Vaccine International

IMMUNIZATIONS

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THE WHITE HOUSE

WASHINGTON

March 1, 2000

VACCINE INITIATIVE EVENT
DATE: March 2, 2000
LOCATION: Cabinet Room
TIME: 11:30 a.m. - 12:30 p.m.

FROM: SAMUEL BERGER
GENE SPERLING Rob Wescott For
NEAL LANE Laura Efros For
MARY BETH CAHILL MBC

I. PURPOSE

To meet with senior White House and Cabinet officials, heads of United Nations Organizations, foundations, the World Bank, vaccine and biotech experts, and the CEOs of the world's major vaccine producers. This is an opportunity to:

- Demonstrate your continued leadership in the fight against diseases disproportionately affecting the developing world;
- Highlight your new $1.5 billion-plus initiative to accelerate vaccine development for diseases such as AIDS, TB, and malaria;
- Achieve a united front with the private sector in supporting the Administration proposals;
- Gain commitments from the private sector to match Administration efforts on vaccine development.

-- We expect each CEO to 1) express support for your vaccine initiative, 2) suggest to us that more public/private research partnerships and guaranteed markets for products would help provide incentives for investing in development of new vaccines for malaria, TB, and AIDS. 3) We expect a series of commitments for investment in vaccines and vaccine development.

II. BACKGROUND

In your speech to the U.N. General Assembly last September, you called for a White House meeting to find ways to accelerate the development and delivery of vaccines for malaria, TB, and AIDS - vaccines for which there is huge need, but little market incentive for industry to develop. In your State of the Union address, you rolled out a significant multi-part proposal to address this need:

- $50 million to the Global Alliance for Vaccines and Immunization to purchase existing high-tech vaccines for developing countries;
- Sharp increases in NIH vaccine research;
- A $1.0 billion tax credit for sales of vaccines for malaria, TB, and AIDS when they are developed;
- Call to the World Bank to dedicate an additional $400-900 million in concessionary loans for health;
- Call to the G-8 and other countries to join us in meeting the challenge.

III. PARTICIPANTS

See Tab B for list of participants.

IV. PRESS PLAN

Pool spray at end of meeting.

V. SEQUENCE

The meeting will start at 11:30, chaired by Gene Sperling.

Gene will open the meeting and summarize the problem. Secretary Shalala and Secretary Summers will outline the key elements of your initiative. The Minister of Health from Uganda will set the stage from the developing country point of view.

You will join in progress.

Attachments

Points to be Made
List of Participants
Closing Remarks
Seating Chart

POINTS TO BE MADE UPON JOINING THE VACCINE MEETING

- **Thank everyone for coming.** Acknowledge **Dr. Kiyonga** [Kee-yong-ga] (Minister of Health from Uganda); **Larry Summers and Donna Shalala, John Podesta, Sandy Berger, David Satcher, Brady Anderson, Jim Wolfensohn, Dr. Gro Brundtland** (DG, WHO and former PM of Norway); **Carol Bellamy** (UNICEF) and the CEOs of the pharmaceutical companies **John Stafford** (American Home Products); **Raymond Gilmartin** (Merck); **Jean-Pierre Garnier** (SmithKline Beecham); **Richard Markam** (Aventis Pasteur).

[**Ask Gene Sperling** to outline previous discussions.]

- Each year in the developing world, we lose millions of lives and billions of dollars to killer diseases like AIDS, malaria, and TB. Last year in Africa, AIDS alone killed ten times more people than all wars did.

- We know the extent of the problem and we're here to focus on solutions. Ultimately the solution must include the development of safe, effective vaccines.

- We've developed vaccines for polio, measles, mumps, rubella, and more than a dozen other diseases. We have the technology to do the same for today's killers.

- I've proposed a significant package of proposals. At G-8 Summit in Okinawa, I will urge our partners to follow suit.

  -- I thank you for doing your part.

- **Potential Discussion Items for Select Attendees by Category**

<u>Multilateral Organizations</u>

- **Ask Jim Wolfensohn (President, World Bank)** to comment on how multilateral development banks are contributing to increasing access to vaccines and health care.

PRIVATE SECTOR (2-3 Minutes of Comments)

Pharmaceutical Companies

- **Ask John Stafford** (CEO of American Home Products) to comment on industry's interests, problems, **solutions** for development of new vaccines.

- Solicit comments from: **Raymond Gilmartin** (CEO, Merck); **Jean Pierre Garnier** (President, SmithKline Beecham); **Richard Markum** (CEO Aventis-Pasteur).

Biotech Companies

- Ask **Sean Lance** (Chiron) to briefly summarize how incentives for the smaller biotech companies differ from those of the larger companies.

