparent.
   d. If the Board approves continued use, the agent will be open to the next 100 requests.
   e. When another 100 patients have received the drug for one month (or at any time prior if the Board so decides), the drug will again be placed on provisional status for a month while the data a

f. If no pattern of toxicity has emerged, the agent will be made available to the next 1000 candidates (total patients exposed - 1110).
g. At this point, the agent is closed to further use by anyone through the Sanctuary unless the Board votes to extend or enlarge the pool of patients receiving the agent.
h. In any case, with each order of magnitude increase in patients taking or having taken the drug, a one month time-out will be observed to allow for collection and analysis of data, provided by the treating physician.

D. Problems
1. Paying for all this
a. Administration
b. Animal toxicology
c. Cell culture
d. Data base
e. Public access
2. Sources
a. Public funds
b. Donations
c. Agents will be provided to any licensed physician in the U.S. for a monthly user fee of *$100* per patient
3. The one patient for whom the agent was a Godsend
a. Any patient/physician user of the Sanctuary who decides to continue to take the agent of study after having been on the agent for more than four months (this being the usual termination point if no effect or toxicity is seen) will be allowed to continue to receive the agent at their discretion, provided they continue to report to the Sanctuary on the patient's condition monthly, and continue to pay the user fee.
b. This grace period will continue for up to six months after the agent has been removed from the Sanctuary for reasons of non-efficacy, but not for reasons of toxicity.
c. If no drug company has decided to pursue the agent for commercial use, and if the Sanctuary has not continued to expand access, or the Sanctuary has dropped the agent from further consideration, the agent will no longer be provided through the Sanctuary.
d. If toxicity was the reason for removal from the Sanctuary, then that agent will not be made available to anyone from that point onward.

Secretary of Energy Advisory Board
Washington, DC 20585

March 4, 1994

NOTE FOR MEMBERS OF THE TASK FORCE ON RADIOACTIVE WASTE

FROM: DAN METLAY

You may be interested in knowing that the Final Report and supplementary volumes have been completed and prepared for printing and distribution. I hope that you will receive them in less than six weeks.

The completion of the report allows me to accept a very attractive offer from the Nuclear Waste Technical Review Board. I shall be part of the senior professional staff with responsibility, among other things, for thinking about how institutional factors affect the technical work conducted by the Office of Civilian Radioactive Waste Management.

I shall start with the Board on March 7, 1994. You can reach me at (703) 235-7743. If you have any questions relating to the work of the Task Force, please contact SEAB's Executive Director, Jake Stewart, whom you know. He can be reached at (202) 586-7092.

Again, it has been a pleasure working with you this past three years.

THE WHITE HOUSE

WASHINGTON

November 29, 1993

MEMORANDUM FOR PAUL STEVEN MILLER
Director of Disability Outreach/White House Office of Presidential Personnel

FROM: Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

SUBJECT: The Sanctuary Task Force Information

Thank you for forwarding the information that you received on the Sanctuary Task Force. As you stated in your note to me, it falls appropriately to this office. I am currently working with the Department of Health and Human Services on the "National Task Force on AIDS Drug Development" that will be announced this week. I have shared this information with the Secretary and others involved in the Task Force.

Thanks again for passing on this information.

Rec'd 11/15/93 amy

NATIONAL AIDS POLICY OFFICE
OFFICE OF THE COORDINATOR

ROUTING SLIP

DATE: 11/8

TO: Alice

FROM: **KRISTINE M. GEBBIE**

_____ For your information

_____ For your action _____

_____

_____ Review and comment by (date) _____

✓ Prepare reply for Coordinator's signature

_____ Reply directly and blind copy Coordinator

_____ **Circulate/**forward to: _____

_____ File

COMMENTS:

need a note back to Miller indicating this was OUR, & then a letter back to Bruce Black & the Task Force

NOV - 3 1993

THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR CHRISTINE GEBBIE

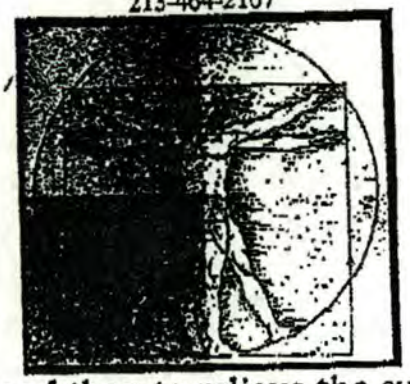
FROM: **Paul Steven Miller**, Director of Disability Outreach/White House Office of Presidential Personnel

DATE: November 1, 1993

RE: The Sanctuary Task Force

The attached information regarding the Sanctuary Task Force was recently forwarded to me, and I feel it is more appropriate for your office. I am therefore forwarding it to you for your attention. Please do not hesitate to contact me if you have any questions or need any more information.

Thomas J. Magee, M.D.
6464 Sunset, Suite 790
Hollywood CA. 90028
213-464-2107



"There is no greater good than to relieve the suffering of another man"

DATE: OCT. 11. 1993

SEND TO: MR. PAUL MILLER

TELECOPIER NO: (202) 456-7259

COMMENTS: DEAR PAUL: SENDING YOU THIS INFO. PER STEVEN BRUCCIANI, A FRIEND HERE.

We are sending 23 pages, including this cover sheet, via telecopier at 2 A.M./(P.M.) If you do not receive all of the pages or if there are any transmittal problems, please contact the undersigned at (213) 464-2107. Our FAX number is (213) 463-2882.

