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CORNERSTONE DEDICATION CEREMONY FOR THE DALE AND BETTY BUMPERS VACCINE RESEARCH CENTER MEET AND GREET PARTICIPANTS
June 9, 1999

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COMMENTS:

Here's the list of outside groups which NIH/HHS will be inviting to the VRE event. Please let us know if ~~you~~ you/OPE has any additions. Thanks for your input.

_____Pages [including this cover]

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Fax Cover Sheet

Date: 3 June, 1999
To: Todd Summers
Fax Number: 202-456-2438
From: Deborah Birx
Ext: 1149

Subject: Briefing Information

Total number of pages 4 including this sheet

Comments: Enclosed you will find the briefing information you requested. This was prepared by my office and is still being officially reviewed by the command. You should expect to receive an official version from the command, but the substance will be the same. If you prefer an e-mail version, please call Kelley Lennon at ext. 1072 and she can forward it to you.

Thank you.

DRAFT

INFORMATION PAPER

MCMR-PLA
2 June 1999

SUBJECT: DEPARTMENT OF DEFENSE (U.S. ARMY) HUMAN IMMUNODEFICIENCY VIRUS RESEARCH PROGRAM

BACKGROUND:

Human Immunodeficiency Virus (HIV), the virus responsible for AIDS, poses a significant threat to the U.S. Military. HIV infection is epidemic in almost every less well developed and potentially unstable region of the world, and the risk for exposure to HIV by DoD personnel is high. Over 19,000 new infections with HIV occur throughout the world each day. In response to this military-relevant infectious disease threat, a congressionally-mandated research program was begun in 1986 to assess and mitigate the impact on U.S. Military readiness by monitoring the spread of HIV infection in military forces and by developing methods to prevent infection. As lead agent for infectious disease research in DoD, the Army has a highly targeted program to address the military concerns of HIV: Surveillance of infection rates and HIV subtypes around the world; **development of vaccines** and other countermeasures to prevent infection; and clinical studies to avoid immune deficiency. The primary focus of this Program is the prevention of HIV infection in military personnel.

PROGRAM HIGHLIGHTS:

- HIV infection is relevant to today's military. Over 400 new infections occur annually in service members, with a significant number occurring during overseas deployments. This uniformly fatal disease also induces significant acute morbidity, which affects fighting readiness.

- The principal objective of the U.S. Military HIV Research Program is protection and preservation of the fighting force through primary prevention of HIV infection, **ultimately by administration of an effective, preventive vaccine.** *Success in achieving this goal will have broad-reaching application for HIV prevention in civilian populations worldwide.*

  Currently, Program efforts focus on:

  1) education of the force

  2) surveillance and threat assessment, and

  3) a vigorous program of vaccine discovery, development, and evaluation.

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- The Program collaborates with multiple U.S. and international agencies and a network of DoD Overseas Biomedical Research Laboratories to provide an effective surveillance network to monitor the emergence of virological trends in the pandemic and **to serve as permanent platforms for evaluation of candidate vaccines in overseas endemic settings.**

- **The Program has effectively leveraged its vaccine R&D funding and resources to pursue a number of novel candidate vaccine approaches and formulations. Extensive use of Cooperative Research and Development Agreements (CRADAs) with private industry greatly extends the resources of the U.S. Military HIV Research Program.**

VACCINE R&D SUMMARY:

The U.S. Military HIV Vaccine Research and Development efforts augment and complement efforts of the DHHS. Domestic clinical trials of candidate vaccines based on the strains of HIV indigenous to the U.S. (genotype B) are conducted to gain familiarity with these novel constructs, to develop an initial safety database to facilitate transition of specific vaccine approaches for evaluation overseas with candidates specifically designed from the HIV viruses which circulate overseas, and, importantly, to harmonize (with the NIH) assays which are critical for evaluating the effects of vaccine candidates on the human immune system.

- Currently, three distinct classes of HIV vaccine candidates (recombinant subunit envelope, canarypox-vectored genes with subunit envelope boost, and facilitated plasmid DNA) are in clinical trials conducted by the U.S. Military HIV Vaccine Program. Clinical evaluation of these constructs is underway in the United States and Thailand. The focus of the Vaccine Development and Evaluation Program in the U.S. and Thailand is to select and then evaluate the most immunogenic of **safe candidate vaccines** for their ability to protect individuals from HIV infection. The current lead candidate is canarypox-vectored HIV (vCP1521) manufactured by Pasteur-Merrieux-Connaught, boosted by a recombinant subunit envelope (clade E, manufacturer TBD). Large-scale field efficacy testing is planned to begin in collaboration with the government of Thailand during 2001.