- **Dr. Don Francis** (VaxGen): I understand you are moving along in testing of an AIDS vaccine. What would have made the development process easier?

- **Dr. Seth Berkley** (International Aids Vaccine Initiative): your organization is funding some significant AIDS vaccine trials as well. How close are we to results?

Foundations

- Solicit comments on approach to vaccine delivery and development from: **Bill Gates, Sr.** (Gates Foundation) (Gates Foundation just gave $750 million over five years for vaccines.); **Tim Wirth** (UN Foundation); **Gordon Conway** (Rockefeller Foundation).

- Excellent discussion. We could go on all afternoon. I am gratified and heartened -- we all have so much yet to do. **so many lives can be saved by working together.**

In moving forward, I have asked Secretary Shalala to convene a meeting of experts from the pharmaceutical industry, biotech, government, and academic sectors to seek ways to hasten R&D for vaccine development. **Secretary Summers, continue your work with industry** to craft incentives to empower the vaccine development process.

Closing Remarks (Pool Spray)

Points for Pool Spray Following Vaccine Meeting

- Meeting to join forces in the fight against diseases that kill people and progress in world's poorest countries. Urgent global challenge: AIDS took 10 times as many lives in Africa last year as war did. Malaria and TB still leave millions of children around the world without parents, millions of parents without children.

- Ultimate solution must include development of effective vaccines. That's how we got rid of smallpox, come close to eliminating polio. So today, we're beginning a partnership to eradicate the leading infectious killers of our time. We're speeding delivery of vaccines, and getting to the heart of this problem: the lack of incentive for private industry to invest in new vaccines potential customers can't afford.

- I've put comprehensive package on the table. $1 billion tax credit to speed invention of vaccines. $50 million contribution to a global fund to purchase vaccines. Big increase in research by NIH. Called on World Bank to dedicate more lending to improve health.

- Private sector is responding, and I want to recognize commitments companies are making.

- Merck is committing to develop an AIDS vaccine not just for strains of the virus that affect wealthy nations, but for strains that ravage poorest countries in the world. And it's donating 1 million doses of Hepatitis B vaccine to those who need it most.

- American Home Products will donate 10 million doses of a vaccine to prevent deadly strains of pneumonia and meningitis in children.

- SmithKline Beecham will expand its malaria vaccine program and begin new vaccine trials in Africa. And it will donate drugs worth $1 billion to eliminate elephantiasis, a crippling tropical disease.

- Aventis Pasteur will donate 50 million doses of polio vaccine to 5 war torn African nations.

- Good beginning. It will save lives, and show we're serious. But more to do. Must build on bipartisan support in the Congress to enact tax credit and funding increase. And I will go to G-8 in Okinawa this summer to urge partners to take similar steps.