DEAR PAUL: ANYTHING - BUD BLACK
YOU CAN HELP US WITH
WOULD BE GREATLY APPRECIATED!

Sanctuary Task Force

1-800-Sanctuary

"There is no greater good than to relieve the suffering of another man"

The FDA's mission is to protect the public against harmful drug toxicities. Since the thalidomide scare of the '60's, the FDA has developed stringent guidelines and regulations for drug approval. It currently costs in excess of $190 million and takes four to ten years to bring a single drug to the marketplace. As a result of the high costs and the lengthy approval process, many potentially beneficial drugs are being tested overseas or are never seeing the light of day. In fact, some of the drugs being tested in Europe were developed at the National Institutes of Health at U.S. taxpayers' expense.

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The Sanctuary Drug Act offers a solution. By establishing a Sanctuary Board comprised of prominent researchers and HIV-treating physicians as an arm of the FDA, potentially beneficial, non-FDA approved drugs warranting scientific investigation will be identified and evaluated. Those agents deemed to be within the range of acceptable risk will be selected for study inclusion. Study participants will be limited to individuals with less than one year to live. Sanctuary will supply and closely monitor the safety and efficacy of therapeutic agents in a structured, uniform study, wherein data will be collected, interpreted and disseminated to physicians via electronic data transmission. This structure will expedite our ability to recognize treatments with the potential for cure, allow alternative therapies to be scientifically evaluated, reduce exploitation by charlatans who prey upon the desperately ill with quack cures, and greatly reduce drug development costs. The expanded national access to drugs and information will also eliminate duplication of research on ineffective agents.

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For further information, please call Brian Magee at (213) 993-0433.

«DATA Brian:Brians letters on projects:articles/pub:clinton letter list»

July 26, 1993

«first name» «last name»
«publication name»
«address 1» «address 2»
«city», «state» «zip»

Dear «title» «last name»,

I recently came across the attached letter that was sent to President Clinton by my brother, Tom Magee, and I wanted to share it with you.

Tom is a Board Certified Internist specializing in HIV care in Southern California and wrote the letter urging the President to enact the Sanctuary Drug Act (SDA). The SDA is an idea he formulated to speed up drug and therapy development, along with information dissemination, in an effort to cure AIDS. Upon reading it, I suggested that he try to get the idea into a public forum where it may be debated, refined and executed, which is why I bring it to your attention today.

Though the idea may be seen as naive by some, I believe some version of it could be implemented by our government at a minimal cost. The benefits from the patients' and doctors' standpoint are immense. If such a program had been in effect 10 years ago, some of the current therapies (AZT/ ddi/ddc, etc.), along with the esoteric therapies (ozone, passive immune therapy, etc.) patients utilize, would not have gone beyond the Sanctuary Phase. This would have allowed other therapies to be tried and freed a lot of money up which could have back into research.

If those affected by this disease don't organize with health insurance and business organizations to send a message to our government demanding change, the memorial we build to remember AIDS victims will make the Vietnam memorial look like a postage stamp on a coffin.

Please feel free to print, reproduce, use or give this material to any party who may be interested in utilizing or publicizing the thoughts contained within it.

If you have any questions, or would like to get in touch with Tom Magee on any other AIDS related matters, please feel free to contact me at (213) 993-0433.

Sincerely,

Brian M. Magee

Encl.

Paul Raeburn
Associated Press
50 Rockefeller Plaza 5th Floor
New York, NY 10020

Andrew Lippman
Associated Press
221 S. Figueroa Ste. 300
Los Angeles, CA 90012

Ronald Kotulak
Chicago Tribune
435 N. Michigan Ave.
Chicago, IL 60611

Deborah Pinkney
Chicago Sun-Times
401 N. Wabash Ave.
Chicago, IL 60611

Steve Buel
LA Weekly
P.O. Box 29905
Los Angeles, CA 90029

Nicholas Wade
New York times
229 W. 43rd Street
New York, NY 10036

Jean Seligmann
Newsweek
444 Madison Ave.
New York, NY 10022

Mike Meyer
Newsweek
11835 W. Olympic Ste. 870
Los Angeles, CA 90064

David Perlman
San Francisco Chronicle
901 Mission Street
San Francisco, CA 94103

Jeff Yarbrough
The Advocate
6922 Hollywood Blvd. 10 th Floor
Los Angeles, CA 90028

Robert Massa
The Village Voice
36 Cooper Square
New York, NY 10003

Andrew Purvis
Time
Time-Life Bldg. Rockefeller Center
New York, NY 10020

Jordan Bonfante
Time
10880 Wilshire Blvd. Ste. 1700
Los Angeles, CA 90024

Steve Findlay
U.S. News and World Report
2400 N. Street N.W.
Washington , D.C. 20037

Doug Levy
UPI
1400 I Street N.W.
Washington , D.C. 20005

Valerie Kuklenski
UPI
316 W. Second Street 6th Floor
Los Angeles, CA 90012

Tim Friend
USA Today
1000 Wilson Blvd.
Arlington, VA 22229

Marilyn Chase
Wall Street Journal
201 California Street Ste. 1350
San Francisco, CA 94111

Abigail Trafford
Washington Post
1150 15 th Street N.W.
Washington, D.C. 20071

Mike Royko
Tribune Media Services
64 East Concord Street
Orlando, FL 32801

Hunter Thompson
C/O Woody Creek Tavern
PO Box 82
Woodycreek, CO 81656

July 26, 1993

President Clinton
1600 Pennsylvania Ave.
Washington, D.C.

