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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.

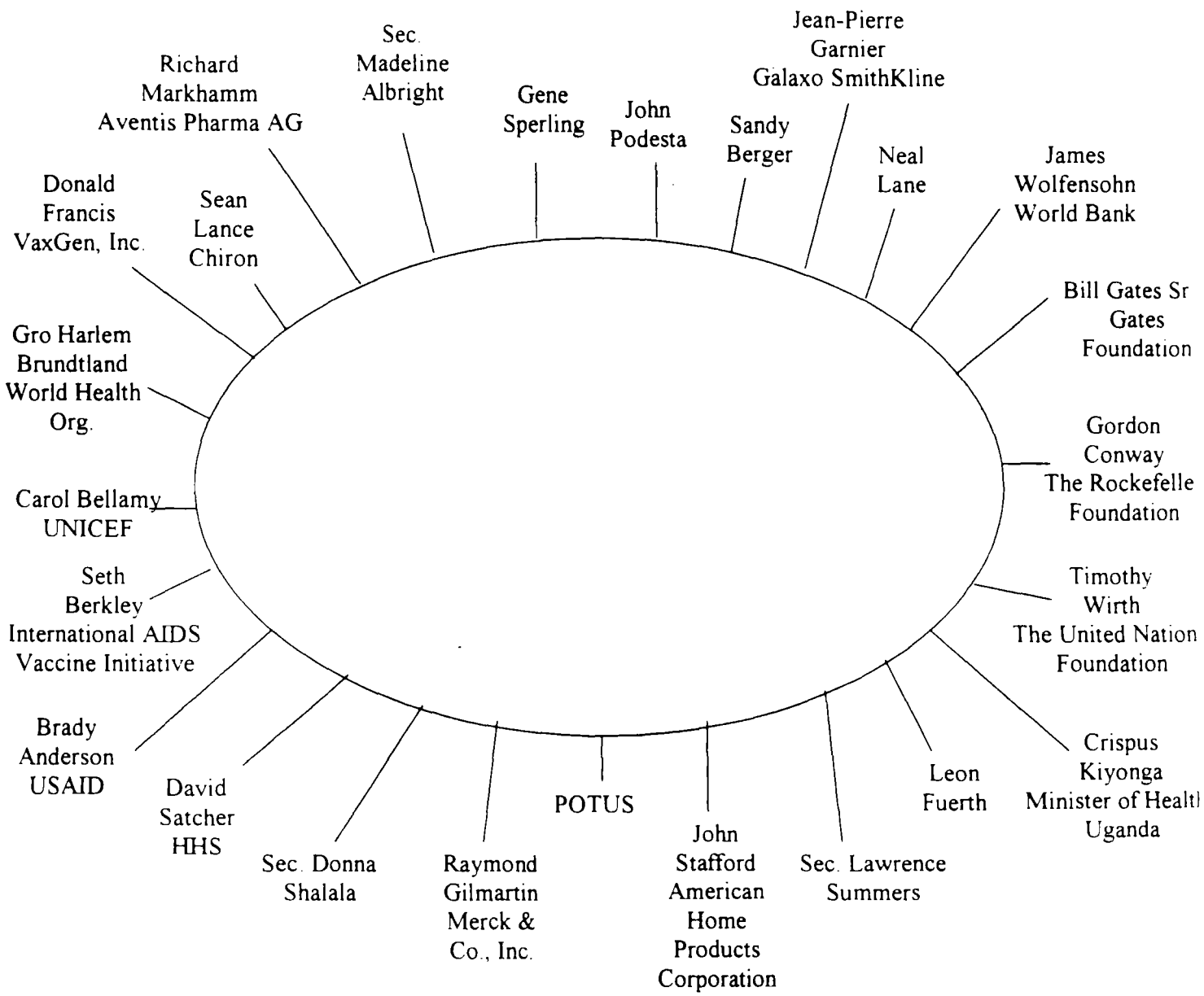
- American Home Products will donate 10 million doses of a vaccine to prevent deadly strains of pneumonia and meningitis in children.

- 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.

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



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

Issue 5= Vaccines

GLOBAL HIV/AIDS AND GLOBAL VACCINES
May 15, 2000

Summary of U.S. Programs: The President is seeking $504 million in FY 2001 for U.S. programs administered by AID, HHS, State, DOD, and DOL that (1) directly combat the HIV/AIDS pandemic in developing countries and (2) will accelerate the development and distribution of vaccines for life-threatening diseases. The requested level would mean increases of $168 million over FY 2000 and $279 million over 1999. In addition, a number of other AID, HHS, Treasury, and State Department programs have significant effects on the effort to combat global HIV/AIDS.

Direct Global HIV/AIDS Programs

USAID: *Child Survival Account* - USAID=s direct HIV/AIDS programs support reduction of HIV transmission - - through interventions to induce lower risk behavior, improve prevention and treatment of sexually transmitted infections, and increase access to critical commodities - - and focus on improving community and home-based care and treatment, caring for children affected by AIDS, and capacity and infrastructure development.

- $ Funding of $244 million was requested in the FY 2001 Budget for AID=s Child Survival and Diseases account for these activities.
- $ The Senate Appropriation Committee (SAC) Foreign Operations bill provides $225 million (House action is not expected until June).

AID=s other HIV/AIDS activities include small *direct* funding programs in the *Economic Support Fund*, *New Independent States*, and *PL 480 food* assistance accounts.

HHS: *Centers for Disease Control and Prevention* -CDC funds prevention-focused activities, including surveillance, technical assistance, and voluntary counseling and testing, in Africa and Asia.

- $ In FY 2001, the President's Budget requested an increase of $26 million to $72 million.
- $ While we are not yet sure, we believe that the House Labor/HHS subcommittee may have underfunded these activities. The Senate Labor/HHS subcommittee has not provided any of the requested increase for CDC, but has provided $10 million to transfer to the Department of Labor for international HIV/AIDS activities.

NIH - direct global HIV/AIDS activities in developing countries include research focused on transmission modes, prevention strategies, including vaccines and microbicides, opportunistic infections, and methods to prevent mother-to-child transmission. In the U.S., NIH also directly supports training of foreign investigators and research to protect the blood supply in developing countries.

- $ The FY 2001 Budget includes $2.1 billion for HIV/AIDS research, of which $101 million is direct funding and $813 million is indirect funding.
- $ The Senate and House subcommittee FY 2001 marks include a $2.7 billion total increase for NIH. Although the Congress does not typically focus on NIH's international HIV/AIDS efforts, this research will likely be funded above the FY 2001 Budget.

Departments of Defense and Labor: The FY 2001 Budget proposed $10 million for DoD to engage in military-to-military training exercises, and $10 million for Labor to work with labor unions in the preparation of HIV/AIDS transmission prevention programs.

- $ It is not yet clear whether Defense funding and associated authority were included in recent House Appropriations Subcommittee or House and Senate Authorization Committee markups (the Senate Appropriations Committee has not yet acted).
- $ The Senate provided the requested Labor funding in the Labor/HHS Subcommittee bill as noted under the HHS item above; the House did not provide funding for Labor in its version of the bill.

State: *GAVI* - The FY 2001 Budget proposal includes a new $50 million contribution to fund vaccine purchase, research and development, and infrastructure development in developing countries. The Senate Foreign Operations full-committee markup provided the full $50 million requested, but in a new USAID Global Health account, rather than as requested in the State Department's International Organizations and Programs account.

Other Programs that affect Global HIV/AIDS

USAID: *International Family Planning* - these programs help to prevent the spread of HIV/AIDS by distributing condoms and providing reproductive health programs.

- $ Funding of $541 million was requested for USAID family planning activities in FY 2001.
- $ The SAC Foreign Operations bill provides $425 million, $116 million less than the request but $52 million above FY 2000.

Department of Treasury: *Debt Forgiveness* - The Cologne debt initiative provides debt relief to heavily indebted poor countries (HIPCs) to free their internal resources for priority poverty reduction programs, of which HIV/AIDS programs are now an integral part. The U.S. supports this initiative through bilateral debt reduction and contributions to the multilateral HIPC Trust Fund, but lack of U.S. contributions to the HIPC Trust Fund to date limit the ability of the program to provide full debt reduction to reforming countries, including those with significant HIV/AIDS problems.

- $ Funding requests include $210 million in a FY 2000 supplemental and $150 million in the FY 2001 Budget for the HIPC Trust Fund and $75 million in FY 2001 for bilateral programs.
- $ The Senate Foreign Operations Committee bill provides only the $75 million bilateral funding.

Multilateral Development Banks (MDBs) - The World Bank's *International Development Association* (IDA), which lends $6-7 billion annually to the poorer developing countries, provides technical assistance and loans for public Health infrastructure and HIV/AIDS prevention. For FY 2000-2002, IDA plans on committing $400 million out of current resources and is proposing significant increases, which will depend in part on full U.S. contributions. *The African Development Fund* (AfDF) also funds HIV/AIDS programs and has established a

permanent task force on HIV/AIDS.

- $ The FY 2001 Budget requested $836 million for IDA and $100 million for the AfDF.
- $ The Senate Foreign Operations committee bill provides $750 million for IDA and $72 million for AfDF.

HHS: *NIH* - NIH=s indirect funding supports research to understand how the HIV virus causes disease. Laboratory studies are developing vaccine candidates, microbicides, and other prevention methods that can eventually be tested in international settings and which will ultimately have worldwide applicability (see discussion of FY 2001 request and Congressional action under "direct programs" NIH item).

State: *World Health Organization (WHO)* - Approximately 3-4 percent ($12 million) of WHO=s budget goes to direct AIDS programs.

- $ The FY 2001 Budget requested $108 million for the U.S. assessed contribution to WHO.
- $ The Commerce, Justice and State Subcommittees in the House and Senate have not yet begun appropriations action.

International Organizations and Programs (IO&P) - UNICEF and the UN Development Program (UNDP) have HIV/AIDS programs (for which we have not yet been able to determine an exact funding levels). The U.S. provides voluntary contributions to UNICEF and UNDP.

- $ The FY 2001 Budget requested $110 million for UNICEF and $90 million for UNDP.
- $ The Senate Foreign Operations committee bill provides the request for UNICEF and $85 million for UNDP.