List of Participants

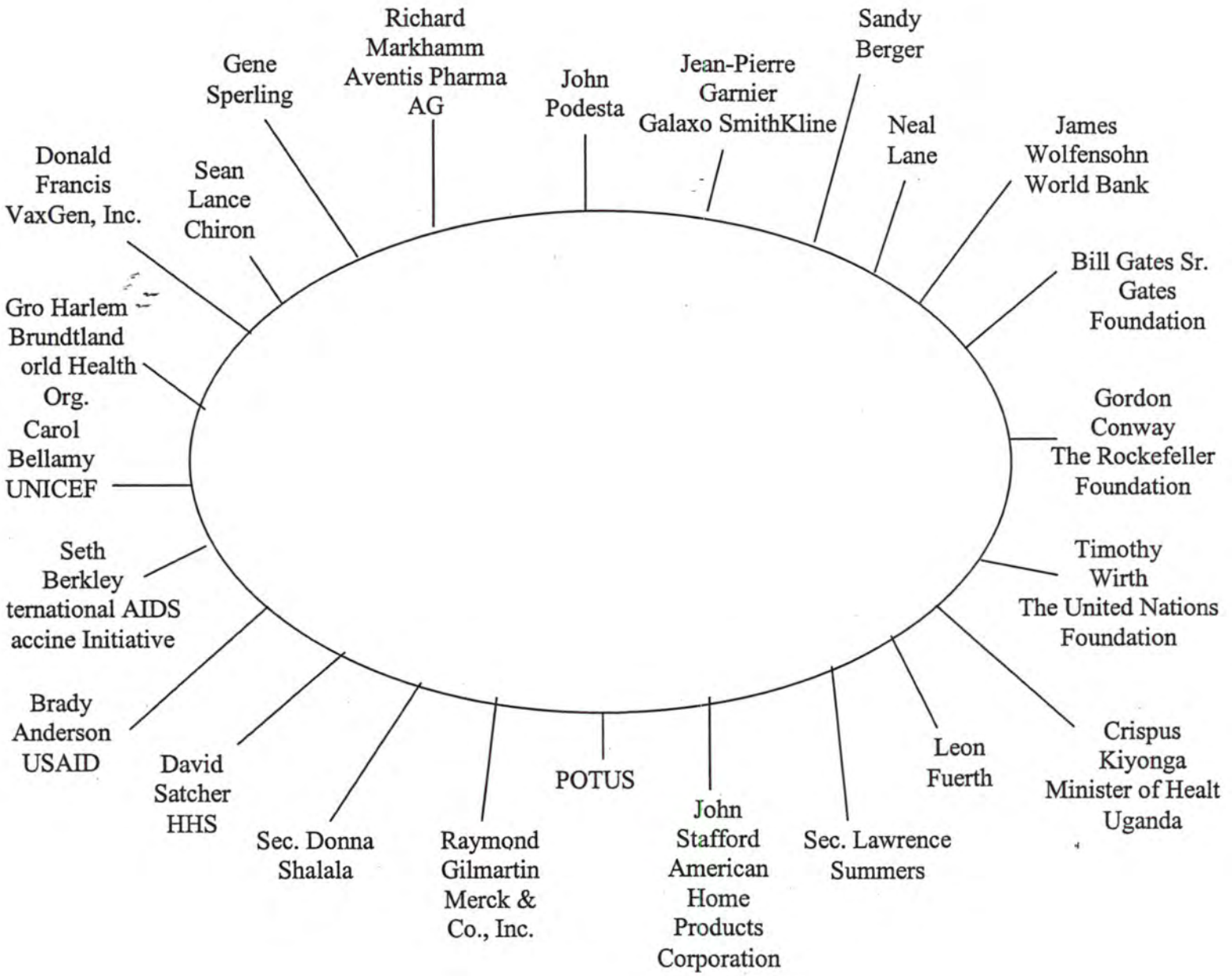
Administration

The President
Secretary Lawrence Summers
Secretary Donna Shalala
John Podesta
Samuel Berger
Neal Lane
Gene Sperling
Leon Fuerth
Melanne Verveer
Sandra Thurman
David Beier
Mara Rudman
Chris Jennings
David Satcher, Surgeon General
Brady Anderson, Administrator, USAID
Major-General John Parker, Commander, Army Medical Research Command
Ambassador George Moose, U.S. Ambassador to the UN, Geneva
Sheryl Sandberg, Chief of Staff, Department of the Treasury
Anthony Fauci, Director, National Institute for Allergy and Infectious Diseases, NIH
Gary Nabel, Director, AIDS Vaccine Research Center, NIH

Outside Participants

Crispus Kiyonga, Minister of Health, Uganda
James Wolfensohn, President, World Bank
Gro Harlem Brundtland, Director-General, World Health Organization
Carol Bellamy, Executive Director, UNICEF
Richard Markham, President and CEO, Aventis Pasteur
Jean-Pierre Garnier, President Designate, SmithKline Beecham
John Stafford, President and CEO, American Home Products
Raymond Gilmartin, President and CEO, Merck
Donald Francis, President, VaxGen
Sean Lance, Chairman and CEO, Chiron
Bill Gates, Sr., Bill and Melinda Gates Foundation
Gordon Conway, President, Rockefeller Foundation
Timothy Wirth, President, United Nations Foundation
Jeffrey Sachs, Professor, Harvard University
Seth Berkley, President, International AIDS Vaccine Initiative
Nils Daulaire, President and CEO, Global Health Council
Herbert Brown, Past President and Chairman-elect, Rotary International

Presidential Meeting on Vaccines
March 2, 2000
Cabinet Room
11:30 a.m.



THE CLINTON-GORE ADMINISTRATION: NEW PARTNERSHIPS TO DEVELOP & DELIVER VACCINE TO DEVELOPING COUNTRIES

March 2, 2000

Today, President Clinton Will Meet With Leaders of Industry, Foundations, and International Organizations to Announce New Partnerships to Develop and Deliver Vaccines For Diseases -- Including HIV/AIDS, Malaria, and Tuberculosis – For Developing Countries. In his State of the Union Address, the President said, "*I ask the private sector and our partners around the world to join us in embracing this cause. We can save millions of lives together, and we ought to do it.*" At this meeting, key leaders of pharmaceutical and biotechnology companies, international organizations, foundations, and the public health community will endorse the President's Millennium Vaccine Initiative, released last month, and announce new commitments to develop and deliver vaccines to developing countries. The President will also call upon Secretary Shalala to convene a meeting of experts from industry, government, and academia to address impediments to vaccine development in the private sector and to strengthen public-private partnerships.

