PR NCETON PRO. ECT 55 NC.

Tuberculosis Initiative

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May 27, 1998

First Lady Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mrs. Clinton,

In your recent speech before the World Health Assembly in Geneva, you provided an excellent account of the severity and urgency of many global health crises. We are particularly pleased by your emphasis on the prevention and treatment of infectious diseases like tuberculosis.

Major public addresses such as yours are exactly what is now required to revive this nation's awareness of these profoundly neglected health causes. TB is one of the most disproportionately unheeded pandemics, yet it is the world's number one infectious killer and the death toll is rising every year. Few people in this country are aware of the enormous burden TB exacts from the citizens of developing countries, and the clear and present threat that drug resistant strains pose to the health and national security of the United States. TB kills more women than all causes of maternal mortality combined, yet most Americans consider it a disease of the past. The *yearly* death toll from land mines is matched by TB *every single day*, however many journalists and even public officials believe we have won the war against tuberculosis.

You have the unique capacity to refocus America's attention on health issues of major global importance, and this speech was an exemplary first step. Now, as you said, "We must put our hearts, our minds, and our resources in action." In South America, you witnessed the unprecedented successes that can be achieved through the use of directly-observed treatment for tuberculosis patients. As you saw, the WHO-recommended regimen, Directly-Observed Treatment, Short-course (DOTS) is a very simple system, that the World Bank determined to be one of the world's most cost-effective health interventions. Successful application of DOTS has produced cure rates above 85% in places as diverse at New York, Peru, China, Tanzania, and Bangladesh. In most countries, the overall effect of DOTS on the primary health infrastructure and the incidence of infectious diseases has been remarkable.

For the health and stability of developing nations, and to protect Americans from multi-drug resistant TB (MDR-TB), it is time for the U.S. to make a significant investment in DOTS for the most severely affected nations of the world. USAID's new infectious disease initiative is a good beginning, but this pilot project must be expanded to other key regions of the world. MDR-TB is already threatening to overwhelm the public health systems of "hot-zones" such as Latvia, Estonia, Russia, the Dominican Republic, Argentina, and the Ivory Coast. Unless we ensure the rapid application of DOTS in these

and other countries, epidemics of MDR-TB will become commonplace in many more countries.

A global assault on TB will also require significant commitments from the WHO, and from developing nations. The U.S. should make use of its diplomatic influence to encourage endemic nations to dedicate resources to the control of TB within their borders. Additionally, the U.S. should help to accelerate the introduction of WHO Secretary General-Elect Gro Harlem Brundtlandt's "Roll Back Malaria" and "Roll Back TB" initiatives. Currently the WHO Global TB Programme's total annual budget for the application of DOTS is a paltry $11 million. Dr. Brundtlandt should be supported in significantly increasing funding for the TB program, in accordance with its prominence among causes of death globally.

Finally, with the introduction of the President's "Research Fund for the 21st Century," now is the time for the U.S. to make a meaningful investment in research on the infectious diseases of major global health importance identified by USAID's new initiative. DOTS can make a significant impact on the global disease burden, but without an effective TB vaccine, we will not be able to control TB over the long-term. Now that scientists have read the entire genetic code of the TB microbe, the potential for the development of new drugs, diagnostics, and vaccines has never been better. This March, a working group of TB and vaccine experts, convened by Secretary Shalala, met to formulate a national "Blueprint for a Tuberculosis Vaccine," which sets the course for accelerated development of a TB vaccine, but without new funding, this initiative cannot get under way.

Thank you, Mrs. Clinton, for your dedication to the health of the world's population. We hope that you will work with us to significantly increase U.S. commitments to global health.

Sincerely,

Ralph Nader
Steering Committee

Enclosures: informational packet

cc: Mr. Sidney Blumenthal, Dr. Laura Efros, Mr. Tom Friedman, Mr. Leon Fuerth, Mr. David Halperin, Mr. Chris Jennings, Dr. Donald Jordan, Dr. David W. Kampt, Mr. Peter Rundlet, Mr. Eric Schwartz, Mr. Michael Waldman, and Mr. Joel Wilson.

MS-
re-TB

(Tuberculosis) RW

① This seems very promising

② We should conf. call/meet with Sid B.

③ Is this an intl or domestic initiative. Intl seems most effective, DOTS + Seem domestic. (Intl)

④ What would we do ✓ propose note to Lew & USAID or WHO

⑤ Can you talk to Summers about this & how it relates to AIDS

⑥ Can you check w/ Bianchi to see if we've done anything on TB? No per Bianchi

⑦ The memo seems very good, we should just give them an idea of what we'd do. → see above

(8) I count 6 significant bullets in the SOTU we worked on. That's not bad.

Tom

MEMORANDUM

TO: **BRUCE REED, ELENA KAGAN**

FROM: **TOM FREEDMAN, MARY L. SMITH**

RE: **TUBERCULOSIS INITIATIVE**

DATE: **JANUARY 27, 1997**

SUMMARY

The rate at which cases of tuberculosis (TB) are occurring is increasing dramatically. The World Health Organization (WHO) believes that the world is on the brink of an epidemic. WHO proposes the expansion of an anti-TB strategy known as DOTS, Directly Observed Treatment, Short-course. DOTS is the careful monitoring of patients for six to eight months as they take a daily dose of four different drugs.