GLOBAL HIV/AIDS AND GLOBAL VACCINES				
(BA in Millions)				
			Pres Bud	Approps
DIRECT FUNDING	FY 1999	FY 2000	FY 2001	Bill
USAID				
Child Survival Acct	135	179	244	FO
Economic Support Fund	2	1	3	FO
New Independent States	2	4	4	FO
Development Fund Africa		6		FO
PL 480 Food		10	10	AGR
HHS/CDC	11	46	72	L/HHS
HHS/NIH Research (non-vaccine)	55	65	71	L/HHS
HHS/NIH Vaccines	19	25	29	L/HHS
DOD	0	0	10	NS
DOL	0	0	10	L/HHS
State/IO&P/GAVI	0	0	50	FO
TOTAL	224	336	504	
INDIRECT FUNDING (Account totals)				
USAID/Family Planning	385	372	542	FO
condoms	(9)	(7)	(7)	FO
STDs and AIDS	*	*	*	FO
Treasury				
HIPC Trust Fund	0	210	150	FO
World Bank/IDA	800	771	836	FO
African Fund	128	127	100	FO
HHS/NIH AIDS non-vaccine research	485	541	575	L/HHS
HHS/NIH HIV/AIDS Vaccine Research	164	213	238	L/HHS
State/CIO/WHO	108	108	108	CJS
State/IO&P	205	190	200	FO

Explanatory Notes

Note: Numbers in this section are straightforward and contained as line items in the President's Budget.

Purchase of condoms for family planning which also contributes to HIV/AIDS prevention.

Typically 5-10% of family planning funds goes to reproductive health, for STDs and AIDS.

The FY 2000 number is a supplemental request for the multilateral HIPC Trust Fund. Host countries are to use resources freed up by the HIPC debt relief initiative to strengthen health care, which increasingly incorporates HIV/AIDS control and prevention, as well as other priority poverty reduction programs.

IDA plans lending of $400 million over FY 2000-2002 for HIV/AIDS as well as a new health/vaccine initiative and public health infrastructure lending. Annual total IDA lending is $7B.

The African Development Bank Fund has established a permanent task force on HIV/AIDS to develop a multi-sectoral policy for future assistance that should increase commitments from the 14% of past health lending that has gone directly to AIDS activities.

NIH basic and behavioral biomedical research activities on prevention of perinatal transmission, opportunistic infections, including TB, and risk factors will lead to better preventive interventions that may be used overseas.

This portion of NIH vaccine research may lead to a preventive vaccine for use overseas

Approximately 3-4% ($12M) of WHO's Budget, to which the US provides an assessed contribution, goes directly to AIDS programs.

UNICEF and UNDP, which the US funds through the International Organizations & Programs (IO&P) account, have HIV/AIDS programs with as yet unknown funding levels.

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.

THE WHITE HOUSE

WASHINGTON

September 29, 1999

Mr. Victor Zonana
Vice President for Public Affairs
International AIDS Vaccine Initiative
810 Seventh Avenue
New York, NY 10019-5818

Victor

Dear Mr. Zonana:

Thank you for your letter. The Administration is dedicated to helping find a vaccine for HIV/AIDS. In fact, the President announced on September 21, 1999 that he will host a conference on vaccine development. This Conference will bring together pharmaceutical company CEOs, scientists, foundation heads, members of Congress, academic experts and other interested parties to hear their concerns and ideas. Together, this group will develop workable economic and technical solutions to promote private sector investment and new public-private partnerships to develop vaccines for TB, HIV/AIDS, malaria and other diseases of the developing world.

Although the Administration is reviewing HR 1274, "The Lifesaving Vaccine Technology Act of 1999," we clearly support the goal of encouraging the development of lifesaving vaccines, including those that will prevent HIV infection. We too understand the importance of engaging the private sector and appreciate your efforts in this area. I can assure you that finding an HIV vaccine continues to be a top priority of this Administration.

Sincerely,

John Podesta
Chief of Staff to the President

cc: Sandra Thurman

International AIDS
Vaccine Initiative

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New York, NY
10019-5818. USA
www.iavi.org
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fax: 212-843-0480

need reply

September 21, 1999

John Podesta
Chief of Staff
The White House
Washington, DC 20500

Dear John,

I hope this letter finds you well. I am pleased to report there is life after the Clinton Administration – not nearly as exciting as our daily David Satcher confirmation sessions in the Roosevelt Room, but fun and rewarding nevertheless.

I am writing to bring to your attention legislation that would help cement the President's legacy in championing an AIDS vaccine. Nancy Pelosi's bill, HR 1274, "The Lifesaving Vaccine Technology Act of 1999," would provide targeted tax credits to companies doing research in HIV, tuberculosis, and malaria vaccines. While the NIH does an excellent job with basic research, fully engaging the pharmaceutical industry is critical if we are to achieve the President's goal of an AIDS vaccine by 2007, as *The Economist* recently reported. (I'm told the President was impressed with the article).

This legislation has many virtues: it is inexpensive, pro-industry, and has strong support within the public health community (American Public Health Association, Global Health Council, AIDS Action, Program for Appropriate Technology in Health, among others). Our Congressional allies tell us it could easily be slipped into Omnibus or final tax legislation.

Given the President's re-stated goal of developing an AIDS vaccine by 2007, the lack of Administration support to date is puzzling and could reflect badly on the Administration. Believe Treasury has some minor technical objections but believe they could be overcome. I very much hope the Administration will make the enactment of this legislation a priority. Thanks for your consideration.

Sincerely,

Victor

Victor Zonana
Vice President for Public Affairs

Todd A. Summers
09/29/99 02:48:45 PM

Record Type: Record

To: Fern Mechlowitz/WHO/EOP@EOP

cc:
Subject: Zonona letter

Thanks for sending along the letter from Victor. I must say, he's as wormy as ever.

Your response was fine. I would make just a few changes:

- the second paragraph, replace with, "Although the Administration is reviewing HR127, "The Lifesaving Vaccine Technology Act of 1999," we clearly support the goal of encouraging the development of lifesaving vaccines, including those that will prevent HIV infection. We too understand the importance of engaging the private sector and appreciate your efforts in this area. I can assure you that finding an HIV vaccine continues to be a top priority of this Administration."

- I would include Sandra Thurman as a cc on the response letter so that Zonona knows that there's inter-EOP communication.

If you have questions or want to discuss, let me know. Again, we appreciate the head's up.

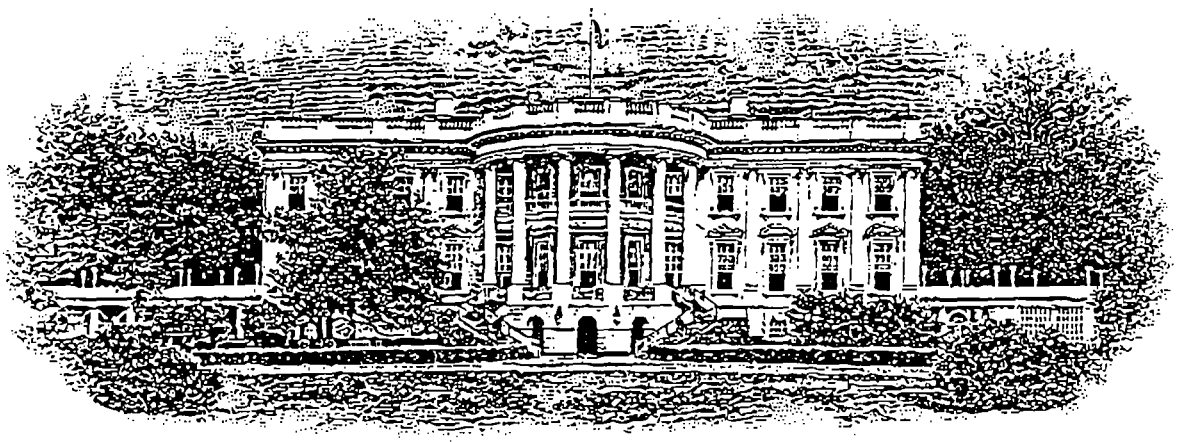
Todd

THE WHITE HOUSE

WASHINGTON

EXECUTIVE OFFICE OF THE PRESIDENT

OFFICE OF THE CHIEF OF STAFF



Please Deliver To: Attn: Mary (for Todd Summers)

Fax Number: 6-2438

Sender: Fern Mechlowitz (6-7256)

Date: 9/29

Pages Including Cover: 3

Message: Todd - Here is a letter and draft response that I wrote. Will you please look at it and advise?

Thank You, Fern

NOTE: The information contained in this facsimile message is CONFIDENTIAL and intended for the recipient ONLY. If there is any problem with this transmission or you mistakenly received this facsimile, please call (202) 456-6798. Thank You.

International AIDS
Vaccine Initiative

810 Seventh Avenue
New York, NY
10019-5818. USA
www.iavi.org
e-mail: info@iavi.org
phone: 212-655-0201
fax: 212-843-0480

need reply

September 21, 1999

John Podesta
Chief of Staff
The White House
Washington, DC 20500
Dear John,

I hope this letter finds you well. I am pleased to report there is life after the Clinton Administration – not nearly as exciting as our daily David Satcher confirmation sessions in the Roosevelt Room, but fun and rewarding nevertheless.

I am writing to bring to your attention legislation that would help cement the President's legacy in championing an AIDS vaccine. Nancy Pelosi's bill, HR 1274, "The Lifesaving Vaccine Technology Act of 1999," would provide targeted tax credits to companies doing research in HIV, tuberculosis, and malaria vaccines. While the NIH does an excellent job with basic research, fully engaging the pharmaceutical industry is critical if we are to achieve the President's goal of an AIDS vaccine by 2007, as *The Economist* recently reported. (I'm told the President was impressed with the article).

This legislation has many virtues: it is inexpensive, pro-industry, and has strong support within the public health community (American Public Health Association, Global Health Council, AIDS Action, Program for Appropriate Technology in Health, among others). Our Congressional allies tell us it could easily be slipped into Omnibus or final tax legislation.