The President And The CEOs Of The Four Largest Vaccine Manufacturers Will Announce Unprecedented Levels Of Corporate Support To Vaccinate The World's Children. Today, industry will respond to the President's call with important new steps as CEOs of the four largest vaccines manufacturers – Merck and Co., Inc., American Home Products Corporation, Glaxo SmithKline Beecham, and Aventis Pharma AG – will announce that they will donate millions of doses of state-of-the-art vaccines – worth more than $150 million – to those in the developing world and make a renewed commitment to step up research and development on vaccines for HIV/AIDS and malaria.

- Merck and Co. will donate one million doses, worth $100 million, of RECOMBIVAX - HB - a vaccine to prevent Hepatitis B;
- American Home Products Corp. will announce a donation of 10 million doses of Haemophilus influenza type-B (Hib) conjugate vaccine to GAVI to protect more than 3 million children in developing nations;
- SmithKline Beecham will announce expansion of its malaria vaccine program and also renewed its pledge to donate $1 billion to eliminate lymphatic filariasis (elephantiasis);
- Aventis Pharma announced a donation of 50 million doses of polio vaccine to Africa.

These Private Sector Commitments Build On The Administration's Millennium Vaccine Initiative, Announced by the President In His State of the Union Address. The major components of the Millennium Vaccine Initiative include:

- $50 million in the President's FY2001 budget as a contribution to the vaccine purchase fund of the Global Alliance for Vaccines and Immunization (GAVI);
- Presidential leadership to ensure that the World Bank and other multilateral development banks dedicate an additional $400 million to $900 million annually of their low-interest rate loans to health care services;
- Significant increases in federally funded basic research on diseases that affect developing nations;
- A new tax credit for sales of vaccines for infectious diseases to accelerate their invention and production;
- A call to our G-7 partners to join our efforts to ensure a future market for these vaccines.

The President Will Also Recognize the Unprecedented Contributions From The Philanthropic Community. This includes a $750 million contribution from The Bill and Melinda Gates Foundation to the vaccine purchase fund of the Global Alliance for Vaccines and Immunization. The President also praised new models for public-private partnerships, including the International AIDS Vaccine Initiative, which announced that it will invest more than $10 million this year to triple the number of AIDS vaccine candidates moving toward trials.

The Scope Of The Problem of Infectious Disease In Developing Countries:

- While sub-Saharan Africa accounts for only 1/10 of the global population, over 70% of individuals infected with AIDS globally live there. There is a 60% chance that a 15-year old in Zambia will die of AIDs today. Thirteen million sub-Saharan African children have now lost one or both of their parents to AIDS.
- One-fourth of all deaths each year worldwide – 13 million people – are the result of infectious diseases.
- Over 8 million children die each year of centuries-old diseases – and more than 3 million of these deaths could be

prevented by existing vaccines.

- Immunization is one of the most cost effective health interventions. It costs only $15 to immunize a child, yet in developing countries, children remain 10 times more likely to die of a vaccine-preventable disease than those in the industrialized world. Twenty percent of children worldwide lack access to basic immunization services.
- Only 2% of all global biomedical research is devoted to the major killers in the developing world.

Details of the Corporate Commitments Include:

- Merck will donate one million doses, worth $100 million, of RECOMBIVAX – HB – a vaccine to prevent Hepatitis B – over five years. Merck will collaborate with the Global Alliance for Vaccines and Immunization (GAVI) to identify countries that will most benefit from this vaccine. Merck also reaffirmed its commitment to the discovery of new vaccines for diseases of global significance, including HIV/AIDS. Merck committed to developing AIDS vaccines for strains of the virus found not only in the industrialized world, but in the poorest countries as well.

- American Home Products Corp. announced a donation of 10 million doses of Haemophilus influenza type-B (Hib) conjugate vaccine to GAVI. As a result, more than 3 million children in developing nations will be protected from one of the leading causes of deadly pneumonia and meningitis.

- SmithKline Beecham announced a commitment to expand its malaria vaccine program and will begin malaria vaccine trials in Africa for the most critical population – children. The trial would begin in the Gambia as early as this autumn. SB also renewed its pledge to donate $1 billion to eliminate lymphatic filariasis (elephantiasis), which destroys lives in 80 countries.

- Aventis Pharma announced a donation of 50 million doses of polio vaccine to Africa. This donation will support the WHO and UNICEF-led drive to end polio in five war-torn African nations. Aventis also reaffirmed its commitment to maintain the largest private AIDS vaccine research program and is moving forward with clinical trials in Africa, Asia, the United States, Europe, and soon, the Caribbean.

