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THE WHITE HOUSE

WASHINGTON

June 12, 2000

David Gluck, MD, FACPrM
150 East 69th Street
New York, NY 10021

Dear Dr. Gluck:

Thank you for your letter of May 3rd, 2000, in which you detailed the successes of experiments with low dose naltrexone performed by your colleague, Dr. Bernard Bihari.

I apologize for the delay in our response. The findings of Dr. Bihari's research are indeed encouraging, though as the Office of National AIDS Policy is primarily policy-oriented in our activity, the National Institutes of Heath and Center for Disease Control may be better able to address the research concerns that you raise.

Please know that the Clinton Administration is doing all that it can to respond effectively to this devastating epidemic that is sweeping the globe.

Thank you for your letters, and I wish you and Dr. Bihari all the best in your continued research.

Sincerely,

Sandra L. Thurman
Director
Office of National AIDS Policy

sent 6/14/00

NIH / CDC
policy v. res.

May 16, 2000

FAX TO: **Sandra Thurman**
White House AIDS Policy Director
736 Jackson Place Washington, DC 20503
(202) 456-2437 (voice) (202) 456-2438 (fax)

Dear Director Thurman:

I am deeply disappointed that, although I faxed an extensive and detailed description to you on May 3rd that described a proven (for 14 years now in a large HIV/AIDS practice in New York City) and strikingly successful therapeutic approach to the disease, I am yet to receive any acknowledgment from you or your staff.

Let me now add that a publicly held, biopharmaceutical corporation has just done due diligence on all of Dr. Bihari's data concerning the use of low dose naltrexone and has found the record compelling -- they now have given him a written offer concerning financial agreements surrounding their intention of running clinical trials. BUT, since the therapy involves the off-label use of an already-approved-by-the-FDA medication, there is no reason why Africa &Asia should have to wait for 2 or more years for the confirmatory trials. Low dose naltrexone (3mg each night) has essentially NO side effects. For God's sake, are you listening!?! Why don't you send some qualified professional to see the evidence -- it's waiting at Dr. Bihari's office on 15th Street in Manhattan!

Please let me know that you are there and paying some attention. Dr. Bihari stands ready to answer any questions you may have -- his telephone number, again, is (212)929-4196. With an estimated 33 million people worldwide already infected, every day's delay is terribly costly.

Sincerely,

David Gluck, MD, FACPrM
Assoc. Prof. of Medicine-emeritus, Cornell Medical College
Board-certified in Internal Medicine & in Preventive Medicine
150 East 69th Street, NYC, NY 10021
(212) 734-5109
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Incomplete

FAX TO:

May 3, 2000

Sandra Thurman
White House AIDS Policy Director
736 Jackson Place
Washington, DC 20503 (202) 456-2437 (voice) (202) 456-2438 (fax)

Dear Director Thurman:

I am writing to apprise you of a **therapeutic breakthrough in the treatment of HIV/AIDS** that should be ideal for the desperate situation now being faced in Africa, certain areas in Asia, and other underdeveloped nations generally. Low dose naltrexone **[LDN]** has been used successfully in a large HIV/AIDS private practice in New York City by its brilliant discoverer, Bernard Bihari, MD, since 1986. It tips the scale against the virus by upgrading the immune system, and it does this with one small capsule (**naltrexone 3mg**) at bedtime each night -- a medicine that has shown itself to be extraordinarily effective, to have virtually no side effects, and to be very low in cost! Full dose **naltrexone (50mg) has been FDA-approved for many years** now, for other uses. It will probably be at least two or three years more before clinical trials can be finally financed and accomplished so that the FDA can approve LDN for its new uses at this new low dose. But **there is no reason why desperate populations can't begin to take advantage of it in this interim period.** Pilot studies in any volunteer country of this entirely safe, inexpensive, low-dosage, once-daily medicine would, within a year's time, clearly demonstrate its efficacy! The full-dose medication is produced by DuPont Pharma, by Barr Labs, and by at least one other generic manufacturer.

As of March 13, 2000, Dr. Bihari still had more than 20 patients with AIDS in his practice who have refused antiviral Rx and who have maintained stable CD4 levels for eight or more years on LDN alone or on LDN plus acyclovir. All of these patients started with CD4 counts of greater than 300. Bihari indicates that most patients with lower CD4 counts showed a decline in CD4 number and percentage over time, though much more slowly than untreated patients used to. It is because of this striking efficacy, this ability of LDN to prevent further immune-system deterioration over time, to sharply reduce the incidence of any opportunistic infections and to drastically diminish mortality, that I beg you to contact Bihari and look at the clinical records, the accumulated laboratory data over the years, and if you like, interview the patients. Although it is not a cure for the AIDS virus, its therapeutic effects could, perhaps, save millions of affected persons from falling into disability and death, and could have a healing effect on whole nations and their economies. This is why "attention must be paid!"