Given the President's re-stated goal of developing an AIDS vaccine by 2007, the lack of Administration support to date is puzzling and could reflect badly on the Administration. Believe Treasury has some minor technical objections but believe they could be overcome. I very much hope the Administration will make the enactment of this legislation a priority. Thanks for your consideration.

Sincerely,

Victor

Victor Zonana
Vice President for Public Affairs

DRAFT

September 29, 1999

Mr. Victor Zonana
Vice President for Public Affairs
International AIDS Vaccine Initiative
810 Seventh Avenue
New York, NY 10019-5818

Dear Mr. Zonana:

Thank you for your letter. The Administration is dedicated to helping find a vaccine for HIV/AIDS. In fact, the President announced on September 21, 1999 that he will host a conference on vaccine development. This Conference will bring together pharmaceutical company CEOs, scientists, foundation heads, members of Congress, academic experts and other interested parties to hear their concerns and ideas. Together, this group will develop workable economic and technical solutions to promote private sector investment and new public-private partnerships to develop vaccines for TB, HIV/AIDS, malaria and other diseases of the developing world.

Although the Administration has not publicly stated its support for HR 1274, "The Lifesaving Vaccine Technology Act of 1999," we support effective initiatives that promote the development of an HIV/AIDS vaccine. We would also like to see the private sector become more involved in this effort. I can ensure that the development of a vaccine is indeed a priority for this Administration.

Sincerely,

John Podesta

PLM/JOHN CORRIGAN

AIDS VACCINE ADVOCACY COALITION

December 28, 1999

President Clinton
The White House
Washington, DC 20500

Dear Mr. President:

We are writing because we understand you are making critical decisions about what to include in an Administration proposal on vaccine development. We urge you to include a vaccine tax credit provision in this larger package.

The AIDS Vaccine Advocacy Coalition (AVAC) has as its mission to improve the political, scientific, public, and economic environment for developing a vaccine against HIV. To address the unfavorable economics so accurately summarized in Jeffrey Sachs Economist article, Helping the World's Poorest, and the paucity of industry involvement identified in our annual reports, we helped design the Lifesaving Vaccine Technology Act that was introduced in the House by Rep. Nancy Pelosi and in the Senate by Sen. John Kerry this year.

You have already spoken of this problem at least three times in major addresses (State of Union 1997, Morgan State 1997, United Nations 1999). In the last weeks we've heard that you are considering a package of initiatives to address health in the poorest countries, and particularly prevention of the three diseases identified in our bill (HIV, malaria and TB) as part of your Administration's plans for the coming year, but that most of the initiatives to stimulate progress by industry are "pull" initiatives which of course we support strongly. They should be very valuable when put into place.

We still think though that a substantial credit for the few companies that are or could be willing to work on these specific scientific and product development problems would have extraordinary impact given its cost and we believe its inclusion in the package would strengthen the entire package. The benefit would immediately be achievable and influential as a demonstrable commitment to the same goals this year, at no direct cost and with an easily manageable amount of lost revenue for government. The beauty of this approach is that it demonstrates commitment and only costs a fraction of the amount invested by companies themselves. It requires participants to justify their work in business terms, but makes it easier for them to do so. It rewards companies that have already made this commitment and believe in it, encouraging them to persevere, and it should at least capture the attention of companies that could take this on but have not for a variety of reasons. Unlike other push mechanisms like direct funding of private R&D, it is available to all and not limited by available funding.

Modeled after the successful R&E Credit and the Orphan Drug Act, this approach differs from them in that it offers industry a financial incentive that they've told us could shift the balance of choosing to pursue certain research and development efforts over others. Unlike the R&E Credit, it is designed to reward the biotech and vaccine/pharmaceutical industry for tackling the most important public health challenges. Unlike the Orphan Drug Act, its primary focus is preclinical, when pull mechanisms are most remote.

AVAC • 1701 K STREET, NW, SUITE 600 • WASHINGTON, DC • 20006
PHONE: (202) 387-5517 • FAX: (202) 452-6804

We are at a critical time when new public-philanthropic initiatives for each of the three most devastating diseases are beginning and seeking cooperation from private partners. This government-initiated stimulant to industry could tap the potential of those who really know how to get products to market when a great deal of science is waiting to be picked up. It allows companies to set their own balance between their stated missions for public health and their belief in developing products that would have wide usage and visibility. Creating an assured market is of course an excellent ultimate goal, but different companies view this differently. Some would rather set their own prices and justify a vaccine product based on its intrinsic value to individual countries rather than dealing with large public ventures that have not historically done a great job with deployment and that can create public price pressure with consolidated markets and moral arguments.

We know a tax credit isn't the complete answer, but it does use the taxing power of government to send a clear message to industry from the people. This would be particularly valuable from an administration that has been accused of scapegoating the pharmaceutical industry in the health care debate. It holds this industry to their oft-stated humanitarian goals, at face value, while supporting their proven business methods for getting things done efficiently and well.

We hope you will decide to include the vaccine tax credit as part of the larger efforts that you are trying to mobilize. The tax credit wouldn't interfere with a company's rights to their discoveries or pricing, but it does require submission of a plan for global access and distribution within one year of licensing, which has been the biggest problem for deploying proven vaccines in the past and present. Development, access, and deployment are all big issues, but development comes first and needs to be boosted right now.

We are available to discuss this strategy and vaccine economics with you further if you wish.

Sincerely yours,

Rose McCullough

Rose McCullough
Interim Executive Director
AIDS Vaccine Advocacy Coalition

Aventis Pasteur

Aventis

December 16, 1999

Mr. Christopher Jennings
Deputy Assistant to the President
For Health Policy Development
216 Old Executive Office Building
17th and Pennsylvania Ave., NW
Washington, DC 20502

Dear Chris:

On behalf of Aventis Pasteur (formerly Pasteur Merieux Connaught) the world's largest vaccine manufacturer, we are pleased that the White House is planning a conference on development of therapies and vaccines to combat AIDS, malaria and tuberculosis. As a company which is devoting considerable resources in these areas we hope to participate actively with you in both the development of, and participation in such a conference. I can tell you that our company's interest is at the highest domestic and international chief executive level.

I understand from talking with you that detailed planning is not yet underway. I would appreciate information as to when you intend to hold the conference and how you contemplate it being organized and implemented.

I look forward to hearing from you and helping you in this worthwhile endeavor.

I can be reached at 202-898-3193.

Sincerely,

Geoffrey G. Peterson
Director of Federal Government Affairs

GGP/lc
cc: Nancy Hernreich
Bruce R. Lindsey
Steven J. Ricchetti
Sandra L. Thurman
Richard J. Tarplin
Kevin L. Thurm

Aventis Pasteur Inc. · 801 Pennsylvania Avenue NW Suite 725 · Washington DC 20004
Telephone 202-898-3193 · Fax 202-371-1107

AIDS VACCINE ADVOCACY COALITION

December 28, 1999

cc: Sandy Thurman
TBC Jack. Place

Mr. John Podesta
Chief of Staff
The White House
Washington, DC 20500

Dear Mr. Podesta:

We are writing because we understand that critical decisions about what to include in an Administration proposal on vaccine development may be made soon. The AIDS Vaccine Advocacy Coalition (AVAC) has as its mission to improve the political, scientific, public, and economic environment for developing a vaccine against HIV. To address the unfavorable economics so accurately summarized in Jeffrey Sachs Economist article, Helping the World's Poorest, and the paucity of industry involvement identified in our annual reports, we helped design the Lifesaving Vaccine Technology Act that was introduced in the House by Rep. Nancy Pelosi and in the Senate by Sen. John Kerry this year.

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PHONE: (202) 387-5517 • FAX: (202) 452-6804

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We hope you can use your influence within the Administration to make this case as part of the larger efforts that you are trying to mobilize. The tax credit wouldn't interfere with a company's rights to their discoveries or pricing, but it does require submission of a plan for global access and distribution within one year of licensing, which has been the biggest problem for deploying proven vaccines in the past and present. Development, access, and deployment are all big issues, but development comes first and needs to be boosted right now.

We are available to discuss this strategy and vaccine economics with you further if you wish.

Sincerely yours,

Rose McCullough

Rose McCullough
Interim Executive Director
AIDS Vaccine Advocacy Coalition

FACSIMILE TRANSMISSION

DEPARTMENT OF THE TREASURY
OFFICE OF INTERNATIONAL AFFAIRS
WASHINGTON, D.C. 20220

January 27, 2000

To: Distribution

fax:

From: Under Secretary
Timothy F. Geithner

Phone: (202) 622 - 0656
Fax: (202) 622 - 0417

Number of pages including cover: 7

Subject: Vaccines Initiative

Attached is the final (we hope) one-page fact sheet on the President's vaccines initiative and a supplemental paper with policy rationale and additional explanation. This has been cleared through the OMB clearance process.

Inter-Agency Working Group on USG Vaccine Initiative

Co Chairs: Hattie Babbitt, Deputy Administrator, USAID
Timothy F. Geithner, Under Secretary; International Affairs, Treasury

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	Chris Jennings	456-5557	456-5560
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	Betsy D'Jamoos	690-5405	690-6061
	Peggy Hamburg	690-7383	690-7858
	Bill Raub	690-5874	690-5874
	Deborah van Zinkernagel	690-7560	690-5560
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	Bob Kyle	395-3513	395-4657
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OSTP	Laura Efros	456-6028	456-6065
	Gerald Hane	456-6028	456-6064
OVP	Richard Saunders	456-9500	456-9501
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	Ann Richards	647-1681	647-4427
	Chris Walker	647-7453	647-5444
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	Joyce Holfeld		712-4727
Treasury	Len Burman	622-0605	622-0120
	Joe Eichenberger	622-1228	622-1231
	Doug Elmendorf	622-2633	622-0563
	Barbara Herz	622-1228	622-0419
	Sheryl Sandberg	622-0073	622-1906
	Helen Walsh	622-1228	622-1265

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.

Final Draft 26 Jan 8:00 PM

January 27, 2000

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POLICY RATIONALE AND ADDITIONAL EXPLANATION

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- 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 by 20 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 50 percent more funding than in FY 2000 and nearly double the FY 1999 level. NIH will focus on studying the body's defense mechanisms against TB, and developing and studying TB 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.