The President's Millennium Vaccine Initiative:

In his State of the Union address, President Clinton called for concerted international action to combat infectious diseases, which kill more than eight million children worldwide and orphan millions more. Recognizing that vaccines are a critical, cost-effective weapon in the fight against these diseases, the President announced a multi-part Millennium Vaccine Initiative:

- A new financial commitment to purchase and deliver existing vaccines in poor countries. As Vice President Gore told the U. N. Security Council earlier this month, the Administration's FY 2001 budget includes a proposed $50 million contribution to the vaccine purchase fund of the Global Alliance for Vaccines and Immunization (GAVI).

- Increased investments in health in developing countries. The President is calling on the World Bank and other multilateral development banks to dedicate an additional $400 million to $900 million annually of their low-interest-rate loans to expand immunization, prevent and treat infectious diseases, and build effective delivery systems for other basic health services. These investments are as central to economic progress as investments in education and physical infrastructure, and they would build on the new focus on basic health services that we have supported as part of the Highly Indebted Poor Countries (HIPC) debt initiative. This proposed shift in existing resources does not require additional U.S. budget expenditures.

- A significant increase in basic research on diseases that affect developing nations. The Administration's FY 2001 budget for the National Institutes of Health includes a sharp step-up in research critical to the development of vaccines for malaria, tuberculosis, and HIV/AIDS.

- A new tax credit for sales of vaccines for malaria, tuberculosis, and HIV/AIDS to accelerate the invention and production of these vaccines. Because developing countries often cannot afford to buy vaccines, the market provides little incentive for pharmaceutical companies to develop vaccines for diseases that disproportionately affect those countries. This tax credit would provide such an incentive, because every dollar paid by a

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DEPARTMENT OF THE TREASURY
WASHINGTON, D.C.

UNDER SECRETARY

December 8, 1999

MEMORANDUM FOR DISTRIBUTION

FROM: Timothy F. Geithner TFG
Under Secretary for International Affairs

SUBJECT: Meeting on Vaccines and Medicines Initiative

As you know, the President has asked his team to identify specific avenues and instruments through which we might be able to make a contribution to better vaccine and medicine delivery in the developing countries. Attached is a memo that outlines some proposals on this issue.

I would like to invite you and a designated colleague to an inter-agency meeting at the Treasury Department to discuss the status of these efforts.

I look forward to seeing you here in the Large Conference Room (Room 3327), on Friday, December 10 at 1PM. Please call my Assistant, Ms. Pat Griffin, at 622-0656 for building clearance information.

12/8/99

Proposal for Financial Initiatives on Vaccines

This memo outlines a proposal to help eradicate diseases that disproportionately affect the world's poor. The proposal rests on three pillars.

1. A new financial commitment to purchase and deliver vaccines in developing countries. To this end, we propose to:

   - Contribute $50 million to GAVI's existing purchase fund from the FY 2001 budget. This contribution is critical to demonstrating our commitment to this effort and to encouraging contributions by other governments.

   - Call for the establishment of a $5 billion multilateral Millennium Trust Fund over the next five to ten years for the purchase of AIDS, malaria, and TB vaccines for the developing world, with funding by private donors, governments, and international institutions. Indicate that once an acceptable framework has been negotiated, the Administration will seek a substantial U.S. commitment from the Congress.

2. A new dedication to encouraging public and private sector research and development efforts to focus on these diseases. To this end, we propose to:

   - Establish a tax credit for the sale of new vaccines.

   - Increase funding for basic research on malaria and TB. Of the three targeted diseases – AIDS, malaria, and TB – only research on AIDS receives significant government funding. Thus, we propose an increase in NIH funding for research on malaria and TB.

3. A recognition that investments in health are critical to economic progress for developing nations. To this end, we propose to:

   - Call on the multilateral development banks (MDBs) to earmark 10 percent of their concessional funds, in addition to current health expenditures, over an initial period of five to ten years to:
     - ensure immunization of 95 percent of children in the poorest countries for nine common diseases;
     - prevent and treat common respiratory and diarrheal infections, malaria, and tuberculosis;
     - improve infrastructure for delivery of vaccines and medicines.

     This earmarking would finance approximately $900 million in annual expenditures in addition to the $1.3 billion in MDB concessional funds now devoted to health care. Such a large shift in funds would be consistent with an overall re-orientation toward core social

priorities of official "soft" (or concessional) lending to the poorest countries that we have pursued in the context of the Highly Indebted Poor Countries (HIPC). Existing funding addresses a broad range of health system issues, but experience argues in favor of focusing funds more directly on basic services such as immunization, treatment, and prevention of the most prevalent infectious diseases.