In an attempt to spread the information, Dr. Bihari has made board presentations at many of the International AIDS Conferences, and has had his monographs published by the San Francisco Aids Foundation and others. In an attempt to get the support needed to be able to finance the multi-million dollar clinical trials needed to gain FDA approval, we have contacted foundations, philanthropists, chairman of clinical departments at medical centers, corporate medical directors of major corporations, as well as an array of pharmaceutical companies. In virtually every instance, as a lone private practitioner, he has been met with either stony silence &/or disbelief (e.g., "That's surely been studied already and it doesn't work!"), or the ironic "Catch-22" question, "What peer-review journals have published one of your prospective clinical trials?" [Of course, clinical trials are *just* why we've been trying -- in vain -- to raise a fortune for over a decade now!] We even have e-mailed Dr. Peter Piot of WHO-AIDS on three occasions and never received a reply from his staff. Two, out of many e-mails, sent to AIDS workers in Africa received replies. An informational website is maintained by me (see below).

Since the advent of HAART four years ago, Bihari has used it in combination with low dose naltrexone in all of his patients with lower CD4s. Nearly all of his 155 patients in this category are on at least one protease inhibitor and either nevirapine or two nucleoside analogues. There have been at least three interesting findings in this group:

1. **The viral load breakthrough rate in 3 1/2 years has been only 14%.** More than 85% have remained HIV RNA-PCR undetectable during this period. Reports from other

treatment groups have shown an average breakthrough rate of 30-50% in the first twelve months, and 60-70% by the end of three years. The only difference in the treatment approach that could explain this is that all of Bihari's HIV patients are taking low dose naltrexone.

2. **Seventy-five percent of those on HAART and low dose naltrexone, including the few with viral-load breakthroughs, are showing a slow secondary rise in CD4s, which generally begins after 18 months on HAART.** In many cases, this late rise in CD4s has exceeded 50% and in all cases has been persistent. The medical literature does not appear to have studies showing this phenomenon in patients not on naltrexone.

3. **None of the more than 150 patients on protease inhibitors have developed lipodystrophy, except for four who stopped naltrexone.** These are four patients who stopped naltrexone in their early months of HAART, all of whom began to develop lipodystrophy six to nine months later. All four eventually resumed naltrexone. Two experienced complete reversal of lipodystrophy signs after nine or ten months back on the medication. The other two have shown significant movement toward reversal at six months. Dr. Bihari speculates about the relative role of high cortisol levels and low endorphin levels in the development of lipodystrophy. He suggests that naltrexone's ability to raise endorphins to counterbalance cortisol levels may be responsible for its protective role.

Low dose naltrexone [LDN] is just 3mg of the standard 50mg dose of naltrexone that has been FDA-approved for many years now (and is sold by DuPont Pharma as ReVia). The prescription of LDN by a physician represents an off-label use of an FDA-approved medication, which is both legal and ethical. LDN has no apparent side effects of significance [i.e., the only one known is the possible appearance of sleep disturbance seen in a minority of patients during the first week or two of LDN use]. The only contraindications: it probably should not be used during pregnancy and, being a narcotic antagonist, it obviously cannot be used simultaneously with any narcotic medication. The 50mg dose of naltrexone carries a warning against its use in the face of hepatic problems (but that was based on experiments with 300mg doses), although that hasn't proven to be a problem at 50mg, and clearly is not a problem at 3mg. A month's supply of LDN at a local pharmacy costs **$24**.

The discoverer of LDN's groundbreaking clinical effects in HIV/AIDS (and in other illnesses that involve the immune system), Bernard Bihari, MD, is a friend I've known since childhood. His office is at 29 West 15th Street in Manhattan. Please call him at **(212) 929-4196** with any questions -- he is in his office afternoons and evenings. Or please call me (my number is given below). I've appended a brief CV of Bernie. Up until 1999, his practice had focused in the main on the treatment of HIV/AIDS. He is presently applying to the NCI to present his case series on LDN's strikingly successful effects on a variety of cancers. I have posted a website, **www.lowdosenaltrexone.org** , for the interest of physicians and the public, that has detailed background information on LDN's uses. Please see the site and its links for many details on the history of prescription LDN in hundreds of Bihari's patients over the years, as well as information on the research background.

There has now accumulated a large body of basic research in neuroimmunology that confirms the role of endorphins as one of the brain's key mechanisms in the regulation of the immune system. **Notably, it was the original work by I. Zagon, Ph.D., in the early 1980's at Hershey Medical Center in Pennsylvania that triggered Bihari's interest, and from which he derived his insight that a clinically-useful immune system up-regulator might be feasible. Zagon and colleagues at Penn State have continued their successful (and prolific) laboratory research on metenkephalin to this day.** Apparently, the nightly, brief opioid-receptor blockade induced by LDN when taken at bedtime leaves a marked increase in endorphin and metenkephalin levels in its wake throughout each following day, which leads to the several beneficial effects that are being noted.