PRESIDENT CLINTON:
ADDRESS TO THE UNITED NATIONS GENERAL ASSEMBLY
September 21, 1999

"Let us resolve in the bright dawn of this new millennium to bring an era in which our desire to create will overwhelm our capacity to destroy. If we do that, then through the United Nations and far-sighted leaders, humanity finally can live up to its name."

President Bill Clinton
September 21, 1999

Today, in New York City, President Clinton addressed the opening session of the United Nations General Assembly. The President spoke on the challenges facing the international community in the next century, including fighting poverty and disease, combating regional and ethnic violence, and thwarting the spread of weapons of mass destruction. The President announced a number of new and ongoing health initiatives designed to prevent diseases that disproportionately affect developing areas of the world.

Waging a War Against Poverty and Disease. President Clinton urged prosperous countries to do more to fight poverty, hunger, and health care crises by:

* opening world markets for global competition;
* coming to the aid of struggling countries burdened with debt;
* taking action to halt global climate change; and
* improving access to health care for the poor.

The President announced the following commitments in the fight against global diseases:

* a request to Congress for a substantial increase of $108 million to fight polio;
* a proposed $100 million in additional funds to combat the global HIV/AIDS epidemic; and
* a White House meeting with public health experts, pharmaceutical company leaders, and others to discuss ways to accelerate the development and delivery of vaccines for malaria, tuberculosis, AIDS, and other diseases affecting developing nations.

Combating Ethnic and Regional Violence Around the World. The President called on the UN to strengthen its role in preventing and stopping outbreaks of ethnic and regional violence, including:

* establishing an international coalition against genocide to stop the flow of money and arms to those who commit crimes against humanity;
* creating police institutions, accountable to citizens and the law, in countries emerging from conflict; and
* training and rapid deployment of international peacekeeping forces.

Fighting the Spread of Weapons of Mass Destruction. President Clinton urged the international community to combat the proliferation of nuclear, chemical and biological weapons. Specifically, the President called for:

* a renewed commitment to the Non-Proliferation Treaty;
* a strengthening of the Biological Weapons Convention;
* more rapid progress on a treaty to ban production of fissile materials used to make nuclear weapons;

* support for the Convention on Physical Protection of Nuclear Materials; and
* Senate advice and consent to the Comprehensive Nuclear Test Ban Treaty.

Clinton Presidential Records
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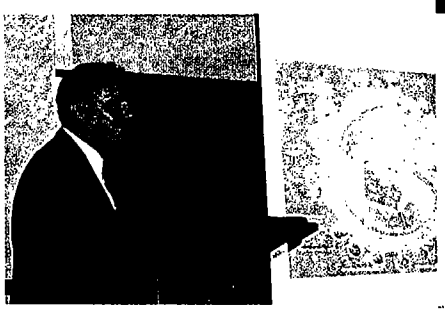
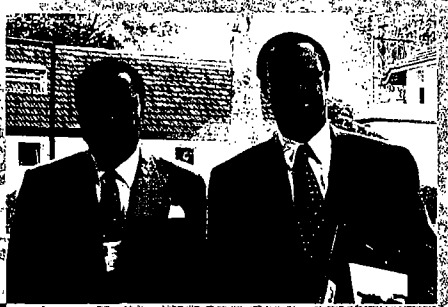
Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

Proceedings
Uganda Vaccine Workshop

HIV Diagnostics and Genetic Variation in the Context of HIV Vaccine Studies



The Windsor Lake Victoria Hotel
Entebbe, Uganda
30 September – 1 October 1999



The Guardian

Thursday September 30 1999

UK gives lead with Aids vaccine cash

Development

Sarah Boseley
Health Correspondent

Clare Short, the international development secretary, will use her speech at conference today to announce a government contribution of £14m to research into an Aids vaccine for the developing world.

It will be the first contribution by any government to the international Aids vaccine initiative, set up three years ago to hasten the development of a vaccine that is the only hope for millions in Africa, where Aids is cuting a swath through a generation of young people with dire consequences for the future of the continent. Some countries in south America and Asia are also badly hit.

In spite of the urgent need, progress is slow because the pharmaceutical industry, which funds most research into new drugs and vaccines, sees greater profits in producing Aids drugs for Europe and the United States that are unaffordable in Africa. Such treatment can cost £1,000 a month.

"The science says that an Aids vaccine should be possible in five years," said Ms Short yesterday. "But we know that market forces will not deliver the research.

"There isn't the rate of return that the pharmaceutical industry expects. But we need to work in partnership with the private sector. They have got the labs and the capacity to do the work.

"The £14m is leverage, to help with the early costs and encourage the private sector into collaboration. We have been talking with the big British pharmaceutical companies and have had a lot of positive response. The atmospherics have changed."

Ms Short said she hoped other governments would follow Britain's lead — so far there have been donations from US foundations but no other government money.

She will also announce a further £20m to help eradicate polio, which the World Health Organisation is attempting to achieve through mass vaccinations.

"We're well on course. New infections are going down and down. But it is in countries where there is war and conflict that it is most difficult. This money is to help some of the work in those countries, like Angola."

It was wonderful to know that such a damaging disease as polio, that had disabled so many in the past, was disappearing, she said. "I think people care about these things, but think the money is little dollops of charity.

"But we can work in more strategic ways. We can use aid interventions as leverage — it is what both these things are about."

US EDITION

FINANCIAL TIMES

World Business Newspaper http://www.ft.com THURSDAY SEPTEMBER 30 1999 USA $1.00 Canada C$2.00 Bermuda $2.00

Campaign for Aids vaccine receives $23m boost

By Clive Cookson and Andrew Parker

The government will today give a £14m ($23m) boost to the International Aids Vaccine Initiative. It will be used to research and test vaccines to prevent HIV, the virus that can cause Aids, spreading in developing countries that cannot afford expensive anti-viral drugs.

The grant is the first big government grant for IAVI, a New York-based non-profit organisation which has been funded mainly by charities and companies. "This is a big addition to our funding [currently about £35m ($57m)] and will enable us to launch more vaccine development partnerships," said Seth Berkley, president.

The first two partnerships were launched last November. One is a collaboration between Oxford University and the University of Nairobi to produce a two-component vaccine aimed at HIV strains circulating in Kenya.

"It is moving ahead rapidly and we expect to begin clinical trials in humans in the first quarter of next year," said Dr Berkley.

The second project, pairing the University of Cape Town with AlphaVax, a US biotechnology company, is moving more slowly. It is likely to begin clinical trials at the end of next year.

The UK funding is likely to enable IAVI to go ahead with partnerships involving China and India, which have expertise in vaccine manufacturing and potentially huge Aids problems.

The formation of IAVI was a reflection of frustration with the failure of the western world's medical research bodies and pharmaceutical companies to come up with a viable Aids vaccine, despite 15 years of effort.

But Dr Berkley said the scientific problem had to be cracked, if a public health catastrophe in Africa and Asia were to be prevented.

1998 Survey

NEW MEDICINES IN DEVELOPMENT FOR

AIDS

PRESENTED BY AMERICA'S PHARMACEUTICAL COMPANIES

113 Medicines in Testing for AIDS Offer Hope that Remarkable Progress Will Continue

Innovative medicines helped cut the death rate from AIDS nearly in half last year—the biggest single-year drop in history for a major cause of death. Nearly 16,000 fewer Americans died of AIDS last year than the year before, and AIDS no longer numbers among the top 10 causes of death in the United States. But the numbers don't tell the whole story. Thanks to breakthrough medicines, AIDS patients are not only living longer—they are going back to work, taking care of their families, contributing to society, and looking forward to a future they didn't think they had.

Considering that the virus that causes AIDS was identified only 15 years ago, the progress made against this disease by pharmaceutical research has been a remarkable achievement. A pharmaceutical company won FDA approval of the first drug to treat AIDS in 1987. Now—only 11 years later—there are 54 approved medicines to treat AIDS and related conditions and another 113 in development.

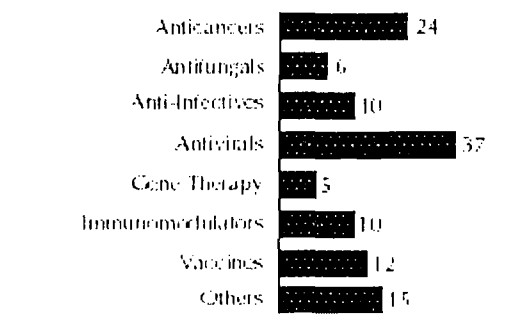
In the past year alone, five new medicines were added to the arsenal of weapons against AIDS:

- Sustiva™, from DuPont Pharmaceuticals, is a once-daily non-nucleoside reverse transcriptase inhibitor in capsule form that reduces the number of pills patients have to take and can be used in combination with other antiviral drugs by both adults and children.
- Vitravene™, from Isis Pharmaceuticals and CIBA Vision, is the first in a new class of medicines that use "antisense" technology to switch off genes that trigger disease. The new medicine is injected into the eyes of AIDS patients who haven't responded to standard treatments for CMV retinitis, a virus that can cause blindness.
- Priftin®, from Hoechst Marion Roussel, is the first major advance in the treatment of tuberculosis in 25 years. Tuberculosis attacks the weakened immune systems of AIDS patients and accounts for about one-third of all deaths of HIV-infected individuals.
- Trovan™, developed by Pfizer, is a broad spectrum antibiotic that targets hospital-acquired infections that AIDS patients are susceptible to.
- Famvir®, from SmithKline Beecham, is the first and only approved oral drug for the treatment of herpes in people with HIV infection.

The new medicines in development for AIDS and AIDS-related conditions include:

- 37 antivirals, including several "second generation" protease inhibitors with simplified dosage requirements, a novel anti-HIV compound discovered in the Sarawak rain forest in Malaysia, the first of a new class of drugs that block the entry of the AIDS virus into cells, and an antibody-like molecule produced in the milk of transgenic animals.
- 24 anticancer medicines to treat such AIDS-related cancers as lymphoma and Kaposi's sarcoma, which affects some 12,000 people each year.
- 12 vaccines, including one now in large-scale human clinical trials in the United States and Thailand.
- 16 anti-infectives and antifungals to fight opportunistic infections.