Mr. President,

Please find the enclosed letter that was previously sent to you. I understand that your schedule is very busy and you may not have had the time to review the letter. Due to my personal belief of its importance, I have decided to send the letter to the following publications.

- Chicago Tribune
- Chicago Sun-Times
- LA Weekly
- New York times
- Newsweek
- San Francisco Chronicle
- The Advocate
- The Village Voice
- Time
- U.S. News and World Report
- UPI
- USA Today
- Wall Street Journal
- Washington Post
- Tribune Media Services

I hope to speak with you soon.

Sincerely,

Brian Magee

Dear Doctor (or Colleague),

As a fellow physician treating HIV/AIDS patients, I'm sure you have become as frustrated at the inability to gain access to therapies for our desperately (or terminally) ill patients as I have. I've recently come upon an idea that addresses this situation and would like your feedback on it.

The Sanctuary Drug Act would establish a vehicle to supply and monitor the efficacy of non-FDA approved drugs for the terminally ill. Sanctuary proposes that those with 6-12 months to live be allowed to try untested drugs in a structured study, where data is collected from and disseminated to participating physicians. This structure would speed up our ability to recognize agents with a great potential for cure, allow alternative therapies to be scientifically evaluated, eliminate the charlatans who prey upon the desperately ill, and greatly reduce drug development costs. Perhaps as importantly, many terminally ill persons who feel they have nothing to lose would welcome the opportunity to make the *end of their lives* more meaningful by advancing knowledge in this area while giving hope for a cure to others.

Thank you for your hard work and compassion.

Please indicate your endorsement of this concept below.

Sincerely,

Thomas J. Magee, MD

Please take a minute to FAX back your interest in this concept to The Sanctuary Act Foundation.

☐ **Yes** I would support the Sanctuary Act.

☐ **Yes** I would support the Sanctuary Act and would like to participate in studies for my patients.

☐ Please send me more information to:_____

_____

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- A. Life-threatening, incurable illness
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C. The agent is subjected to the following questions in order to accelerate placement in the Sanctuary:

1. Has the agent ever been or is it currently being used in humans for another purpose? In either case, toxicity is known and the agent may go directly to Sanctuary unless it has been excluded in Section V/B.

2. Testing

a. Assuming no animal toxicity is found, and the agent has never been used in humans for any purpose, the agent being considered for Sanctuary status must have at minimum the LD_{50} status (the dosage necessary to kill 50% of the test animals) in mice prior to being placed in Sanctuary. If no LD_{50} exists (some medications are so harmless, you can't really kill a test animal with any reasonable amount of the agent), then the agent must be shown to be tolerated at a dose at least 30 times greater than that expected to be used in humans as estimated on a mg/kg dosing schedule, and as derived from cell culture calculations using a volume of distribution of total body water (for example, let us say that 1 microgram/ml of compound Y is shown to kill all HIV infected cells in cell culture, has no cell culture toxicity on healthy cells up to 2 times this dose, and further, no LD_{50} could be found in mice at doses 30 times greater that estimated to be used in humans on a mg per Kg basis. Then the mice should tolerate .6 x the body mass in Kg= total body water in liters. [total body water in mls] x [1 microgram/ml] x 30 = the dose needed to be tolerated by the mouse.).

b. Animals will be maintained for one month post-exposure to assess more long-term pathological effects, and will be studied via necropsy to look for organ damage prior to placement of the agent into Sanctuary. If organ damage is found, the compound is excluded.

3. Once the agent of interest has cleared the prior hurdles, it will be placed in Sanctuary

a. Initially, the drug will be released to ten physicians for use by ten patients, for one month.

b. The drug will be placed on provisional status for an additional month while data on original patients is being reviewed.

c. At this point, the Board will either approve continued use, or remove the agent from Sanctuary if an obvious pattern of toxicity is apparent.

d. If the Board approves continued use, the agent will be open to the next 100 requests.

e. When another 100 patients have received the drug for one month (or at any time prior if the Board so decides), the drug will again be placed on provisional status for a month while the data a reviewed.

f. If no pattern of toxicity has emerged, the agent will be made available to the next 1000 candidates (total patients exposed - 1110).

g. At this point, the agent is closed to further use by anyone through the Sanctuary unless the Board

votes to extend or enlarge the pool of patients receiving the agent.

h. In any case, with each order of magnitude increase in patients taking or having taken the drug, a one month time-out will be observed to allow for collection and analysis of data, provided by the treating physician.

D. Problems
1. Paying for all this
a. Administration
b. Animal toxicology
c. Cell culture
d. Data base
e. Public access
2. Sources
a. Public funds
b. Donations
c. Agents will be provided to any licensed physician in the U.S. for a monthly user fee of *$100* per patient
3. The one patient for whom the agent was a Godsend
a. Any patient/physician user of the Sanctuary who decides to continue to take the agent of study after having been on the agent for more than four months (this being the usual termination point if no effect or toxicity is seen) will be allowed to continue to receive the agent at their discretion, provided they continue to report to the Sanctuary on the patient's condition monthly, and continue to pay the user fee.
b. This grace period will continue for up to six months after the agent has been removed from the Sanctuary for reasons of non-efficacy, but not for reasons of toxicity.
c. If no drug company has decided to pursue the agent for commercial use, and if the Sanctuary has not continued to expand access, or the Sanctuary has dropped the agent from further consideration, the agent will no longer be provided through the Sanctuary.
d. If toxicity was the reason for removal from the Sanctuary, then that agent will not be made available to anyone from that point onward.