- Explore ways to encourage debtor countries to devote the financial benefits of HIPC debt relief to reaching these same goals. To help reach the HIPC goal of lower child mortality, we propose to include a set of intermediate health-service targets in all Poverty Reduction Strategy papers (the main papers guiding social sector spending, including resources freed up by debt relief).

- Work with bilateral and multilateral creditors to create swaps programs of debt-for-vaccines-and-medicines. Currently, we do not have legislative authority to engage in debt swaps with official debtors outside of very specific areas. We are now exploring the possibility of expanding this authority to include initiatives like debt-for-vaccines swaps, but clearly this process will take time.

Background

Infectious diseases impose an enormous social and economic burden for poor countries. They cause almost half of all deaths worldwide of people under age 45, with six illnesses causing 90 percent of these deaths: an estimated 3.5 million from respiratory infections, 2.3 million from AIDS, 2.2 million from various diarrheal infections, 1.1 million from malaria, 0.9 million from measles, and 1.5 million from tuberculosis.

There are strong public policy arguments for providing additional finance to developing countries for vaccines and medicines to combat these diseases. The victims of infectious diseases in developing countries do not have the resources to pay for vaccines and drugs. As a result, the effective market as perceived by pharmaceutical companies is very small, and the companies do not invest enough in research and development for these diseases. In addition, developing countries have serious difficulties maintaining basic health care facilities that can deliver vaccines and medicines. Finally, because disease travels swiftly among the continents, improved health in developing countries is a global public good in the sense that all countries benefit from a lower risk of global epidemics.

Although most discussions of this topic have focused on vaccines only, we propose extending part of this initiative to include medicines and other preventive measures as well. For the present time, effective vaccines do not exist to treat the majority of the diseases that affect developing nations. Our current efforts must therefore include medicines and other preventive measures. (Note: it is critical that we specify which diseases we are willing to provide treatment of – common respiratory and diarrheal infections, malaria, and tuberculosis – to ensure that our efforts have maximum impact on the health of the citizens of the developing world. If it is not feasible to limit our focus to these diseases, we should limit our proposal to cover vaccines only.) For the future, we propose to focus on encouraging the development of vaccines alone because vaccines are more likely to provide cost-effective disease control and because the momentum of the world's current efforts are focused on vaccines.

The cost of providing existing and future vaccines and medicines to developing countries is uncertain, although estimates are invariably high. The Global Alliance for Vaccines and Immunizations (GAVI) estimates that providing nine currently available vaccines for all children in the world's poorest countries would cost $750 million in 2000 and would double in cost by 2010. Six of these vaccines (for DPT, measles, polio, and TB) are included in the Expanded Program on Immunization (EPI) that now reaches about 80 percent of the world's children. Therefore, GAVI will focus its initial efforts on increasing use of the other three vaccines (for Hepatitis B, yellow fever and Haemophilus influenzae b [Hib]), which it estimates will cost roughly $300 million per year for the next 5 years. The cost of developing new vaccines is much more speculative. However, Michael Kremer has noted that an upper bound on the price paid for vaccines would be their social value; he estimates that a fund capitalized with $100 per life potentially saved over the next 25 years by vaccines for malaria, TB, and HIV would cost $12 billion.

President Clinton Unveils Millennium Initiative to Promote Delivery of Existing Vaccines in Developing Countries and Accelerate Development of New Vaccines

January 27, 2000

In his State of the Union address, President Clinton will call for concerted international action to combat infectious diseases in developing countries. These diseases cause almost half of all deaths worldwide of people under age 45, killing over eight million children each year and orphaning millions more.

The President committed the United States to addressing this terrible problem in his September speech to the United Nations General Assembly. Now the President is asking for foundations, pharmaceutical companies, international agencies, and other governments to join us in this task, and he is announcing these specific elements of his Millennium Initiative:

- **A new financial commitment to purchase and deliver existing vaccines in poor countries.** As Vice President Gore told the U. N. Security Council earlier this month, the Administration's FY 2001 budget will include **a proposed $50 million contribution to the vaccine purchase fund of the Global Alliance for Vaccines and Immunization (GAVI).**

- **Increased investments in health in developing countries. The President is calling on the World Bank and other multilateral development banks to dedicate an additional $400 million to $900 million annually of their low-interest-rate loans to expand immunization, prevent and treat infectious diseases, and build effective delivery systems for other basic health services.** These investments are as central to economic progress as investments in education and physical infrastructure, and they would build on the new focus on basic health services that we have supported as part of the Highly Indebted Poor Countries (HIPC) debt initiative. This proposed shift in existing resources does not require additional U.S. budget expenditures.