STATISTICS ON TUBERCULOSIS

- Tuberculosis is the single greatest infectious killer in the world, causing 8 million illnesses and 3 million deaths every year, more than all other infectious diseases combined. Source: World Health Organization (WHO) 1997.

- Today the TB microbe is harbored by up to 2 billion people (approximately one-third of world's population), about a tenth of whom will become sick and infectious. Source: U.S. News & World Report, March 31, 1997.

- Currently there are 7.5 million active cases of TB worldwide. Source: WHO.

- In 1995, the United States reported 8.7 cases of TB per 100,000, a total of 22,860 cases, of which 4.1 percent were in correctional institutions. In 1996, a total of 21,337 cases of TB were reported to the CDC from the United States, a 6.7 percent decrease from 1995.

- In 1990, it is estimated that $700 million was spent to treat the 26,000 U.S. cases of TB that year. Source: CDC.

- New, multi-drug resistant strains of TB are threatening to make TB incurable again, as it was before a cure was found in 1952. Multi-drug resistance is a man-made phenomena and is created by inconsistent or partial TB treatment. Many patients do not take their medicines for the entire six-month treatment period or stop treatment because they no longer have outward symptoms. In addition, nearly two-thirds of those who are prescribing TB medication are putting people at risk for MDR TB because they are prescribing the wrong combination of drugs.

- A person with AIDS is ten times more likely to contract TB.

- Reasons for the increases in TB cases include the spread of HIV resulting in reduced natural immunity, immigration from developing countries, and the breakdown of health-care systems in Russia and Eastern Europe following the collapse of communism.

- The world's TB epidemic will rise above nine million active cases annually within 20 years if governments fail to swiftly change the way they handle the disease. Source: WHO.

- The American Lung Association estimates that improvements in TB control could increase economic output in developing countries by $24 billion annually. Source: WHO.

PROPOSED INITIATIVE

- In 1997, the World Health Organization urged the expansion of an anti-TB strategy known as DOTS, Directly Observed Treatment, Short-course. DOTS is the careful monitoring of patients for six to eight months as they take a daily dose of four different drugs. The main feature of DOTS is that a health worker observes the patient swallowing every dose and monitors his or her progress until the disease is cured.

- The WHO proposed a $20 million kick-off program in 1997, which includes the following parts:
  - TB and MDR (multidrug-resistant TB) surveillance to gather data about the extent of TB infection throughout the world ($3 million).
  - Containment of TB "hot-zones" by expanding the DOTS strategy and training local health officials ($14 million).
  - Research to fine-tune strategies for containing TB outbreaks, to develop better diagnostics for TB, and to develop a reliable animal model on which candidate TB vaccines could be tested ($3 million).

- The WHO initiative targets 13 countries, including Russia, China, and Mexico, that harbor three-fourths of the world's estimated 20 million active TB cases.

- Six months of medication cost between $11 and $40, making the total cost of treating an infectious TB patient about $100 to $500, depending on the country.

- The WHO would like to raise the DOTS treatment rate from one in ten to seven in ten patients worldwide. The world's governments and aid agencies would need to spend an additional $500 million a year to achieve a 70 percent DOTS treatment rate.

REASONS FOR DOTS AND EXPECTED RESULTS

- More than 70 nations have used DOTS this decade, and data show its effectiveness in places as different as New York City and Peru. Source: U.S. News & World Report, March 31, 1997.

- At present, DOTS is used for no more than 10 percent of the world's TB patients. Source: WHO.

- DOTS typically achieves cure rates of 80 to 90 percent, compared with about 40 percent for unsupervised treatment. Source: WHO.

- If DOTS were used, 7 out of 10 TB victims will receive the treatment over the next decade and 10 million lives will be saved in the next 10 years.

- Faulty treatments are worse from a public health prospective than no treatment at all. Statistically, if 10 people were left untreated, 5 would die and 2 would remain uncured and infectious, and the remaining 3 would be cured by their own natural defenses. But of every 10 on an incomplete drug regimen, only 2 would die while 4 would remain uncured and infectious. One infectious person typically would infect 10 to 15 additional people in a year. Thus, inadequate treatments tend to double the rate of transmission. These inadequate treatments, where people did not take the drugs until they were completely cured not simply symptom-free, also create drug-resistant strains of TB. Source: U.S. News & World Report, March 31, 1997.

- Today, the WHO estimates that 50 million people carry the extraordinary durable form of tuberculosis known as MDR, or multidrug-resistant TB. MDR treatment can cost $250,000 a patient, and still some 40 to 50 percent will die. Source: U.S. News & World Report, March 31, 1997.

CONGRESSIONAL INTEREST

The Princeton Project 55 Tuberculosis Initiative has been in contact with members of Congress who might be in favor of increasing appropriations to USAID for the purpose of combating infectious diseases. The Princeton Project identified the following as the most supportive: Sen. Patrick Leahy (D-VT), Sen. Daniel Inouye (R-HI), Sen. Tom Harkin (D-IA), Sen. Frank Lautenberg (D-NJ), and Sen. Patty Murray (D-WA), Rep. Rodney Frelinghuysen (R-NJ), Rep. Nita Lowey (D-NY), Rep. Sidney Yates (D-IL), Rep. Nancy Pelosi (D-CA), Rep. Estaban Torres (D-CA), and Rep. David Obey (D-WI).