MEDICINES IN DEVELOPMENT FOR AIDS*



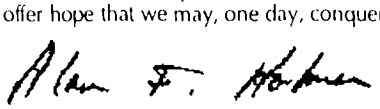
*Some medicines are listed in more than one category.

- 10 immunomodulators designed to boost the immune system's ability to fight AIDS.
- 5 gene therapies, including a promising approach that uses genetically engineered T cells to seek out and destroy cells infected with HIV.

In addition, companies are developing a variety of medicines to improve the quality of life for AIDS patients. These include treatments for such AIDS-related conditions as dementia, aphthous ulcers, diarrhea, severe pain, and AIDS wasting.

Despite the good news about a decline in AIDS deaths, there is a need for these new medicines and for further research. The rate of new HIV infections in the United States—about 40,000 per year—is unacceptably high, and AIDS is still the leading killer of young African Americans. Pharmaceutical researchers are responding to this continuing need by exploring whole new approaches to the disease and by looking at new combinations and new uses of existing drugs. For example, scientists are working on ways to rebuild AIDS-ravaged immune systems. Companies are also researching ways to stop the virus through the "co-receptors" that the virus needs to gain entry into cells. Researchers are also studying whether a combination of two protease inhibitors combined with one or two other antiviral medicines would be more effective than the current combination of one protease inhibitor plus two other drugs. There are also studies to determine whether treating pregnant HIV-positive women with protease inhibitors can further reduce transmission of the virus to babies and to assess the differing responses of men and women to anti-HIV therapy.

The 113 new medicines in development and the ongoing commitment of the pharmaceutical industry to AIDS research offer hope that we may, one day, conquer this terrible disease.



Alan F. Holmer
President
PhRMA

AIDS Medicines in Development

ANTICANCERS

Product Name	Company	Indication	Development Status	
9-aminocampto-thecin	National Cancer Institute *Bethesda, MD*	AIDS-related Kaposi's sarcoma	Phase II NCI TRIAL	(WMA)
9-cis-retinoic acid	National Cancer Institute *Bethesda, MD* Ligand Pharmaceuticals *San Diego, CA*	AIDS-related Kaposi's sarcoma	Phase I/II NCI TRIAL	(WMA)
A-007	Dekk-Tec *New Orleans, LA*	AIDS-related Kaposi's sarcoma	Phase I	(WA)
ATRAGEN® tretinoin	Aronex Pharmaceuticals *The Woodlands, TX*	AIDS-related Kaposi's sarcoma	Phase II completed	(WMA)
bryostatin-1	National Cancer Institute *Bethesda, MD*	AIDS-related lymphoma	Phase II NCI TRIAL	(WMA)
DaunoXome®† daunorubicin citrate liposome injection	NeXstar Pharmaceuticals *Boulder, CO*	non-Hodgkin's lymphoma and certain leukemias	Phase I/II	(WCMAB)
DepoCyt™ cytarabine liposome injection	Depotech *San Diego, CA*	neoplastic meningitis	Phase III	(WCMAB)
G3139	Genta *San Diego, CA*	non-Hodgkin's lymphoma	Phase I/II	(WA)
gallium nitrate†	National Cancer Institute *Bethesda, MD*	AIDS-related non-Hodgkin's lymphoma	Phase II NCI TRIAL	(WMA)
interleukin-12	National Cancer Institute *Bethesda, MD*	AIDS-related Kaposi's sarcoma, AIDS-related lymphoma	Phase I/II NCI TRIAL	(WMA)
LIDAKOL® n-docosanol	LIDAK Pharmaceuticals *San Diego, CA*	AIDS-related Kaposi's sarcoma (see also antivirals)	Phase II	
ONTAK® denileukin diftitox	Seragen/Ligand Pharmaceuticals *San Diego, CA*	non-Hodgkin's lymphoma	Phase III	(WCMAB)
Panretin® Gel alitretinoin	Ligand Pharmaceuticals *San Diego, CA*	AIDS-related Kaposi's sarcoma	application submitted	(WMA)
Panretin® Oral alitretinoin	Ligand Pharmaceuticals *San Diego, CA*	AIDS-related Kaposi's sarcoma	Phase III	(WCMAB)
Paxene™ paclitaxel	IVAX/Baker Norton Pharmaceuticals *Miami, FL*	AIDS-related Kaposi's sarcoma	application submitted	(M)
peldesine (BCX-34)	BioCryst Pharmaceuticals *Birmingham, AL*	cutaneous T-cell lymphoma (see also immunomodulators)	Phase I	(WM)

WCMAB codes in parentheses to right of development status:
W — Women are included in the human clinical trials for this product.
C — Children are included in the human clinical trials for this product.
M — Racial and ethnic minorities are included in the human clinical trials for this product.
A — This product is being developed with the intent of labeling and marketing for use in women.
B — This product is being developed with the intent of labeling and marketing for use in children.
†—Denotes medicines that have been approved by the FDA for other uses.

ANTICANCERS

Product Name	Company	Indication	Development Status	
Proleukin®† aldesleukin interleukin-2 (IL-2)	National Cancer Institute *Bethesda, MD* Chiron *Emeryville, CA*	AIDS-related Hodgkin's lymphoma (see also immunomodulators)	Phase II NCI TRIAL	(WMA)
SU-5416	SUGEN *Redwood City, CA*	AIDS-related Kaposi's sarcoma	Phase I/II	
thalidomide†	Andrulis Pharmaceuticals *Beltsville, MD*	AIDS-related Kaposi's sarcoma (see also immunomodulators)	Phase II	(WMAB)
thalidomide†	National Cancer Institute *Bethesda, MD* EntreMed *Rockville, MD*	AIDS-related Kaposi's sarcoma	Phase II NCI TRIAL	(WMA)
topotecan	SmithKline Beecham *Philadelphia, PA*	progressive multifocal leukoencephalopathy (PML)	Phase II	
VIMRxyn™ hypericin	VIMRx Pharmaceuticals *Wilmington, DE*	cutaneous T-cell lymphoma (topical phototherapy)	Phase I/II	
Virulizin®	Imutec Pharma *Scarborough, Ontario*	AIDS-related malignancies, including lymphoma and Kaposi's sarcoma	Phase I/II	(WMA)
Zyrkamine mitoquazone	ILEX Oncology *San Antonio, TX*	AIDS-related non-Hodgkin's lymphoma	Phase II completed	(WCMA)

ANTIFUNGALS

Product Name	Company	Indication	Development Status	
AmBisome®† liposomal amphotericin B	NeXstar Pharmaceuticals *Boulder, CO*	cryptococcal meningitis, histoplasmosis	Phase III completed	(WMAB)
NYOTRAN™ liposomal nystatin	Aronex Pharmaceuticals *The Woodlands, TX*	candidemia, systemic fungal infections, cryptococcal meningitis, aspergillosis	Phase III	(WCMAB)
Oramed™ 0.5% glyminox	Biosyn *Philadelphia, PA*	HIV-related oral candidiasis	Phase II	(WMA)
Sporanox® itraconazole (intravenous)	Janssen Pharmaceutica *Titusville, NJ*	systemic mycoses	Phase III	
triazole	Schering-Plough *Madison, NJ*	opportunistic fungal infections	Phase II	
UK-109,496 voriconazole	Pfizer *New York, NY*	aspergillosis, candidiasis	Phase III	

ANTI-INFECTIVES

Product Name	Company	Indication	Development Status	
BWPT	Biomune Systems *Salt Lake City, UT*	cryptosporidiosis	Phase II	(WCMAB)
dapsone†	Jacobus Pharmaceutical *Princeton, NJ*	*Pneumocystis carinii* pneumonia (PCP) prophylaxis	Phase III	
dapsone† and pyrimethamine and folinic acid	Jacobus Pharmaceutical *Princeton, NJ*	PCP and toxoplasmosis prophylaxis	Phase III	(WMAB)
dapsone† with trimethoprim	Jacobus Pharmaceutical *Princeton, NJ*	PCP treatment	Phase III	
Mepron™† atovaquone	Glaxo Wellcome *Rsch. Triangle Park, NC*	PCP prophylaxis	Phase III	
nitazoxanide (NTZ)	Unimed Pharmaceuticals *Buffalo Grove, IL*	cryptosporidiosis	Phase III	(WMAB)
rifalazil (KRM-1648)	PathoGenesis *Seattle, WA*	tuberculosis	Phase II	(WMA)
Sporidin-G™ bovine immunoglobulin concentrate, *C. parvum*	Galagen *Arden Hills, MN*	cryptosporidiosis	Phase II	
SYNSORB Cd	SYNSORB *Calgary, Alberta*	AIDS-related diarrhea due to *Clostridium difficile*	Phase II	
Zithromax† azithromycin	Pfizer *New York, NY*	cryptosporidiosis, toxoplasmosis	Phase III	

ANTIVIRALS

Product Name	Company	Indication	Development Status	
1263	Glaxo Wellcome *Rsch. Triangle Park, NC*	CMV retinitis in AIDS patients	Phase I/II	
ABT-378	Abbott Laboratories *Abbott Park, IL*	HIV infection	Phase II	(WMAB)
AG 1549 (non-nucleoside reverse transcriptase inhibitor)	Agouron Pharmaceuticals *La Jolla, CA*	HIV infection, AIDS	Phase II	(WCMAB)
Agenerase™ amprenavir	Glaxo Wellcome *Rsch. Triangle Park, NC* Vertex Pharmaceuticals *Cambridge, MA*	HIV infection, AIDS	application submitted	(WCMAB)
Alferon LDO®† interferon alfa-n3	Interferon Sciences *New Brunswick, NJ*	AIDS (see also immunomodulators)	Phase I/II	(WMA)
Alferon N Injection®† interferon alfa-n3	Interferon Sciences *New Brunswick, NJ*	HIV infection	Phase III	(WMA)
		HIV & hepatitis C co-infection (see also immunomodulators)	Phase II	(WMA)