It has been hell for a dozen years now, seeing the wonderful and unparalleled results in Bernie's private practice growing from month to month, wanting to shout it from the rooftops, and having no

one in authority willing just to cross the street to see the evidence. Please consider the ***millions of people*** whose lives are at stake with this plague of HIV, the numbers of nations that are being terribly afflicted, the enormous commitment of funds now being made available by the US alone to help combat it, PLEASE, PLEASE, realize that, with almost no effort or expenditure by you, you can affirm everything and more about low dose naltrexone with just a flick of your finger by sending certified reviewers. PLEASE do not dismiss what I am telling you here out of hand -- it is all the truth and will make a tremendous difference for mankind. There really is no downside to this, other than ignoring it because of the institutional blinders we have already encountered so tragically, so many times....

Sincerely,

David Gluck, MD, FACPrM
Assoc. Prof. of Medicine-emeritus, Cornell Medical College
Board-certified in Internal Medicine & in Preventive Medicine
150 East 69th Street, NYC, NY 10021
(212) 734-5109
dgluck@pol.net

P.S. - I don't doubt for a moment that this would make a wonderful legacy for the Clinton Administration.

Addendum:

CURRICULUM VITAE

BERNARD BIHARI, MD
29 West 15th Street
New York, NY 10011
(212) 929-4196

EDUCATION
- BA - Cornell University, Ithaca, NY 1949-1953
- MD - Harvard Medical School, Boston, Mass. 1953-1957

TRAINING
- 1962-1965 - Resident, Department of Psychiatry, Columbia-Presbyterian Medical Center, N.Y.State Psychiatric Institute
- 1960-1962 - Research Associate in Neurophysiology, Section on Physiology, Laboratory of Clinical Science, N.I.M.H., Bethesda, Maryland
- 1959-1960 - Resident, Department of Neurology, Massachusetts General Hospital, Boston, Mass.
- 1958-1959 - Resident, Department of Medicine, Beth Israel Hospital, Boston Mass.
- 1957-1958 - Intern, Department of Medicine, Beth Israel Hospital, Boston, Mass.

CERTIFICATION
- Board Certified, American Board of Psychiatry and Neurology; 1970
- New York State Medical License 088158

FACULTY APPOINTMENTS
- 1981-Present - Clinical Associate Professor, SUNY / Health Science Center at Brooklyn
- 1968-1980 - Assistant Professor, Department of Psychiatry, Mount Sinai School of Medicine
- 1959-1960 - Instructor in Neurology, Harvard Medical School

ACTIVITIES
- 1991-Present - Medical Director, Foundation for Integrative Research, Inc. New York, NY
- 1989-1991 - Executive Director/Medical Director, Community Research Institute, New York, NY
- 1981-1989 - Director, Division of Alcoholism and Drug Dependence, SUNY/Health Science Center at Brooklyn

• 1978-1980 - Deputy Commissioner, Program Development and Evaluation (Deputy for Public Health Programs), NYC Department of Health
• 1977-1978 - Commissioner, New York City Addition Services Agency, and Deputy Commissioner for Addictions, NYC Department of Health
• 1974-1977 - Assistant Commissioner for Addictions, NYC Department of Health
• 1972-1974 - Chief, Alcoholism Treatment Program, Department of Psychiatry, Morris J. Bernstein Institute of Beth Israel Medical Center, New York
• 1971-1972 - Chief, Drug Addiction Service, Department of Psychiatry, Morris J. Bernstein Institute of Beth Israel Medical Center, New York

RESEARCH PROJECTS

I. Low Dose Naltrexone in the Treatment of AIDS. Principal Investigator: Bernard Bihari, MD, Funded by Foundation for Integrative Research, at SUNY/Health Science Center at Brooklyn 1985 - 1986

II. HIV Maternal Fetal Transmission Study. Co-investigator: Bernard Bihari, MD, Funded by National Cancer Institute and National Institute of Child Health and Human Development, at SUNY/Health Science Center at Brooklyn 1987 - 1990

III. Collaborative Prospective Cohort Studies of Heterosexual Transmission of HIV and Related Retroviral Infections. Co-investigator: Bernard Bihari, MD, Funded by National Institute of Health and National Institute of Allergies and Infectious Diseases at SUNY/Health Science Center at Brooklyn 1987 - 1990

IV. Lentinan as an Immunomodulator (Phase 1/11 Placebo Controlled Dose Response Study of Lentinan in Patients with HIV Infection and 2000/500/mm CD4 Lymphocytes). Principal investigator: Bernard Bihari, MD, at CRI. Sponsored by Lenti-Chemico, Teaneck, N.J. 1989 - 1990

V. Rifabutin Therapy for the Prevention of Mycobacterium-Avium Complex (MAC) Bacteremia in AIDS Patients with CD4 Counts = 200: A Double-Blind, Placebo-Controlled Trial, Principal Investigator: Bernard Bihari, MD, at CRI. Sponsored by Adria Pharmaceutical, Columbus, Ohio 1990 - 1993

VI. Methionine Enkephalin (MEK): Phase 1/11, Double-Blind, Placebo-Controlled, its Safety, Toxicity and Possible Immune Modulatory Effects, Principal Investigator: Bernard Bihari, MD, at CRI Sponsored by TNI, Willamette IL 1990-1991.

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