OUTLINE FOR PROPOSED SANCTUARY DRUG ACT

I. PATIENT QUALIFICATIONS
- A. Life-threatening, incurable disease
- B. Expected to have less than six months to live
- C. Informed consent waivers, liability waivers
- D. Mentally competent
- E. Physician's verification of A through D

II. PHYSICIAN REQUIREMENTS
- A. Agrees to report to Sanctuary board on regular basis on patient status
- B. Pays nominal fee for Sanctuary drugs
- C. Limited to 100 patients/Sanctuary drug/year
- D. Provide Sanctuary drugs to patients at cost

III. SANCTUARY DRUG/AGENT REQUIREMENTS
- A. Meets Sanctuary toxicity standards based on animal studies
- B. Are not deemed dangerous or ineffective by the Sanctuary board
- C. Are supplied to the Sanctuary at no cost by manufacturers
- D. Removal from Sanctuary
  1. No marked improvement in patients, as compared with the natural progression of the disease, has been reported by physicians
  2. Shown to be dangerous
  3 More than 50,000 requests have been received by Sanctuary

IV. SANCTUARY BOARD
- A. Researchers, physicians, community activists
- B. Maintain an acceptable standard of toxicity
- C. Add to and remove from the Sanctuary medications/devices
- D. Maintenance and dissemination of anecdotal results from participating physicians
- E. Allowing/disallowing physician participation in program based on physicians' compliance with reporting requirements
- F. Transmit toxicological summary data to physicians
- G. Use funds collected from participating physicians to pursue the study of the toxicology of agents chosen by the committee for inclusion in Sanctuary that do not have drug company sponsorship or prior toxicological data (i.e., natural compounds or compounds showing promise in cell culture studies, but unattractive to drug companies for patent or profit reasons)

V. DRUG MANUFACTURERS
- A. May submit agents to Sanctuary without liability or loss of rights to compounds
- B. May simultaneously pursue phase one, two, or three protocols as recognized by the FDA

VI. BENEFITS
- A. Speed in recognizing agents with great potential for cure
- B. Agents without great profit potential would be evaluated/utilized
- C. Alternative therapies scientifically evaluated
- D. Drug development costs could be greatly reduced
- E. Purity and dosageof agents would be standardized, assuring:
  1. Patient safety
  2. A level playing field for comparison of agents
- F. Charlatanism reduced
- G. Tens of thousands of productive lives might be salvaged

THE PROCESS BY WHICH AN AGENT IS PLACED INTO THE SANCTUARY, IS MADE AVAILABLE, AND IS TAKEN OUT OF SANCTUARY

Membership to Sanctuary:

Anyone may be admitted to Sanctuary committee status provided that they have treated more than 500 HIV patients during their career as a primary caring physician.

Sanctuary shall have 10 members the first year and 20 members the second year; their terms will be for two years. This group will be appointed by the governor of the state or president of the US.

Meetings will be held on a monthly basis via satellite up link, down link, or ISDN interactive video phones. All meetings will be recorded and available to the public. The equipment will be provided by the Sanctuary to its members while the physician is a member of the Sanctuary, and will be transferred to new physicians at the end of their tenure.

Physicians will not receive any compensation for serving on the Sanctuary, but will be indemnified against tort actions by the state or federal government.

1) Discovery

a) An agent becomes known to the members of the Sanctuary through:

1) Reading
2) Anecdotal experience

b) The agent is subjected to the following questions in an attempt to eliminate it from placement in the Sanctuary:

1) Is the agent currently available to physicians via the compassionate use program? If so, exclude the agent from further consideration.
2) Is the agent available in a foreign country? Through use of a prescription the patient can obtain this already. If so, exclude the agent from further consideration.
3) Is there evidence of effect against HIV in non-tumor human cell culture systems, e.g., PBMC's? If no effect in this system, the agent is excluded from further consideration until such data become available. May be a task of the Sanctuary division.
4) Is the toxic to therapeutic ratio in human non-tumor cell culture less than 2[1]? If so, the agent is excluded from Sanctuary.

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[1] All agents are toxic if given in large enough amounts, e.g., water. We currently accept the use of Digoxin in our treatment of congestive heart failure and the therapeutic to toxic ration is approximately 2, that is, twice the

c) The agent is subjected to the following questions in order to accelerate placement in the Sanctuary:

1) Has the agent every been used in humans, albeit for another purpose, or is the agent currently used in humans for another purpose? In either case the toxicity in humans is known. If so, it may go to Sanctuary directly[2], provided it has not been excluded in Section b.

2) Testing

a) Assuming no animal toxicity is known, and the agent has never been used in humans for any purpose, the agent being nominated for Sanctuary status must have at minimum the LD-50[3] status in the mouse prior to being placed into Sanctuary, and if no LD-50 exists[4], then the agent must be shown to be tolerated at a dose of at least 30 times that expected to be used in humans as estimated on a mg/kg dosing schedule, and as derived from cell culture calculations using a volume of distribution of total body water.[5]

b) Animals will be maintained for 1 month post exposure to assess for more long term pathologic effects, and will be studied via necropsy to look for organ damage prior to placement of the agent into Sanctuary. If organ damage is found, the compound is excluded.

