

IMMUNIZATIONS

PHOTOCOPY
PRESERVATION

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

February 10, 2000

In his State of the Union address, President Clinton called 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, 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, HIV/AIDS, and any infectious disease that causes over 1 million deaths annually worldwide, in order to accelerate the development 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.

- 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 (diphtheria-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.

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 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 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.
- A call to the G-7. This summer in Okinawa, the President will work with our G-7 partners to ensure a future market for critically needed vaccines.

NGO Commitment:

- The **International AIDS Vaccine Initiative** announces that it will invest more than \$10 million this year to triple the number of AIDS vaccine candidates it is moving toward trials.

World Bank Commitment -- not yet confirmed:

- Wolfensohn is likely to announce that he will call for the IDA governors to establish a \$1 billion revolving fund for cost-effective vaccines and therapeutics now, and new vaccines in the future. The fund would be replenished each year and, therefore, would be a strong signal to industry that money will be available to purchase new vaccines. (Note that the wording is weak to avoid the appearance that the proposal is being driven solely by the U.S. This perception could unravel Wolfensohn's proposal.)

DRAFT

*FOR PRESS
CALLS*

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

March 2, 2000

Fact Sheet

New Partnerships for Vaccine Development

Today the President and members of his Cabinet met with leaders of pharmaceutical and biotechnology companies, international organizations, foundations, and the public health community to join forces to develop and deliver vaccines for diseases that ravage poor nations, including HIV/AIDS, malaria, and tuberculosis. Infectious diseases cause almost half of all deaths worldwide of people under age 45, killing over eight million children each year and orphaning millions more. This meeting follows last month's release of the President's Millennium Vaccine Initiative, which calls for sharp increases in vaccine research at the National Institutes of Health, new investments for the purchase and delivery of existing vaccines, and a substantial tax credit for the private sector to speed the development of new vaccines.

In his State of the Union, 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."

Today, industry responded with important new steps. In the meeting at the White House, CEOs of the four largest vaccines manufacturers – Merck and Co., Inc., American Home Products Corporation, Glaxo SmithKline Beecham, and Aventis Pharma AG announced their intention to step up research and development on vaccines for HIV/AIDS and malaria. To save lives now, industry executives also announced that they will donate millions of doses of state-of-the-art vaccines – worth more than \$150 million -- to those who need them most.

The President recognized the unprecedented levels of support by the philanthropic community, including 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 it is moving toward trials.

The President also called 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 applauded the strong bipartisan support in Congress for international disease prevention efforts and called for the passage of new measures to hasten the development and delivery of vaccines.

Unprecedented Levels of Commitment from Industry:

The CEOs of the four largest vaccine manufacturers – Merck, American Home Products, SmithKline Beecham, and Aventis Pasteur -- announced the following:

- 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 UNICEF to support the objectives of 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 Fall. SB also renewed its pledge to donate \$1 Billion to eliminate lymphatic filariasis (elephantiasis), which destroys lives in 80 countries.
- Aventis Pasteur 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.

New Commitment to Developing and Delivering Vaccines:

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 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.
- **A call to the G-7.** This summer in Okinawa, the President will call upon our G-7 ~~partners to join our efforts to ensure~~ a future market for critically needed vaccines.

March 1, 2000

GOOD OVERVIEW OF WHY WE ARE
HERE, WHAT WE ARE
TRYING TO DO."

ACTION

MEMORANDUM FOR SAMUEL R. BERGER

FROM: KENNETH W. BERNARD

SUBJECT: Vaccine Meeting with the President

The President's meeting to encourage vaccine development for diseases of poor countries, especially for AIDS, TB and malaria, is scheduled for Thursday, March 2 at 11:30 a.m.

Most of the major players in the international vaccine arena will be there, including the heads of UNICEF, WHO and the World Bank, the CEOs of the four major vaccine producers, biotech firms, foundations and many others (TAB B).

Gene Sperling will be chairing the meeting until the President arrives.

At some point in the meeting, the President will join and do his own introductory remarks. Gene may then wish to summarize progress in the meeting thus far, and hand the chair to the President who will pick up the scenario.

Specific "deliverables" from the companies are substantial -- including new research for malaria and AIDS vaccines, and large contributions of HiB, hepatitis and polio vaccines for developing countries (Tab E).

Several editorials from outside experts (including a Nobel Laureate) have been written and we are attempting to have them placed. CEOs and others have indicated they will be available for press questions at the stakeout.

Concurrence by: Gayle Smith, Jamie Baker, Laura Efros, Tom Malinowski, Valerie Guarnieri, John Duncan, Dan Shapiro

RECOMMENDATION

That you sign the memorandum to the President at Tab I.