ANTIVIRALS

Product Name	Company	Indication	Development Status	
Aztec® zidovudine (controlled release)	Verex Laboratories *Englewood, CO*	early HIV infection, AIDS	Phase III	(WMA)
BCH-10652 (reverse transcriptase inhibitor)	BioChem Pharma *Laval, Quebec*	HIV infection	Phase I	(WCMAB)
BMS 200475	Bristol-Myers Squibb *Princeton, NJ*	hepatitis B	Phase II	(WMAB)
BMS 232632 (protease inhibitor)	Bristol-Myers Squibb *Princeton, NJ*	HIV infection	Phase I	(WCAB)
calanolide A (non-nucleoside reverse transcriptase inhibitor)	Sarawak MediChem Pharmaceuticals *Lemont, IL*	HIV infection	Phase I/II	(WMAB)
DEHOP	SunPharm *Jacksonville, FL*	AIDS-related chronic diarrhea	Phase II	(WMA)
DMP-450 (second generation protease inhibitor)	Triangle Pharmaceuticals *Durham, NC*	HIV infection, AIDS	Phase I/II	(WCMAB)
FTC (nucleoside analogue)	Triangle Pharmaceuticals *Durham, NC*	HIV infection, AIDS, hepatitis B	Phase II/III	(WCMAB)
GEM-132	Hybridon *Cambridge, MA*	CMV retinitis in AIDS (intravenous administration)	Phase II	
		CMV retinitis in AIDS (intravitreal administration)	Phase I/II	
Invirase®† saquinavir mesylate in combination with **Norvir™** ritonavir and either **Retrovir®** zidovudine (AZT) or **Epivir®** lamivudine (3TC)	Hoffmann-La Roche *Nutley, NJ*	HIV infection in adults	Phase III	(WMA)
LIDAKOL® n-docosanol	LIDAK Pharmaceuticals *San Diego, CA*	oral-facial herpes (see also anticancers)	application submitted	
lobucavir	Bristol-Myers Squibb *Princeton, NJ*	CMV infection in AIDS, hepatitis B, herpes viruses	Phase II	(WMAB)
lodenosine (f-ddA)	National Cancer Institute *Bethesda, MD* U.S. Bioscience *W. Conshohocken, PA*	HIV infection	Phase I/II NCI TRIAL	(WCMAB)
MKC-442 (non-nucleoside reverse transcriptase inhibitor)	Triangle Pharmaceuticals *Durham, NC*	HIV infection, AIDS	Phase III	(WCMAB)
NIBA	Octamer *Berkeley, CA*	HIV infection	Phase I	(WA)

ANTIVIRALS

Product Name	Company	Indication	Development Status	
Panavir®† probucol	Vyrex *La Jolla, CA*	HIV infection, AIDS	Phase II	(WMA)
PMPA (oral)	Gilead Sciences *Foster City, CA*	HIV infection	Phase II	(WMAB)
PNU-140690 protease inhibitor	Pharmacia & Upjohn *Kalamazoo, MI*	HIV infection, AIDS	Phase II	
Preveon™ adefovir dipivoxil	Gilead Sciences *Foster City, CA*	HIV infection	Phase III completed	(WCMAB)
PRO 367	Progenics *Tarrytown, NY*	HIV infection	Phase I	
PRO 542	Progenics *Tarrytown, NY*	HIV infection	Phase I/II	
PRO 2000 gel	Procept *Cambridge, MA*	HIV infection	Phase I NIAID TRIAL	
T-20 (fusion inhibitor)	Trimeris *Durham, NC*	HIV-1 infection	Phase II	(WCMAB)
valganciclovir	Hoffmann-La Roche *Nutley, NJ*	treatment of CMV retinitis	Phase III	
Valtrex™† valacyclovir	Glaxo Wellcome *Rsch. Triangle Park, NC*	suppression of CMV infection and disease	Phase III	(WMA)
Veldona® Lozenge interferon-alpha	Amarillo Biosciences *Amarillo, TX*	HIV-related oral human papillomavirus warts	Phase II	(WMA)
VIDEX®† didanosine (ddI) (once daily formulation)	Bristol-Myers Squibb *Princeton, NJ*	HIV infection	Phase III	
VIDEX®† didanosine (ddI) (combination use)	Bristol-Myers Squibb *Princeton, NJ*	HIV infection	application submitted	(WCMAB)
Zerit™† stavudine (first-line use in combination)	Bristol-Myers Squibb *Princeton, NJ*	HIV infection	application submitted	(WCMAB)
Ziagen™ abacavir	Glaxo Wellcome *Rsch. Triangle Park, NC*	HIV infection	application submitted	
Zintevir™ AR177	Aronex Pharmaceuticals *The Woodlands, TX*	HIV infection	Phase I/II	(WMA)

GENE THERAPY

Product Name	Company	Indication	Development Status	
CTL (adoptive immunotherapy)	Targeted Genetics *Seattle, WA*	HIV infection	Phase I	(WMA)
HIV-IT(V)	Chiron Viagene *San Diego, CA*	HIV infection	Phase II	(WMA)
HMR 4004 (gene-modified T-lymphocytes)	Hoechst Marion Roussel *Kansas City, MO*	HIV infection, AIDS	Phase II	

GENE THERAPY

Product Name	Company	Indication	Development Status	
RevM10polAS (HSC-1P)	Novartis Pharmaceuticals *East Hanover, NJ* SyStemix *Palo Alto, CA*	HIV infection	Phase I/II	(WMA)
T-cell gene therapy	Cell Genesys *Foster City, CA*	HIV infection	Phase II	(W)

IMMUNOMODULATORS

Product Name	Company	Indication	Development Status	
Alferon LDO® interferon alfa-n3	Interferon Sciences *New Brunswick, NJ*	AIDS (see also antivirals)	Phase I/II	(WMA)
Alferon N Injection® interferon alfa-n3	Interferon Sciences *New Brunswick, NJ*	HIV infection	Phase III	(WMA)
		HIV & hepatitis C co-infection (see also antivirals)	Phase II	(WMA)
Ampligen	HemispheRx Biopharma *Philadelphia, PA*	HIV infection	Phase II	(WMA)
Anticort procaine HCl	Steroidogenesis Inhibitors *Las Vegas, NV*	HIV infection	Phase I/II	(WMA)
Leukine®† sargramostim	Immunex *Seattle, WA*	prevention of HIV-associated opportunistic infections	Phase III	(WCMAB)
Multikine™ leukocyte interleukin injection	CEL-SCI *Vienna, VA*	restore immune response in HIV-infected patients	Phase I	(WMA)
peldesine (BCX-34)	BioCryst Pharmaceuticals *Birmingham, AL*	HIV infection, psoriasis (see also anticancers)	Phase I	(WM)
Perthon abavca	Advanced Plant Pharmaceuticals *New York, NY*	HIV infection	Phase I/II	(WMAB)
Proleukin®† aldesleukin, interleukin-2 (IL-2)	Chiron *Emeryville, CA*	HIV infection (see also anticancers)	Phase II/III	(WCMA)
thalidomide†	Andrulis Pharmaceuticals *Beltsville, MD*	oral and esophageal aphthous ulcers, HIV viral load	Phase II/III NIAID TRIAL	(WMAB)
		AIDS, HIV infection (immune system restoration), prurigo nodularis (see also anticancers)	Phase II	(WMAB)

VACCINES

Product Name	Company	Indication	Development Status	
AIDS vaccine	United Biomedical *Hauppauge, NY*	HIV infection	Phase I	(WMA)
ALVAC™-120TMG (vCP205)	Pasteur Merieux Connaught *Swiftwater, PA*	HIV infection prophylaxis	Phase II	

VACCINES

Product Name	Company	Indication	Development Status	
ALVAC™-120TMG pol nel (vCP1433) (vCP1452)	Pasteur Merieux Connaught *Swiftwater, PA*	HIV infection prophylaxis	Phase I	
Genevax-HIV® 400-003 (end/rev) facilitated DNA-based vaccine	Wyeth-Lederle Vaccines *Malvern, PA* a unit of Wyeth-Ayerst Laboratories *Philadelphia, PA*	HIV infection prophylaxis and treatment	Phase I	
Genevax-HIV® 400-047(gag/pol) facilitated DNA-based vaccine	Wyeth-Lederle Vaccines *Malvern, PA* a unit of Wyeth-Ayerst Laboratories *Philadelphia, PA*	HIV infection prophylaxis and treatment	Phase I	
gp120	VaxGen *Brisbane, CA*	HIV infection treatment and prophylaxis	Phase III	(WM)
gp160 MN/LAI-2	Pasteur Merieux Connaught *Swiftwater, PA*	HIV infection prophylaxis	Phase I	
HGP-30	Viral Technologies (CEL-SCI) *Vienna, VA*	HIV infection treatment	Phase I	(WMA)
		HIV infection prophylaxis	Phase I completed	(WMA)
HIV peptide AIDS vaccine	National Cancer Institute *Bethesda, MD*	early HIV infection	Phase I NCI TRIAL	(WMA)
HIV vaccines (gp120)	Chiron *Emeryville, CA*	AIDS	2 in Phase II	
TBC-3B recombinant vaccine	Therion Biologics *Cambridge, MA*	AIDS	Phase I	(WMA)

OTHERS

Product Name	Company	Indication	Development Status	
ACT (activated cellular therapy)	Neoprobe *Dublin, OH*	AIDS	Phase II	(WMA)
Advantage 24	Columbia Laboratories *Miami, FL*	prevention of sexually transmitted diseases, including HIV infection	Phase III	
Androderm® testosterone replacement	SmithKline Beecham *Philadelphia, PA*	HIV wasting	Phase III	
Androgel™-DHT didydrotestosterone gel	Unimed Pharmaceuticals *Buffalo Grove, IL*	HIV wasting syndrome in men	Phase II	
DPI3290	Delta Pharmaceuticals *Chapel Hill, NC*	severe pain	Phase I	(WM)
HIV therapeutic	United Biomedical *Hauppauge, NY*	block progression from HIV infection to AIDS	Phase I	(WMA)
Memantine	Neurobiological Technologies *Richmond, CA*	AIDS-related dementia, AIDS-related neuropathic pain	Phase II	(WCMA)