3) Provisional release

a) Prior to receiving any medication or agent from the Sanctuary a video-taped discussion between the treating physician and the treated patient will be recorded in which all the risk and the unknowns are discussed and the patient agrees to hold harmless all parties involved in the production, administration, distribution and involvement in the Sanctuary.

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treatment dose of this medication can kill you. Congestive heart failure has a very poor natural history with the average survival being somewhere around 6 months to 1 year.

[2] I am thinking of one of the early syphilis drugs which was found to have anti-HIV activity, but is no longer made as it has been superseded by better agents for the treatment of syphilis; nevertheless, it was previously used in humans and its toxicities could be gleaned from the literature of the time.

[3] LD-50 refers to the dose of drug necessary to kill 50% of the animals.

[4] Some medications are so harmless that you really can't kill the test animal with any reasonable amount o the agent.

[5] For example, let us say that 1 microgram/ml of compound Y is shown to kill all HIV infected cells in cell culture having no cell culture toxicity on healthy cells up to 2 times this dose, and further, no LD 50 could be found in mice at doses 30 times greater that estimated to be use in humans on a mg per Kg basis. Then the mice should tolerate .6 x the body mass in Kg= total body water in liters. (Total body water in mls) x (1 microgram/ml) x 30 = the dose needed to be tolerated by the mouse.

b) All patients who petition the Sanctuary for agents must have less than 6 months to live as determined by current actuarial tables on HIV as determined by the CDC, and further supported by a statement from their treating/requesting physician.

c) Assuming that the agent of interest has cleared the prior hurdles, it will be placed in Sanctuary. The drug will be released to 10 treating physicians for ten patients initially, and then held in a provisional status for one month during which the drug will not be released until data from the initial 10 patients has been reviewed by the committee. The committee will have two choices, either to approve continued use or to remove the agent from the Sanctuary. If an obvious pattern of toxicity is present in the eyes of the committee, the agent will be removed from the Sanctuary. If no pattern of toxicity exists, in the eyes of the committee, then the agent of interest will be open to the next 100 requests. When another 100 patients receive the agent, or at any time prior if the committee so decides, the agent is again placed in provisional status and distribution is held for another month. At the end of the month the data will be reviewed again by the committee, and if no pattern of toxicity exists, the agent will be open to1000 more candidates (total patients exposed =1110), and then closed to further use by anyone through Sanctuary unless the committee votes to extend or enlarge the pool of patients receiving the agent. In any case, with each "order of magnitude"[6] increase in patients taking or having taken the drug, a one month time-out will be observed to allow for the collection and analysis of data, provided by the treating physician.

d) The problem of paying for the Sanctuary and the cost of running animal toxicology, making and shipping drugs, and maintaining a public access bulletin board "data base." Agents will be provided to any licensed physician in the US, provided that a user cost of 100 dollars has been paid for each months worth of agent received.

e) The problem of "The one patient for whom the agent was a God send." Any patient/physician user of the Sanctuary who decides to continue to take the agent of study after having been on the agent for more than 4 months (this being the usual termination point if no effect or toxicity is seen), will be allowed to continue to receive the agent at their discretion provided they continue to report to the Sanctuary on the patient's condition monthly and continue to pay the user fee. This grace period shall continue for up to six months after the agent has been removed from the Sanctuary for reasons of non-efficacy, but not for reasons of toxicity. Thereafter if no drug company has decided to pursue the agent for commercial use and if the Sanctuary as not continued to expand access and/or the Sanctuary has dropped the agent from further consideration, the agent will no longer be provided through the Sanctuary. If toxicity was the reason for removal from the Sanctuary, then no agent will be made available to anyone from that point forward.

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[6] An order of magnitude is a factor of 10, so the number 1000 differs from the number 1 by 3 orders of magnitude

June 2, 1993 3:45 am

Dear President and Mrs. Clinton,

I am writing to you at the suggestion of a friend; I am a HIV treating physician in Los Angeles plagued by the recurrent absurd situation I find my patients in and thought you might benefit from my thoughts on this situation.

The horror of HIV infection in human beings is disabling to behold. One of my more pleasant patients, Fred, was just placed in the hospital yesterday with both lower extremities swollen beyond recognition and bloody fluid dripping from wounds that opened spontaneously in his flesh - this is from his Kaposi's sarcoma which was brought into his life by his HIV infection. To be sure, there are treatments; yet the best treatment - little more than fat mixed with an already approved form of chemotherapy, daunarubicin - is not available for him, but has been under clinical investigation for the last 4 years and running.[1] Who are we protecting?

A ten year old boy that I cared for died from starvation Saturday, caused by Mycobacterium Avium infection in his intestines; but he didn't just die, he died of diarrhea - chronic, unremitting, embarrassing, foul diarrhea which was brought into his life by his HIV infection.

These poignant examples are but of few of my daily frustrations and my friend suggested that I need to express my concerns over our current drug approval process as it relates to terminally ill patients, especially AIDS patients, and offer a suggestion which could improve your political standing on health issues in general, and most especially my patient's afflicted with AIDS. I feel, with a slight addendum to the FDA's mandate, you could accelerate the finding of a cure for this disease and others. I will try for brevity, but clearly could go on for hours.