- **A significant increase in basic research on diseases that affect developing nations.** The Administration's FY 2001 budget for the National Institutes of Health includes **a sharp step-up in research critical to the development of vaccines for malaria, tuberculosis, and HIV/AIDS.**

- **A new tax credit for sales of vaccines for malaria, tuberculosis, and HIV/AIDS to accelerate the invention and production of these vaccines.** Because developing countries often cannot afford to buy vaccines, the market provides little incentive for pharmaceutical companies to develop vaccines for diseases that disproportionately affect those countries. This tax credit would provide such an incentive, because **every dollar paid by a qualifying organization to buy a qualifying vaccine would be matched by a dollar of tax credits – representing up to $1 billion of additional funding for future vaccine purchases.** The President is calling on other governments to make similar purchase commitments, so that we can ensure a future market for these critically needed vaccines.

ADDITIONAL EXPLANATION

Infectious Diseases Pose a Mounting Social and Economic Burden on Developing Countries – And a Threat to Our Health As Well.

- More than eight million children die each year of centuries-old diseases like malaria, tuberculosis, and respiratory and diarrheal diseases. Deaths from the modern scourge of AIDS are climbing rapidly. Altogether, as many children die of infectious diseases each year as the total number of combatants who perished in World War I.

- In an interconnected and highly mobile world, health crises in other countries are a threat to everyone. We have seen this with HIV/AIDS, with the resurfacing of tuberculosis, and with the outbreak last year of West Nile encephalitis in New York. According to the Global Health Council, during the past 50 years, at least five times as many Americans have died from communicable diseases that have come from the developing world than have died in military conflicts.

Vaccines Are One of the Most Cost-Effective Ways to Improve the Well-Being and Productivity of the Poorest Countries – And Medicines and Other Basic Health Services Are a Necessary Complement.

- It costs about $17 to immunize a child, but millions of children die each year of diseases that could be prevented by existing vaccines. Indeed, children in developing nations are 10 times more likely to die of a vaccine-preventable disease than children in developed nations. And these tragedies occur in spite of the enormous efforts of UNICEF and others to vaccinate children, which save 3 million lives each year.

- Highly effective vaccines do not yet exist for malaria, TB and AIDS, which take over 5 million lives each year. But developed nations have the scientific and technological capacity to make new vaccines possible. For example, recent work on genetic sequencing, including the human genome, will open vast possibilities.

- Another health investment with very high returns is simple preventive and curative services. Providing this basic health care together with vaccines would save millions of lives each year.

A $50 Million Contribution to GAVI to Buy Vaccines For Children – Which Will Save Lives Now and Create Confidence that a Market for New Vaccines Will Exist in the Future.

- GAVI, the Global Alliance for Vaccines and Immunization, was formed as a collaborative effort of UNICEF, the World Health Organization (WHO), the World Bank, private foundations, bilateral aid agencies (including the U.S. Agency for International Development), industry representatives, and developing countries. GAVI established the "Global Fund for Children's Vaccines" with an initial grant of $750 million over 5

years from the Bill and Melinda Gates Foundation. The formal launch of GAVI, and the official announcement of the Gates gift, will occur shortly in Davos, Switzerland.

- A U.S. contribution will help to purchase vaccines for Hepatitis B, Haemophilus Influenzae B (Hib), and Yellow Fever, along with related safe delivery equipment such as auto-destruct syringes. To ensure that GAVI's vaccine purchases complement, rather than replace, existing vaccination efforts, they will be conditional on a country achieving 50 percent coverage of the DTP (diptheria-tetanus-pertussis) vaccine, which is included along with measles and polio in the existing EPI (Expanded Program for Immunization).

- A U.S. contribution will hopefully catalyze significant contributions from other countries and foundations. It will also add crucial credibility to the international community's commitment to provide a market for new vaccines when they are developed.

We Must Shift Existing International Resources Toward Building Health Infrastructure in Poor Countries That Can Deliver Vaccines and Medicines and Provide Essential Basic Health Services.

- The World Bank and other multilateral development banks (MDBs, such as the African Development Fund) lend money on highly favorable terms to the world's poorest countries. Today, roughly $1 billion to $1-1/2 billion of this so-called "concessional funding" is devoted to health care each year. The Administration proposes to increase that amount by $400 million to $900 million per year, with a focus on:
  - immunization;
  - prevention of diseases using basic measures such as information and condoms for AIDS, treated bed nets for malaria, and stronger systems for containing TB;
  - treatment of diseases, including common respiratory and diarrheal infections; and
  - more effective provision of basic health care.