OTHERS

Product Name	Company	Indication	Development Status	
NEUPOGEN® filgrastim (G-CSF)	Amgen *Thousand Oaks, CA*	treatment of neutropenia in HIV-infected patients	application submitted	
OraLease didofenac and hyaluronic acid (topical gel)	Hyal Pharmaceutical *Mississauga, Ontario*	treatment of painful conditions of aphthous ulcers	Phase II	(WMA)
Oxandrin™† oxandrolone	Bio-Technology General *Iselin, NJ*	weight loss in AIDS patients	Phase III	(WMA)
Provir™	Shaman Pharmaceuticals *S. San Francisco, CA*	AIDS-related diarrhea	Phase II	(WMA)
Remune™ immune-based therapy	Agouron Pharmaceuticals *La Jolla, CA* Immune Response *Carlsbad, CA*	HIV infection treatment	Phase III	(WCMAB)
Savvy™ 1.2% glyminox	Biosyn *Philadelphia, PA*	prevention of HIV transmission	Phase I	(WMA)
Thalomid thalidomide	Celgene *Warren, NJ*	AIDS wasting	Phase III completed	(WMA)
		aphthous stomatitis (ulcers)	Phase III	(WMA)
ziconotide†	Elan Pharmaceuticals *Menlo Park, CA*	management of severe pain (including HIV-infected patients)	Phase III completed	(WMAB)

APPROVED MEDICINES FOR AIDS AND RELATED CONDITIONS

Product Name	Company	Indication
ABELCET® amphotericin B lipid complex	The Liposome Company *Princeton, NJ*	treatment of severe systemic fungal infections in patients refractory to or intolerant of amphotericin B therapy
Alferon N Injection® interferon alfa-n3	Interferon Sciences *New Brunswick, NJ*	genital warts (condyloma acuminata)
AmBisome® liposomal amphotericin B	Fujisawa Pharmaceutical *Deerfield, IL* NeXstar Pharmaceuticals *Boulder, CO*	primary treatment for fever of unknown origin in neutropenic patients, visceral leishmaniasis, secondary treatment for certain systemic fungal infections
Amphocil™ amphotericin B cholesteryl sulfate lipid for injection	SEQUUS Pharmaceuticals *Menlo Park, CA*	aspergillosis, opportunistic systemic fungal infections
Bactrim™ trimethoprim and sulfamethoxazole	Hoffmann-La Roche *Nutley, NJ*	PCP prophylaxis and treatment
Biaxin™ clarithromycin	Abbott Laboratories *Abbott Park, IL*	*Mycobacterium avium* complex (MAC) prophylaxis and treatment
Combivir™ lamivudine/ zidovudine tablets	Glaxo Wellcome *Rsch. Triangle Park, NC*	HIV infection

APPROVED MEDICINES FOR AIDS AND RELATED CONDITIONS

Product Name	Company	Indication
Crixivan® indinavir sulfate	Merck *Whitehouse Station, NJ*	HIV infection
Cytovene® ganciclovir (IV)	Roche Bioscience *Palo Alto, CA*	CMV retinitis prophylaxis and treatment
Cytovene® ganciclovir (oral)	Roche Bioscience *Palo Alto, CA*	CMV retinitis maintenance treatment, CMV retinitis prophylaxis in AIDS patients
Daraprim® pyrimethamine	Glaxo Wellcome *Rsch. Triangle Park, NC*	toxoplasmosis treatment
DaunoXome® liposomal daunorubicin citrate	NeXstar Pharmaceuticals *Boulder, CO*	advanced AIDS-related Kaposi's sarcoma
Diflucan® fluconazole	Pfizer *New York, NY*	cryptococcal meningitis, candidiasis, pediatric use for candidiasis fungal infection prophylaxis and treatment
DOXIL® doxorubicin HCl liposome injection	SEQUUS Pharmaceuticals *Menlo Park, CA*	AIDS-related Kaposi's sarcoma
Epivir™ lamivudine (3TC)	Glaxo Wellcome *Rsch. Triangle Park, NC* BioChem Pharma *Laval, Quebec*	HIV infection
Famvir® famciclovir	SmithKline Beecham *Philadelphia, PA*	recurrent herpes simplex
Fortovase™ saquinavir (soft gel formulation)	Hoffmann-La Roche *Nutley, NJ*	treatment of HIV infection in adults in combination with other antiretroviral agents
Foscavir® Injection foscarnet sodium	Astra USA *Westborough, MA*	CMV retinitis in AIDS patients, acyclovir-resistant herpes simplex virus (HSV) in immunocompromised patients
Gamimune®-N immune globulin intravenous (human)	Bayer, Pharmaceutical Division *Berkeley, CA*	pediatric HIV infection
HIVID® zalcitabine	Hoffmann-La Roche *Nutley, NJ*	in combination with Retrovir® for treatment of adult patients with advanced HIV infection (CD4≤300) who have demonstrated significant clinical or immunologic deterioration, monotherapy for HIV infection in adults with advanced HIV disease
Intron® A interferon alfa-2b (recombinant)	Schering-Plough *Madison, NJ*	Kaposi's sarcoma
Invirase® saquinavir mesylate	Hoffmann-La Roche *Nutley, NJ*	treatment of HIV infection in combination with nucleoside analogues
Marinol® dronabinol	Unimed Pharmaceuticals *Buffalo Grove, IL*	treatment of anorexia associated with weight loss in AIDS patients
Megace® megestrol acetate (oral suspension)	Bristol-Myers Squibb *Princeton, NJ*	treatment of anorexia and cachexia associated with AIDS

Approved Medicines for AIDS and Related Conditions

Product Name	Company	Indication
Mepron® atovaquone	Glaxo Wellcome *Rsch. Triangle Park, NC*	treatment of mild to moderate PCP in individuals intolerant to TMP/SMX
Mycobutin® rifabutin	Pharmacia & Upjohn *Kalamazoo, MI*	MAC prophylaxis in patients with advanced HIV infection
NebuPent® aerosol pentamidine isethionate	Fujisawa Pharmaceutical *Deerfield, IL*	PCP prophylaxis
Neutrexin™ trimetrexate glucuronate for injection	U.S. Bioscience *W. Conshohocken, PA*	treatment of moderate-to-severe PCP in immunocompromised patients, including patients with AIDS, who are intolerant of or are refractory to TMP/SMX or for whom TMP/SMX is contraindicated
Nizoral® 2% Shampoo ketoconazole	Janssen Pharmaceutica *Titusville, NJ*	tinea versicolor (fungal infection)
Norvir® ritonavir	Abbott Laboratories *Abbott Park, IL*	HIV infection (pediatric and adult)
PASER™ Extended Release Granules para-aminosalicylic acid 4-aminosalicylic acid (PAS)	Jacobus Pharmaceutical *Princeton, NJ*	tuberculosis treatment
Pentam® 300 pentamidine isethionate (IM & IV)	Fujisawa Pharmaceutical *Deerfield, IL*	PCP treatment
Priftin® rifapentine	Hoechst Marion Roussel *Kansas City, MO*	tuberculosis
PROCRIT® epoetin alfa	Ortho Biotech *Raritan, NJ*	anemia in Retrovir®-treated HIV-infected patients
Rescriptor® delvaridine	Pharmacia & Upjohn *Kalamazoo, MI*	HIV infection, AIDS
Retrovir® zidovudine (AZT)	Glaxo Wellcome *Rsch. Triangle Park, NC*	HIV positive (asymptomatic [CD4<500] and symptomatic [ARC, AIDS]), pediatric and adult, prevention of maternal/fetal transmission of HIV infection
Roferon®-A interferon alfa-2a, recombinant/Roche	Hoffmann-La Roche *Nutley, NJ*	Kaposi's sarcoma
Septra® trimethoprim and sulfamethoxazole	Monarch Pharmaceuticals *Bristol, TN*	PCP prophylaxis and treatment
Serostim™ somatropin (rDNA origin) for injection	Serono Laboratories *Norwell, MA*	treatment of AIDS-associated cachexia (AIDS wasting)
Sporanox® Capsule itraconazole	Janssen Pharmaceutica *Titusville, NJ*	histoplasmosis, blastomycosis, second-line aspergillosis

APPROVED MEDICINES FOR AIDS AND RELATED CONDITIONS

Product Name	Company	Indication
Sporanox® **Oral Solution** itraconazole	Janssen Pharmaceutica *Titusville, NJ*	esophageal and oropharyngeal candidiasis
Sustiva™ efavirenz	Du Pont Pharmaceuticals *Wilmington, DE*	HIV infection
Taxol® paclitaxel	Bristol-Myers Squibb *Princeton, NJ*	AIDS-related Kaposi's sarcoma
Trovan™ trovafloxacin	Pfizer *New York, NY*	nosocomial pneumonia
Valtrex™ valacyclovir	Glaxo Wellcome *Rsch. Triangle Park, NC*	episodic treatment of recurrent genital herpes and herpes zoster in immunocompetent adults, suppression of genital herpes simplex virus (HSV)
VIDEX® didanosine (ddI)	Bristol-Myers Squibb *Princeton, NJ*	treatment of adult patients with advanced HIV infection who have received prolonged prior Retrovir® therapy, treatment of adult and pediatric patients (over 6 months of age) with advanced HIV infection who have demonstrated intolerance or significant clinical or immunologic deterioration during Retrovir® therapy
Viracept™ nelfinavir mesylate	Agouron Pharmaceuticals *La Jolla, CA*	HIV infection, AIDS (pediatric and adult)
Viramune® nevirapine	Boehringer Ingelheim Pharmaceuticals *Ridgefield, CT*	management of HIV infection in combination with VIDEX® and Retrovir® in previously treated patients for whom current therapy is deemed inadequate
Vistide® cidofovir injection	Gilead Sciences *Foster City, CA*	CMV retinitis in AIDS patients
Vitravene™ fomivirsen	Isis Pharmaceuticals *Carlsbad, CA*	CMV retinitis in AIDS patients
WinRho SD™ Rh_{0}(D) immune globulin intravenous (human)	Univax Biologics *Rockville, MD*	immune thrombocytopenic purpura (ITP) secondary to HIV infection
Zerit™ stavudine (d4T)	Bristol-Myers Squibb *Princeton, NJ*	HIV infection, pediatric HIV infection
Zithromax® azithromycin	Pfizer *New York, NY*	*Mycobacterium avium intracellulare* (MAI) infections (prophylaxis)
Zovirax® acyclovir	Glaxo Wellcome *Rsch. Triangle Park, NC*	herpes zoster/simplex

The content of this survey has been obtained through government and industry sources based on the latest information. **Survey current as of November 6, 1998** . The information may not be comprehensive. For more specific information about a particular product, contact the individual company directly. The entire series of "New Medicines in Development" is available on PhRMA's web site.