[1]Lipisomal daunarubicin (LD), manufactured by Vestar in California, rumored to be approved this month? In actuality Fred could have enroll in a randomized controlled clinical study in which he would have a 50/50 chance of receiving the drug, and when he failed to get better on the alternative treatment (AVB) he would be eligible for the trial drug (LD) - remember daunarubicin is already approved for use in humans in the US by the FDA, and lipisomal technology is nothing more than putting the drug in a fat globule, which increases the drugs half life in circulation and may facilitate its up -take by tumor! I have enclosed Fred's pictures so you might have some idea as to what he is dealing with. Incidentally, he has already had the alternative treatment (AVB) and it failed.

Problems concerning the drug approval process: minimizes the risk of harm, but maximizes the delay; the risk of missing potentially curative treatments.

The current drug approval process (as I understand it) is based on a wish to prevent medical mishaps such as occurred with thalidomide in Europe. It is structured to insure that no medication/device used in the US will ever cause similar untoward events. This model is quite correct when it come to wrinkle creams, cosmetic disorders and other treatments for self-limiting illnesses: clearly these individuals are essentially healthy and can, in reality, only be harmed by the use of untested, poorly tested, *or poorly* understood agents used in the treatment of these conditions; hence all medications *must be tested* to the fullest extent possible prior to their approval/use in the United States.

Unfortunately, for critically ill individuals with less than weeks or months to live, the underlying premises for drug approval are patently false. Those individuals are most certainly going to die, and accordingly, the tolerance for side effects and adverse events caused by drugs is much greater in these individuals' minds, and these individuals can, in reality, only be helped by the use of untested, poorly tested, or poorly understood agents, provided there is some rationale for the agent's use, and more importantly provided that we learn from the use of these agents. Many of my patients would suffer willingly if there was some chance of improving their lot, or even if there was some chance of advancing our knowledge - I would go further and say that several of my patients have said to me that they only wished that someone would learn from their deaths so that others might be helped. What I have learned from their deaths is an infuriated frustration at the knowledge that potentially curative agents sit on the shelves of many laboratories and pharmaceutical companies in this great country while my patients continue to die. That my patients would gladly allow themselves to be experimental subjects, with little more than the expectation of death at the hands of unknown agents, was initially surprising; that they would do this with only the expectation of helping someone else avoid that same agent or extend our knowledge in the treatment of HIV, is heroic and must represent the best of our human nature; unfortunately for these noble souls, little is tried, less learned. [2]

Currently two very promising agents for the treatment of HIV/AIDS are under clinical trials in Europe; both agents are made by United States companies and both companies independently have decided to go to Europe to start human trials on their compounds: GEM-91 by Hybridon corporation and the Protease inhibitor by Abbott Labs Chicago IL. Why? Because of the barriers set-up by our drug approval process/tort system. By all indications both treatments look efficacious if not curative and non-toxic. The reason given by both companies for not initiating United States trials[2] was that it is easier to start clinical trials in Europe as the FDA, in essence, is demanding that the agents be proven non-toxic prior to use. Obviously, at least for the FDA, the best way to do this is to let Europe go first and observe the results, i.e., thalidomide. Unfortunately, when one thinks about it, these results and actions are clearly understandable. Any reasonable

[2]Actually, trials will begin in the US sometime in the future(?) but for now these companies are awaiting FDA approval and completing additional toxicological studies asked for by the FDA

person charged with the task of drug approval in the United States with even a remote interest in keeping their job, home, bank account, reputation etc., would be out their mind to approve any new drug for use in the United States - what could he possibly gain? I maintain a thinking individual would wait on approving any medication/device at least until it had already been approved somewhere else. The risk then being known, he would be assured no harm would come from the use of this medication/device and hence no harm would come to the approver. A thinking individual would do this for two reasons; first, those patients who would need the medication/device on moral grounds (willing to try anything, beyond hope) would by definition be the sickest and undoubtedly have little energy to fight, eventually and shortly dying; thus exerting little or no political pressure on the approver. Secondly, as he would only lose his job if an adverse effect occurred through the use of the new medication he had approved and as this is the substance of the media and the tort courts, which don't die, he would have two very good reasons to delay approval. Clearly, if you want to keep your job in the drug regulatory division, don't approve anything until it is already proven by someone else to be effective and free of side effects. Also, God help the drug company that would push to have any drug approved or used on moral grounds, or try to accelerate approval prior to it being abundantly clear to the regulator that he wasn't going to lose his job by approving a thalidomide- like drug. If one considers the position of the would-be medication/device regulator a little further, one realizes that as a thinking drug regulator, being in the position to make or break any drug company by virtue of control over the approval process, he should have little to contend with from anyone interested in having a medication/device approved for sale or use in the United States; or stated differently, by vindictively delaying approval of a bothersome pharmaceutical company's new drugs one could guarantee not a peep or hint of condemnation would be heard from the drug manufacturers - the only other, directly interested, surviving party in the drug approval process.

What a dilemma, the brightest, most innovative country on the face of the planet isn't using its resources to tame the worst plague of history, is allowing agents like DDI (may substitute DDC, D4T, etc.) to languish for 5 years in clinical studies, only to finally be approved and to be found (or I can tell you will be found) to be poorly effective, at best, in the treatment of HIV; but available to anyone who can afford the cripplingly expensive price[3] (somewhat justified to offset the huge cost of complying with the clinical and toxicological data requirements by the FDA).

Might I suggest the following solution, which is potentially beneficial to my patients, US pharmaceutical manufacturers, our country and you?