- The Administration is exploring ways to use the HIPC debt reform to support this part of the Millennium Initiative. One possibility is to make an increase in vaccination rates one of the performance targets monitored in the HIPC progress reports. This could be accompanied by debtor countries' agreements to include specific improvements in vaccine delivery systems as priority uses of debt relief proceeds. We also expect that all Poverty Reduction Strategy Papers that are prepared for HIPC candidates will discuss the adequacy of budget resources and suggested policy reforms devoted to basic health care.

- This re-direction of resources supports the Administration's overall strategy for global development, which emphasizes poverty reduction and gives a central role to "global public goods" – like health or the environment – in which positive actions taken in one country benefit other countries as well. To meet this objective, these funds should not come from spending on other basic social programs, such as education and health care.

- This aspect of the Millennium Initiative does not require a new budgetary commitment by the United States (or other donor countries). However, the U.S. ability to influence the direction of MDB lending and the use of HIPC proceeds depends crucially on meeting our existing commitments to these aid programs. We will work with other G-8 finance and development ministries to refine this proposal.

- A conservative estimate suggests that if basic health care including immunization were made broadly available, up to 2 million children's lives could be saved each year.

Higher Funding for Basic Scientific Research Through the National Institutes of Health (NIH) and Elsewhere Will Hasten the Development of Vaccines for Malaria, TB, and AIDS.

- The Administration's FY 2001 budget for NIH includes a significant increase in research critical to creating vaccines for these diseases. For malaria and TB, this increase will build on recent advances in the genetic sequencing of these diseases, which have set the stage for major breakthroughs in vaccine development.

- Funding for NIH malaria vaccine research will increase more than 10 percent over the FY 2000 level. Future research will range from pre-clinical studies aimed at improving our understanding of the malaria parasite, through the development of vaccine candidates, to clinical trials judging vaccine efficacy and safety. NIH will also expand its collaboration with scientists in malaria-endemic regions, especially in Africa, to strengthen those regions' capacity for conducting clinical trials of malaria vaccines in the future.

- NIH research on a tuberculosis vaccine will receive over 40 percent more funding than in FY 2000 and more than double the FY 1999 level. NIH will focus on studying the body's defense mechanisms against TB, and developing and studying vaccine candidates. Through its Tuberculosis Research Unit, NIH supports an international multi-disciplinary team to translate advances in basic research into new tools for fighting TB.

- NIH funding for AIDS vaccine research will increase substantially in FY 2001 and will have more than doubled since FY 1997. These additional resources will allow NIH to accelerate basic research on developing vaccine candidates and to significantly expand testing of potential vaccine candidates in both developing and developed countries. The new Vaccine Research Center on the NIH campus, which will be occupied this summer, will receive a sizeable increase in funding for the development and pre-clinical testing of HIV vaccine candidates.

- The Administration is providing strong support for the path-breaking research on infectious diseases being conducted by U.S. military scientists, including the opening (in October 1999) of the Walter Reed Army Institute of Research/Naval Medical Research Center. Working in close collaboration with scientists worldwide, military scientists have developed and tested successful vaccines against Japanese encephalitis and hepatitis A –

and they are working to create vaccines and medicines to protect service people, travelers, and millions of others from malaria, HIV/AIDS, and other infectious diseases.

A New Tax Credit Would Effectively Provide Up to $1 Billion for Future Vaccine Purchases, Speeding the Invention and Production of New Vaccines.

- Current tax law provides substantial incentives for pharmaceutical research and development, including the research and experimentation (R&E) tax credit, the orphan drug tax credit, and an enhanced deduction for charitable contributions of certain products. Nonetheless, pharmaceutical companies may be reluctant to invest in developing vaccines for diseases that primarily afflict people in poor countries, because little or no paying market exists in those countries.

- Under the proposal, the seller of a qualified vaccine could claim a tax credit equal to 100 percent of the amount paid by a qualifying organization that received a "credit allocation" by the U.S. Agency for International Development (AID). The tax credit would match the qualified organizations' expenditures dollar-for-dollar, thereby doubling their purchasing power. A qualifying vaccine would be a new vaccine that received FDA approval for use against malaria, tuberculosis, HIV/AIDS, or any infectious disease that causes over 1 million deaths annually worldwide.

- For 2002 through 2010, AID could designate up to $1 billion of vaccine sales as eligible for the credit. This tax credit would be limited to new vaccines developed to fight these terrible diseases. The credit would provide a specific and credible commitment to purchase future vaccines at reasonable prices. Together with similar commitments from foundations and other governments, it would provide a critical and powerful incentive to accelerate vaccine research and development.