PhRMA Internet address: http://www.phrma.org

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GLOSSARY

acyclovir—A drug used to treat viral infections, such as **herpes simplex** and **herpes zoster (shingles)**.

AIDS—Acquired immune deficiency syndrome.

aphthous stomatitis (ulcers)—Clinical term for "canker sores," which are small, painful ulcers on the inside of the cheek, lip or underneath the tongue.

ARC—AIDS-related complex.

aspergillosis—Infection caused by aspergillus, a fungus found in old buildings or decaying plant matter.

asymptomatic—A medical term that means "without symptoms" or feelings of illness noticed by the patient.

blastomycosis—A rare, non-contagious infection caused by breathing in a particular fungus found in wood and soil. The infection originates in the respiratory tract and usually disseminates to the lungs, skin and bone.

cachexia—Profound and marked state of general ill health and malnutrition.

candidiasis—A fungal (*Candida*) infection, usually of the moist cutaneous areas of the body, including the skin, mouth, esophagus and respiratory tract.

CMV—Cytomegalovirus is sexually transmitted and can occur without symptoms or result in mild flu-like symptoms. As an opportunistic infection in AIDS patients, it can cause **CMV retinitis**, an inflammation of the retina that can lead to blindness if left untreated.

cryptococcal meningitis—A fungal infection affecting the three membranes (meninges) surrounding the brain and spinal cord.

cryptosporidiosis—Caused by a parasite (*Cryptosporidium parvum*) and characterized by chronic, profuse, watery diarrhea accompanied by fever, marked weight loss and enlarged lymph nodes.

genital herpes—See **herpes zoster/simplex.**

genital warts (condyloma acuminata)—Soft warts that grow in and around the entrance of the vagina and the anus and on the penis. They are transmitted by sexual contact and are caused by a **human papillomavirus.**

herpes zoster/simplex—Three strains of the herpes virus often occur in AIDS patients: **Herpes simplex virus I (HSV I)**, which causes cold sores or fever blisters on the mouth or around the eyes, can be transmitted to the genital region. The latent virus can reactivate by stress, trauma, other infections or suppression of the immune system to produce infection. **Herpes simplex II (HSV II)** causes painful sores of the anus or genitals. The virus may lie dormant in nerve tissue and can be reactivated to produce the sores. **Herpes varicella zoster virus (HVZ)**, also called **shingles**, consists of very painful blisters on the skin and follows nerve pathways. It may appear in adulthood as a result of having had chicken pox (caused by the varicella virus) as a child.

histoplasmosis—A disease caused by a fungal infection that can affect all the organs of the body.

HIV positive/infection/disease—Presence of antibodies to the human immunodeficiency virus (the virus that causes AIDS) in the blood. **HIV-I** refers to the most common strain of the virus found in U.S. AIDS patients.

IM—Intramuscular.

immune thrombocytopenic purpura—A condition in which there is destruction of blood platelets by the immune system. The reduced number of platelets may result in abnormal bleeding into the skin (purpura) and other parts of the body.

immunocompromised—A condition in which the immune system fails to defend the body against infection and tumors.

IV—Intravenous.

Kaposi's sarcoma—A rare malignant skin tumor that occurs in some AIDS patients. It can be accompanied by fever, enlarged lymph nodes and gastrointestinal problems.

leukoencephalopathy, progressive multifocal (PML)—Thought to be caused by a slow-replicating, unidentified virus, PML is an extremely rare progressive neurologic disease that occurs particularly in persons immunosuppressed by drugs or disease.

lymphoma—Cancers in which the cells of lymphoid tissue, found mainly in the lymph nodes and spleen, multiply unchecked. Lymphomas fall into two categories. One is Hodgkin's disease, characterized by a particular kind of abnormal cell. All others are **non-Hodgkin's lymphomas**, which vary in their malignancy according to the nature and activity of the abnormal cells.

MAC/MAI—*Mycobacterium avium intracellulare* (MAI) is a bacterial infection that can affect most internal organs, resulting in widely disseminated disease in AIDS patients. **MAC** refers to *Mycobacterium avium* complex.

mycoses—Diseases caused by fungi.

neuropathic pain—Caused by disease, inflammation, or damage to the peripheral nerves, which connect the central nervous system (brain and spinal cord) to the sense organs, muscles, glands, and internal organs.

neutropenia—An abnormally low number of neutrophils (a type of white blood cell) in the circulating blood. An inadequate neutrophil count leaves a patient vulnerable to bacterial and fungal infections.

NIAID—National Institute of Allergy and Infectious Diseases.

nosocomial—Originating or taking place in a hospital.

PCP—*Pneumocystis carinii* pneumonia. A type of lung infection found rarely in the general population but present in nearly 80 percent of all AIDS patients at some time during the course of the disease.

prophylaxis—Treatment intended to preserve health and prevent the spread of disease.

prurigo nodularis—A chronic inflammatory skin disease marked by itchy papules (tiny lumps).

suppression—Treatment intended to keep infection under control and to prevent its progression.

symptomatic—Subjective changes in the body or its functions that may indicate disease or phase of disease, as reported by the patient.

tinea versicolor—A chronic non-inflammatory fungal infection of the skin.

TMP/SMX—Refers to **trimethoprim-sulfamethoxazole**, an approved drug therapy for preventing and treating PCP.

toxoplasmosis—A disease due to infection with the protozoa *Toxoplasma gondii*, frequently causing focal encephalitis (inflammation of the brain).

visceral leishmaniasis—A severe infectious disease marked by fever, progressive anemia, low levels of leukocytes (white blood cells) and enlargement of the spleen and liver.

wasting syndromes—Any number of conditions, such as **anorexia** and **cachexia**, resulting in a loss of body mass, notably protein.

FACTS ABOUT AIDS[1]

	U.S. AIDS Deaths through December 1997	U.S. AIDS Cases through December 1997
Adults/Adolescents	385,968	633,000
Pediatric (under age 13)	4,724	8,086
TOTAL	**390,692**	**641,086**

- The death rate from AIDS dropped by 47 percent in 1997, the biggest single-year decline in history for a major cause of death. Nearly 16,000 fewer people died of AIDS in 1997 than in 1996. The decline was largely due to the increasing use of combination anti-retroviral therapy, including protease inhibitors.
- The rate of new HIV infections in this country—about 40,000 per year—continues at an unacceptably high level.[2]
- Between 1992 and 1996, perinatally acquired AIDS fell 43 percent, dropping another 30 percent in 1997.[3]
- Of the 633,000 cases of AIDS reported in the United States, 84.5 percent were males aged 13 and older, and 15.5 percent were females aged 13 and older.
- For those ages 25-44, HIV dropped from the leading cause of death in 1995 to third-leading in 1996 and fifth-leading in 1997.
- In 1996, an estimated 32,000 people died from HIV/AIDS.

Facts about Opportunistic Infections (OIs)

- The estimated incidence of AIDS OIs in the United States in 1997 was 57,500.
- Of people reported with AIDS-defining OIs, 65 percent were reported with severe HIV-related immunosuppression.
- **Candidiasis** is an important emerging fungal disease. The incidence of hospital-acquired, invasive candidiasis increased 10-fold over the decade of the 1980s.[4] Candidiasis is an opportunistic infection found in more than 90 percent of patients that have had an illness associated with AIDS.[5]
- **Cryptosporidiosis**, a common OI intestinal disease found in people with AIDS, has been found in 15 percent of AIDS patients in the United States.[6]
- Infection with the parasite ***Cryptosporidium*** is among the most common causes of diarrhea in persons with AIDS in the United States.[7]
- **Cytomegalovirus retinitis (CMV)** is an OI that affects at least 40 percent of people with AIDS and is the leading cause of visual loss in this patient population.[8]
- **Hepatitis B** virus infects 100,000-140,000 Americans annually. It is 100 times more infectious than the virus that causes AIDS. In the United States, there are between 1-1.25 million people with chronic hepatitis B infections who can infect other household members and sexual contacts.[9]
- **Human papillomavirus (HPV)** is one of the most common causes of sexually transmitted diseases (STDs) in the world. Experts estimate that as many as 24 million Americans are infected with HPV.[2]
- **Kaposi's sarcoma** is the most common tumor in AIDS patients. It is estimated that about 8,000 to 12,000 new cases are diagnosed in the United States each year.[10]
- **Progressive multifocal leukoencephalopathy (PML)**, a brain-related complication of AIDS, is almost always found in people with late-stage HIV disease. For the period 1981-1995, as many as 5 percent of people with AIDS had PML. Fewer than 89 percent survived more than one year after diagnosis, but 11 percent lived longer than a year with either partial or complete remission.[11]
- **Lymphoma** is a relatively late manifestation of HIV infection; 12 to 16 percent of HIV-infected individuals will eventually die of the disease.[12]
- ***Mycobacterium avium* complex (MAC)** is the most common and probably the most debilitating opportunistic infection of people with HIV/AIDS. MAC is a principal cause of death for AIDS patients.[13]

Sources:

1. Unless otherwise noted, all data were provided by the U.S. Centers for Disease Control and Prevention (CDC).
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3. American Medical Association
4. National Center for Infectious Diseases
5. Project Inform Fact Sheet, Candidiasis, 1/28/96
6. Gay Men's Health Crisis
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8. Chiron Vision
9. National Coalition for Adult Immunization
10. National Cancer Institute
11. San Francisco AIDS Foundation
12. Healthcare Communications Group, L.L.C., 1998
13. National Center for Genome Resources