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[3]Actually if one speaks with the individuals involved in the early AZT studies, one finds that these physicians saw astonishing results in those patients started on this agent (AZT) and these same physicians pushed for rapid approval of this drug - it was, in fact, approved in a very rapid fashion; unfortunately, although AZT is very effective in the AZT naive user, or first time user, this efficacy quickly disappears in 2-6 months leaving the patient with little continuous benefit, but only growing and continuous toxicity. What we are now seeing in the literature concerning the lack of effect(long term benefit) of AZT on survival in HIV infected patients, i.e., the Concord study out of Europe, and the resultant class action law suits filed against Burrows Wellcome for "poisoning" patients-clearly reaffirms the dismal truth and wisdom employed by the thinking drug approvers approach. Clearly, if you want to keep your job in the drug regulatory division, don't approve anything until it is already proven by someone else to be effective and free of side effects.

The Sanctuary Drug Act.

As I understand the FDA to be under the control of the executive branch, and as I understand that its mission and purpose can be changed, amended or appended by executive fiat, I suggest using this power and mandating the following amendment ,creating a separate division, body, committee to the Food and Drug Administration charged with the creation and maintenance of a sanctuary for the human use of currently unproved agents/ devices. As an example: In those individuals deemed and substantiated by their physician as having less than six (6) months of life because of a life - threatening, inourable disease; and having signed all necessary forms of consent and wavers of liability; and being of sound mind, such individuals shall be allowed to have their physician petition the "sanctuary" for the providing of sanctuary agents, to be used by such patients for as long as the providing physicians reports back to the sanctuary on a regular basis to be established by the sanctuary governing board, pays a nominal fee for the agent and is limited to no more than 100 patient requests for any single sanctuary agent in one year. Agents will be placed in sanctuary based on the best judgment of a group of researchers, physicians and community activists and will remain in sanctuary until it is decided that they are dangerous, ineffective or more than 50,000 requests have been processed for the agent. Agents may be removed from sanctuary if no marked improvement in the patients so treated has come to light through anecdotal reporting by the treating physicians and/or as compared with the natural history of the disease itself. Drug manufacturers may submit agents to sanctuary without liability or loss of rights to the compounds and may pursue simultaneously phase one, two, and three protocols as currently recognized by the FDA. The sanctuary will be charged with adding and removing medications/devices from sanctuary status, maintenance and dissemination of a timely account based on the feed-back from physicians using the sanctuary drugs, and in allowing or disallowing physician participation in the sanctuary program based on noncompliance with the sanctuary's reporting requirements. Further, the sanctuary will maintain an acceptable standard of toxicity and ensure such data is present and available on all agents in sanctuary prior to release of compounds from sanctuary to the treating physician: this requirement for limited toxicity shall be judged in, rat, rabbit and dog but no standard on human toxicology will be required on sanctuary agents prior to their release, with all parties being warned as to the limits of the toxicological data. Sanctuary will transmit all toxicological summary data to requesting physicians with the sanctuary drugs. The sanctuary will use the funds it collects from the fee charged for providing agents to physicians/patients to pursue the study of the toxicology on agents decided by committee for use in the sanctuary, but not having drug company sponsorship or prior toxicological data, an example being a natural compound or chemical compound having promise is cell culture studies but not attractive to drug companies for reason of profit, patent etc.

This act would sub-serve several functions:

1) Any agent having tremendous curative power, even if non-patentable or widely available would be immediately obvious to those individuals both in and out of the sanctuary who are familiar with the disease process and would hopefully, having shown such promise in sanctuary, be pursued further in more formal clinical trials.

2) All or most covert use of agents in terminal disease would become public as the sanctuary would have these agents and proponents, or more importantly their patients, could look at the results, or read the anecdotal reports from many physicians who had direct experience with the agent prior to trying it themselves. This would help to limit unsubstansiatable claims made for coffee enemas, or some other less/more absurd treatment done exclusively in one place, i.e., in Mexico, etc., and not capable of being refuted, or even analyzed, as no professional would risk losing their license doing something they had no data/faith in. Nevertheless, these same professionals might, at the patient's request, provide such therapy if available in sanctuary and would by definition report back to sanctuary, thus normalizing the reality of the agent and its effect in a broad group of patients and in a broad range of doctor's hands

By not allowing any one group to dominate the anecdotes or spread nonsense amongst desperate patients, the only motivation served by the sanctuary act, and in the requesting of a sanctuary agent, would be for one's patient's health and survival.

3) This act would provide a restraint on those unscrupulous charlatans who practice beyond and within our borders and drain our citizens/patients of resources. Any physician who cares for the terminally ill can attest that this is very difficult to prevent. By virtue of a sanctuary act a physician could use the same or similar agents as the charlatans. Reports by physicians, all using the same pure agent, could be read by potential sanctuary candidates and physicians prior to embarking on the use of such an agent. Patients would then have many reports to review rather than the one report of cure from one individual with one treatment available only in Mexico, Africa, etc.

4) The great cost of drug development could be brought to a fraction of its current level, as "home-run" agents would be evident and their major toxicities also evident. Small firms with little capital could submit or publish their data as is currently done and the sanctuary committee could select their agent for placement in the sanctuary

5) Agents in the sanctuary would be provided by drug manufacturers at no cost and would be pure, the manufacturer obtaining very rapid data on the agents effect in humans in return for provision of the agent and the toxicological animal data.