Attachments

Tab I Memorandum to the President

Tab A Points for the President (when joining meeting)

Tab B Participants

Tab C Closing remarks for pool spray

Tab D Seating Chart

Tab E Press Release on Deliverables

Tab II Opening points for Gene Sperling

VACCINE INITIATIVE EVENT

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

FROM: SAMUEL BERGER
GENE SPERLING
NEAL LANE
MARY BETH CAHILL

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) Announce 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

- TAB A Points to be Made
- TAB B List of Participants
- TAB C Closing Remarks
- Tab D Seating Chart
- Tab E Press Release on Deliverables

A

GENE,

1395

*You need to be prepared to pick up
here if the president is late. psh*

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, 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

Multilateral Organizations

- 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)

B

List of ParticipantsAdministration

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

Hattie Babbitt, Deputy 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

C

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.

①

NO SEATING CHAIR
AVAILABLE

E

NO PRESS RELEASE
AVAILABLE

GENE,
SUGGESTED POINTS FOR YOU!

1395

POINTS TO BE MADE FOR MEETING ON
MILLENNIUM VACCINE INITIATIVE

Top of Meeting (Gene Sperling to Chair)

- Thank you. The President is determined to overcome the challenges of developing and delivering vaccines so desperately needed around the world -- and to do so in partnership with private industry, with foundations, and with the international organizations that have already done so much in this field. He will be joining us shortly.
- The triumph of vaccines over infectious diseases is one of the great achievements of the 20th century. We've eradicated smallpox and we are on the verge of wiping out polio.
- But over three million children still die needlessly each year -- six every minute -- from diseases that could be prevented by currently available vaccines, and millions more could be saved if we developed new ones. And we all know that the economic incentives for vaccine development simply are not there right now for diseases that disproportionately affect developing countries.
- This is a clear humanitarian challenge -- but it is also much more than that. It's something we have to do if we're going to make any headway against extreme poverty around the world and ensure the survival of many struggling nations.
- That's why the President promised to reach out to all of you when he called for this meeting in his address to the UN last year.
- And that's why in his State of the Union, the President announced a number of significant steps to mobilize the world's scientific and industrial potential, including sharp increases in our research budget, new investments for the purchase and delivery of existing vaccines, and a substantial tax credit for private industry.
- The President is now asking you, as leaders of foundations, international agencies, private industry, and public health experts, to build upon your substantial efforts and join him in this task.

Administration

- I would now like to ask **Secretary Shalala** and **Secretary Summers** to briefly expand on the President's vaccine initiative.

[Turn to **Secretary Shalala** to comment on the research and development aspects of the vaccine initiative -- the "push" incentives reducing cost of investment in vaccines.]

[Turn to **Secretary Summers** to comment on the vaccine purchase, tax credit and World Bank/IDA components of the initiative -- the "pull" incentives increasing the market value of vaccines once developed.]

Checking to see if we ship or sell on a substitute.
For

[For **Dr. Kiyonga**, Ugandan Minister of Health]

- Let's begin with the context from an African point of view. At the Security Council in January, Minister of Health Dr. Kiyonga [Kee-yong-ga] from Uganda spoke eloquently on the impact of AIDS on his country, and the progress Uganda has made in dealing with the disease. Dr. Kiyonga, could you touch on the problem of vaccines and infectious diseases in Africa?

[**Dr. Kiyonga** speaks for 3-4 minutes.]

Thank you, Mr. Minister. Our discussion cannot hope to deal with the wide range of health problems faced by many developing countries. However at this point we have an opportunity to focus on the issue at hand: developing vaccines and delivering them to the world's children.

The following is very optional -- only ask if time permits.

- [Only if time] Ask **Brady Anderson** about health infrastructure. Getting vaccines to children requires health personnel and delivery systems. What are we doing in this area?]

Multilateral and International Organizations

- **Carol Bellamy**: how do you see the role of UNICEF's in promoting development and delivery of vaccines?
- **Dr. Brundtland**, as Director-General of W.H.O and Chair of the Global Alliance on Vaccines and Immunizations, how do you see the push for vaccine development as fitting into your international attack on diseases of poverty?

REVISED DRAFT March 1, 2000

Briefing for the President on the Millennium Vaccines Initiative

- You proposed a \$50 million contribution to the vaccine purchase fund of the Global Alliance for Vaccines and Immunization (GAVI) in the FY 2001 budget.

Status: Discussion of the new budget is just beginning in Congress.

- You proposed a significant increase in the FY 2001 budget for basic research on diseases that affect developing nations.

Status: Same.

- You called 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.

Status: The World Bank has expressed a willingness to shift \$1 billion over three years for basic health care, through a revolving fund of low-interest (IDA) loans. The Bank has not announced any details of its plans. The Asian Development Bank also plans to increase its lending for health, but it has not specified the amount of the increase. We are seeking support from the other G-7 countries for this shift in priorities.

