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THE WHITE HOUSE

WASHINGTON

May 24, 1994

NOTE TO BILL PAUL, M.D.

FROM: Terry Beswick
Senior Research Specialist
Office of National AIDS Policy

Subject: "AIDS Cure Act" and the "Manhattan" promise

Thanks again for considering the IOM planning meeting proposal. I spoke with Ms. Gebbie about our conversations on this, and we agreed that your plans to continue establishment of a circle of scientific advisors are very encouraging. It would be helpful to us if we could hear more about this as it takes shape.

On a separate issue, I have attached a one-page preliminary commentary from Ms. Gebbie on a recently introduced bill from Representative Jerry Nadler (D-NY), the "AIDS Cure Act". Mr. Nadler has not yet sent us the new version of the bill to request endorsement, but we have internally reviewed it in draft form. Our office, other administration officials and members of Congress continue to be lobbied by constituents in favor of this proposal. A summary of the bill, which is an attempt to define a "Manhattan Project" for AIDS research, is also attached.

Overall, while the intent is admirable, we have concerns about the bill, and we do not expect that it will be successful. However, we thought it might be a good idea if you and others in the scientific community could help us articulate what is right or wrong with the "AIDS Cure Act" if and when the President is formally asked for his support.

This statement from Ms. Gebbie, which has not been publicly released, also represents our office's latest effort to re-define a "Manhattan Project on AIDS". If you could take a look at this at your convenience, any insight or additional comments you might have to improve this statement would be greatly appreciated. Our preference at this time would be to re-define "Manhattan Project", rather than reject the phraseology altogether.

If you have any questions, please call me at (202) 690-5560 or by fax at (202) 690-7560.

cc: K. Gebbie ✓
A. Lawrence

THE WHITE HOUSE**Office of National AIDS Policy**

STATEMENT BY KRISTINE GEBBIE, NATIONAL AIDS POLICY COORDINATOR May 11, 1994**COMMENTS ON CONGRESSMAN NADLER'S AIDS CURE BILL**

I can't comment on Mr. Nadler's bill at this time as I haven't seen the new version just introduced, but we have discussed the earlier version with the Representative. We have invited Mr. Nadler to send us the new bill, and we will comment on the specifics of the bill then if asked.

Over the last several months, I have sought to bring some definition to what many people call the "Manhattan Project" for AIDS. Everyone seems to mean something different when they talk about this, but I believe we cannot shy away from evaluating all the different interpretations in circulation. During the campaign, the President promised a "Manhattan Project for AIDS" and we take this very seriously.

From the Administration viewpoint, I am coming to see that, given the state of the science of HIV and the modern communications technologies available to scientists today, we must begin to regard the entire Federal and private AIDS research enterprise in the United States as a "Manhattan Project" for AIDS research. Then, we have to go about the business of making this huge enterprise work to its maximum potential.

I believe that this is the approach that will bring us effective treatments and vaccines most quickly, and the Clinton Administration has taken several significant steps on this path, including:

- the revitalized NIH Office of AIDS Research with its centralized planning and budgeting authorities, now under the leadership of Dr. William Paul;
- a 21% increase to the NIH AIDS research budget this year;
- The National Task Force on AIDS Drug Development, which is working now to identify and remove obstacles to the discovery of effective therapies for HIV/AIDS.

We need to turn the whole national research effort into a truly efficient, working "Manhattan Project" to find safe and effective treatments and vaccines for HIV/AIDS.

We need to improve what we have by enhancing communication, coordination, and collaboration in the public and private sectors, in the U.S. and abroad, in a way that fosters new ideas and ensures that we don't miss the truly important discoveries.

Guiding research priorities while encouraging innovation is an ongoing process that has to continue and has to be accelerated. We have to constantly evaluate where the research is going and what we may be missing, and we have to carefully consider any new ideas that may help create and maintain an environment more conducive to good, productive science.

U. S. REPRESENTATIVE

JERROLD NADLER

8th CONGRESSIONAL DISTRICT - NEW YORK



NEWS RELEASE

FOR IMMEDIATE RELEASE
Tuesday, May 10, 1994

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REP. NADLER AND ACT UP ANNOUNCE INTRODUCTION OF LEGISLATION TO FIND A CURE FOR AIDS

U.S. Representative Jerry Nadler (D - Manhattan & Brooklyn) and members of the AIDS activist group ACT UP today announced the Congressman's introduction of the AIDS Cure Act at a news conference outside the local offices of the Public Health Service at Federal Plaza in lower Manhattan. "It's time to put a stop to the business-as-usual attitude toward finding a cure for AIDS," declared Congressman Nadler. "That's what this bill I am introducing today will do."

The AIDS Cure Act establishes a detailed blueprint for a concerted and concentrated research effort to find a cure for AIDS, akin to the massive scientific research project that led to the development of the atom bomb. "As a presidential candidate, Bill Clinton promised that a 'Manhattan Project' to cure AIDS would be undertaken during his presidency," said Representative Nadler. "My bill is an effort to remind him of that promise, and to keep him to his word," said Congressman Nadler.

Researchers for the Project would be required to suspend potential conflicts of interest, such as financial ties to drug companies, and to represent a broad spectrum of scientific disciplines. In addition, the Nadler AIDS Cure Act would give the power of "eminent domain" to the AIDS Cure Project, enabling the Federal Government to assume the right to release promising treatments that the original patent-holders refuse to develop.