6) The sanctuary allows for a rapid evaluation of many agents with potential for cure, as contrasted with the 9 billion dollars we have spent comparing AZT to DDI. through the ACTG's

7) Patients and physicians stop re-inventing the wheel[4].

[4]One of the truism of medicine is that when a treatment for a disease works, for example the treatment of testicular cancer with 98% cure, there is very little charlatan activity, or alternative medicine in these diseases, however, when current therapy is ineffective there is a burgeoning market in quack cures. Much of the problem with HIV is that we have no effective cure. When one is found, most of the problems surrounding the disease treatment with bizarre agents disappears.

Benefit to United States patients:

1) Untold thousands of patients now go to Mexico, Europe, etc., to seek out "cures" at great expense and untold grief. Given the availability of the same agents through their doctors these same patients (having failed all conventional therapy and with less than 6 months to live) would surely prefer to stay at home and some data could be collected on these agents at the same time.

2) The sanctuary agent might just work. Agents which clearly already work in the test tube could be used in humans in a matter of months rather than years.

Benefit to the United States pharmaceutical manufacturers:

In essence the companies could choose to place drugs in sanctuary and obtain information on its human toxicity and efficacy without spending the 10 million it currently costs to bring an agent through clinical trials. Having such advanced warning on agents under consideration by the drug companies for development is invaluable and for those agents which showed promise in sanctuary, efforts could be accelerated through the normal channels of phase one, two, and three. This would increase the availability of the agent to less ill patients who would not meet the definition of sanctuary users.

Benefit to you:

Clearly more previously healthy young Americans have died from HIV (200K) than have died in W.W.II, Korea and Viet Nam. Recognized or not this is a state of emergency. Each individual who dies of AIDS has on the average 30 years of training spent on him and these same individuals were expected by society to perform for another 30-40 years - what an incredible waste of productive man years. 30 years times 200K men equals 6 million man years of production! These are the individuals who were to pay taxes and take care of society - but now just draw on society and die.

All of those persons infected with HIV- dead or alive - have families that are extremely anxious that something be done and would be extremely grateful to anyone accelerating the process of finding a cure. This addendum to the FDA costs nothing, wins popular support and could dramatically accelerate the discovery of cure. I can think of no greater act that could be done to win popular support for your administration than to allow the terminally ill to go first, and experiment with their and their families' consent and the approval of their physicians, in a situation so desperate for cure.

Purpose of the Sanctuary

1) To allow the free circulation of information on potentially useful agents, written by the treating physicians, on real persons with AIDS to the community at large.
   a) This would discourage the continual pursuit of agents used by prior patients

who died, so that patients don't keep "re-inventing the wheel" [5]

b) Clearly by relying on the anecdotal model small differences of benefit or harm will be missed, but no one needs statistical methods to tell when someone's t cells go up or down by a factor of 3. This change is obvious to all observers - and unfortunately this is the change we need. This sanctuary method would miss small, or in my mind with this disease, inconsequential effects, but large effects would be obvious even if only anecdotally.

c) Patients will continue to seek out quack cures regardless of the laws against them as the preservation of their life would seem a higher good, even if misguided. There isn't enough man-power in the nation to stop a motivated individual told that he is terminally ill from seeking out hopeful alternatives to death -- why waste their experience?

Thank you for hearing me out.

THOMAS J. MAGEE, M.D.

[5]This is quite common in my experience, each new cohort infected with HIV-1 seeks out and tries the same therapies the last, dead, cohort did, e.g. , compound Q, dextran sulfate, ozone, hydrogen peroxide, intravenously hydrochloric acid, passive immunotherapy, etc.. Each desperate cohort attempts to re-invents the wheel which didn't work the first time around. Not only is the lack of efficacy disconcerting but the failure to learn from prior deaths is appalling. This lack of learning is related to two facts: most of the "practitioners of these therapies are either infected physicians themselves or 'alternative healers' and in both cases these data are not made public-the treatments being illegal or the treating physician dying from HIV and with him any information concerning the treatment efficacy or rather obvious lack thereof. During my treating of HIV infected patients I have seen this cycle repeat itself 3 times and I see no end in sight. It has two distressing side effects, one, more effective or even different therapies are not sought out and, two, the burden or proof is placed on the physicians who don't believe these therapies effective. Patients have said to me: "if it can't hurt me don't you think I should do it" or" doesn't it make sense, if ozone, bleach, hydrochloric acid, etc. kills the virus in cell culture won't it kill the virus in my blood" or " I have a friend whose T cells went up 400 by using rectal enemas of bitter melon extracts". How does a physician answer these questions? Scientifically? With what data? In this situation perhaps one can answer an anecdote with another anecdote or several thousand of them. For example, if every one of the individuals who comes to me expressing a desire to do intravenous compound Q could be referred to the Sanctuary data base of 5000 experiences with this agent and if 90% of the patients had died, got worse, did nothing, etc. I would suggest that these same patients initially determined to undertake such therapy would start looking for another treatment modality.

I endorse the idea of the Sanctuary Drug Act and authorize the Sanctuary Task Force to use my endorsement in their efforts to promote the creation of the Sanctuary. I understand that my endorsement implies no obligation on my part, but is simply a reflection of my support of the Sanctuary Drug concept.

NAME _____ DATE _____

Please return to the Sanctuary Task Force at:

Sanctuary Task Force
c/o Knowing, Inc.
6565 Sunset Blvd., Suite 416
Hollywood, CA 90028

or FAX (213) 993-0430