- You proposed a new tax credit for sales of vaccines for malaria, tuberculosis, HIV/AIDS, and any infectious disease that causes over 1 million deaths annually worldwide. Under this proposal, the seller of a qualified vaccine could claim a tax credit of one dollar for every dollar paid by a qualifying organization, such as UNICEF. The credits would be allocated by the U.S. Agency for International Development (AID) and could total up to \$1 billion for 2002 through 2010. The credit would provide a specific and credible commitment to purchase future vaccines, which would create a strong incentive to accelerate vaccine research and development.

Status: We have met several times with pharmaceutical companies to discuss this proposal. The companies would prefer that any new tax incentive also provide near-term support for their R&D efforts on new vaccines. We will be working with Congress and the companies on this issue, but will not be sending up a new proposal. We expect that the pharmaceutical companies will support the final form of the tax credit.

March 1, 2000

MEMORANDUM FOR GENE SPERLING/LAEL BRAINARD

FROM: ROBERT WESCOTT

Subject: Vaccine Meeting With President on March 2

1. What is Happening

The President's meeting with the international vaccine community will take place from 11:30 to 12:30 tomorrow in the Cabinet Room. You will chair the meeting until the President arrives—probably about 20 minutes into the meeting.

The list of announcements by the pharmaceutical companies is quite impressive—donations of vaccine to poor countries ("worth more than \$150 million"), pledges to increase their research commitments to vaccine that particularly affect poor developing countries, etc. The "Fact Sheet" that is attached details the main deliverables that the pharmaceutical companies will be announcing.

- The list of attendees is little changed since earlier this afternoon.
No bias provided by OPL.
- Note that we now are expecting Bill Gates, Sr. to attend (Bill's father, who is active in his charitable work at the Gates Foundation.)

2. What to do to Prepare

Through your preparation for the two meetings last week on vaccines, you know most of the substantive issues here—the President's SOTU pledges, the budget initiatives, etc. We (Ken Bernard, Laura Efros, and myself) have put together the attached suggested points for you to make at the top of the meeting.

- After you speak, you should call on Secretary Shalala, Secretary Summers, and Ugandan Minister of Health Kiyonga [Kee-yong-ga], as indicated in the proposed points.
- When the President joins the meeting, you should be prepared to provide a short summary of what has been said up to that point.
- You should read over the Proposed Points for the President to make when he joins the meeting. It provides a good set of topics and questions for the meeting, and if the President is running late, you should be prepared to start moving down his list.

You also should look over the memo from Ken to Sandy, which provides a good overview of what is happening. Also see the current draft of the memo to the President from you, Sandy, Neal, and Mary Beth.

Attached are the attached list of participants and the preliminary seating chart. (It was prepared before you were set to run the meeting from the beginning, so it will be natural for you to take the seat that Podesta is listed at.)

Finally, the Fact Sheet provides the list of deliverables from the pharmaceutical companies. Behind it are the individual press releases that the companies plan to hand out following the meeting. I will be getting biographies on the CEOs, etc., shortly and will send them over to Melissa.

The meeting will end with a press spray. The President's remarks are attached. After that, the CEOs will step outside and make more detailed explanations of what they are donating, etc.

Summary of Vaccine Deliverables

POTUS Commitments:

POTUS announces new partnership with industry, foundations and international organizations to develop vaccines for AIDS, malaria, tuberculosis, and other devastating diseases.

POTUS calls on Secretary Shalala to convene an experts meeting with industry to strengthen cooperation between industry and government on vaccine development.

POTUS highlights Millennium Vaccine Initiative announced at SOTU, including:

- \$50 M for vaccine purchase;
- Sharp increases in vaccine research at NIH (\$38 M increase for malaria, TB & AIDS);
- \$1 B tax credit for sales of new vaccines;
- Call to MDBs to put \$400-900 M annually into immunization infrastructure;
- Call to G-7 to join USG effort.

Industry Commitments:

Support for the Administration

- **All four companies** make strong, supportive statements about the President's Millennium Vaccine Initiative.

Pledge to expand vaccine research

- **Merck** announces a commitment to develop an AIDS vaccine for strains of the virus found in developing countries, as well as the industrialized world.
- **SmithKline Beecham** announces a commitment to expand its malaria vaccine research program and begin pediatric malaria vaccine trials in Africa.

Donations of the state-of-the art vaccines and drugs

- **Merck** will donate 1 million doses – worth \$100 million – of a vaccine for Hepatitis B over a five-year period.
- **American Home Products** will donate 10 million doses of Hib vaccine, which protects children from deadly strains of pneumonia and meningitis.
- **SmithKline Beecham** renews its pledge to donate \$1 billion worth of drugs for lymphatic filariasis (elephantiasis), which destroys lives in 80 tropical countries.
- **Aventis Pasteur** will donate 50 million doses of polio vaccine to five war-torn African nations.