"There will never be a cure for AIDS until we cure the research," charged Mark Milano, an ACT UP member. "We need to address the fundamental problems of AIDS research. We need to create a research initiative that will emphasize public health concerns over profits -- that will coordinate our vast resources and provide incentives for the sharing of scientific information," said Milano.

Co-sponsors of the bill already include Rep. Major Owens (D - Brooklyn), Rep. Nydia Velazquez (D - Brooklyn, Manhattan, Queens), and Reps. Ron Dellums and George Miller (both D - CA).

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Congress of the United States
House of Representatives
Washington, DC 20515

May 6, 1994

Dear Colleague:

I am writing to invite you to join me in co-sponsoring the "AIDS Cure Act." This bill calls for an all out research initiative to find a cure to AIDS -- one of the most devastating diseases of our time.

Since AIDS was identified in the early 1980's, more than 360,000 cases have been documented and more than 220,000 AIDS related deaths have resulted in the U.S. Further, nearly 1 million Americans are estimated to be HIV-positive, but have not yet contracted AIDS.

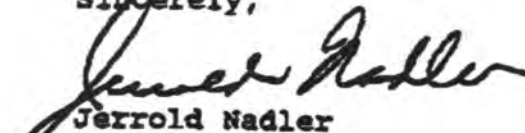
While our current medical research efforts have made some important strides in trying to understand the pathogenesis of AIDS and to identify promising treatments, much more must be done to advance our knowledge of this deadly disease.

My bill calls for a national research effort to find a cure for AIDS. It is a dramatic new approach which resembles the "Manhattan Project" -- the crash program to develop the atomic bomb. This bill would pool the brightest, most committed scientific researchers and best resources to find a cure for AIDS. The Project would accomplish this objective by studying diverse medical theories which may lead to a cure for AIDS.

While the project is independent from the National Institutes of Health, its intent is to supplement ongoing research efforts. The project's funding stream would be independent and would not take away from funding that currently goes to the NIH.

If you are interested in co-sponsoring this very important piece of legislation, please contact Nicole Tucker at x5-5635.

Sincerely,


Jerrold Nadler
Member of Congress

SUMMARY OF THE "AIDS CURE ACT"
Introduced by Congressman Nadler

The purpose of this bill is to establish a coordinated, all-out research project, much like the "Manhattan Project" which developed the atomic bomb, but to find a cure for AIDS.

ESTABLISHMENT OF THE PROJECT

* The Secretary of Health and Human Services would establish the project. The Secretary would be directed to ensure that the project meet two requirements:

- 1) The project shall pursue comprehensive basic science investigations, based on diverse theories and schools of thought to better understand the development of AIDS.
- 2) The project shall identify, based on this work, all promising curatives and oversee their timely and adequate testing.

* While the project would be independent of the NIH, it would work cooperatively with the NIH in finding a cure for AIDS. The AIDS Cure Act would be funded separately from the NIH and would not take away from any funding which currently goes to the NIH.

* All primary research staff and administrators would be financially compensated only by the project. They would be required to suspend their affiliation with other institutions during their work with the project in order to avoid conflicts of interests.

* The project would conduct research trials of new treatments.

GOVERNING COUNCIL

* The project would be governed by a council of scientists and clinicians representing diverse approaches to science; people with AIDS and HIV; and advocates from all affected communities. People with HIV and AIDS would be in the majority to ensure accountability of the Project.

* The council would set policy, and oversee and evaluate research priorities, ethical standards, conflict of interest rules and hiring of researchers.

COORDINATING COUNCIL

* A coordinating committee would be established to facilitate communication among the different scientists working on the project, in order to evaluate the progress of the projects' work.

OPEN AND PRODUCTIVE RESEARCH PATHS

* Thorough consideration would be given to both conventional and

other medical approaches and scientific theories, and researchers representing diverse approaches would be on the primary research staff as well as be contributing researchers.

- * All populations of people with AIDS and HIV would be given equal consideration in the study of the disease.

- * Information generated by the project would be made freely available to researchers, health care providers, people with AIDS and HIV and their advocates as soon as it is available.

- * Curatives developed by the researchers would not result in financial gain to any private organization, and would be made available to all affected people regardless of ability to pay.

EXTRAORDINARY POWERS

- * The Secretary would have the extraordinary powers to do the following:

- utilize, in cooperation with the agencies, any and all existing United States Government funded research entities nationwide to clinically test promising cures.

- * The Project may exercise the right of eminent domain to obtain the following:

- Obtain from public and private organizations, with just compensation, samples of all potential curatives and all data (excluding medical records to protect the privacy of subjects) regarding their development (including safety and efficacy data) as well as other information, materials, or products deemed crucial to the project, but protect the privacy of research subjects and the researcher over which the project will be exercising the right of eminent domain.

- Once obtaining, through eminent domain, the research of an outside researcher, the project shall make all efforts to preserve appropriate recognition of the scientist's work. The project shall also afford any researcher, whose work is acquired through eminent domain, an opportunity to participate in the project with just compensation.

- Use existing pharmaceutical company facilities (with just compensation) for the production of promising curatives to be utilized in project research and, if effective, to produce such curatives in sufficient amounts to be disseminated to all people needing them.

- * Eminent domain may be used only after reasonable attempts at cooperation have failed and after the project has determined whether the research is essential information to the project's research and is unavailable other than through eminent domain.