- Pre-clinical R&D of a number of novel candidates is being pursued by the Program, primarily through CRADAs with industry partners. In addition to small animal and macaque studies of novel immunogens (many of which are conducted under the auspices of an NIH contract as a simian vaccine evaluation unit), the U.S. Military HIV Research Program is poised to play a roll in the initial manufacture (by good manufacturing practices – GMP) of several of these new candidate vaccines. This is possible through the Walter Reed Army Institute of Research bioproduction facility at Forest Glen, Maryland. Currently, the Program plans to produce (with corporate partner AlphaVax and the International AIDS Vaccine Initiative) HIV particles based on the Venezuelan Equine Encephalitis replicon platform, and (with corporate partner AVANT Immunotherapeutics) recombinant anthrax antigen-vectored HIV core polypeptides which are called Therapore™HIV.

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- Field efforts to prepare for large-scale testing of promising HIV candidate vaccines have been underway in Thailand since 1991. During this period, there has existed an effective alliance with multiple U.S. Government agencies (CDC, NIH, USAID). Efforts in collaboration with the Royal Thai Government have been extensive: national HIV surveillance, development of multiple field sites as potential venues for efficacy testing of promising candidates, creation of a phase I/II AIDS vaccine evaluation network at four academic and government sites, development of extensive in-country laboratory capability and technology transfer to conduct vaccine evaluations, and successful planning, implementation and completion of large multicenter human clinical trials. All vaccine development in Thailand is conducted with candidates incorporating elements of the indigenous Thai HIV (genotype E).

- More recent efforts, beginning last year, have focused on development of a similar field capability in collaboration with government and academic collaborations in Uganda. Vaccine development opportunities in Uganda are unique and complementary to other program efforts. Distinct genotypes of HIV (A and D) co-circulate in this region of the world. The ability to address efficacy and its breadth requires access to sites with such viral diversity. This is a critically important question to be answered in developing vaccines that will be effective for military populations. Again, close coordination with other U.S. Government agencies is envisioned, and will be critical to the success of U.S.-sponsored vaccine development efforts in Uganda.

AVAC "EIGHT YEARS AND COUNTING... WHAT WILL SPEED DEVELOPMENT OF AN AIDS VACCINE?":

In general, we find AVAC's assessments to be accurate. We believe we will be able to conduct a field efficacy trial in Thailand, as stated above. In regards to our pre-clinical activities, we are quite diverse; our resources must be spread in such as way as to avoid excessive risk and optimize our opportunities for devlopment and evaluation of potentially improved future generation candidate vaccines.

A new initiative within the military infectious disease research program and the U.S. Army Medical Research and Materiel Command (of which this Program is one element) calls for annual external peer review – which may meet AVAC's suggestion for increased public input and scientific review.

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*** ACTIVITY REPORT ***
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*** TX REPORT ***
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TRANSMISSION OK

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SUBADDRESS	
CONNECTION ID	
ST. TIME	06/03 16:38
USAGE T	01'12
PGS. SENT	6
RESULT	OK

FACSIMILE

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May 1999

STATUS OF AIDS VACCINE RESEARCH AT NIH

Background

In his commencement address at Morgan State University on May 18, 1997, President Clinton asked the nation to commit to creating a vaccine against AIDS within 10 years. To accelerate this quest, he announced that a new Vaccine Research Center would be established at the National Institutes of Health (NIH).

Last year, AIDS vaccine advocates marked the anniversary of this announcement by designating May 18 as AIDS Vaccine Awareness Day. Communities nationwide organized teach-ins and other activities to educate people about AIDS vaccine research and to honor the several thousand U.S. volunteers who have already participated in clinical trials of experimental AIDS vaccines. The National Institute of Allergy and Infectious Diseases (NIAID) supported their efforts by coordinating national media contacts. Similar events are planned again this year to mark this anniversary.

This document summarizes progress in NIH-sponsored AIDS vaccine research in the two years since the President's commencement address at Morgan State University.

Vaccine Research Center at the NIH

- Since the announcement of the new Vaccine Research Center, and even before building began, a core group of NIH scientists with expertise in immunology, virology, and vaccine development has met regularly to help develop the concept of the "Center without walls."
- Construction of the $30 million, 50,000-square-foot Center building started in August 1998 and is expected to be completed in mid-2000. When fully operational, the state-of-the-art facility will house around 100 scientists and support staff. The scientists will be able to take a vaccine from concept through vaccine design and pilot-lot production.
- On April 11, 1999, Dr. Gary Nabel of the University of Michigan was named the Center's first director. Dr. Nabel has begun recruiting scientific staff and charting the Center's research course. He is a superb scientist who has excelled at the frontiers of virology, immunology, gene therapy, and molecular biology. His research career has focused on developing gene therapy for AIDS and novel vaccine strategies against cancer and the Ebola virus.
- This summer, the NIH will dedicate the cornerstone of the Center building. The event is being planned to include the President and Health and Human Services Secretary Donna E. Shalala as well as former U.S. Senator Dale Bumpers and his wife Betty Bumpers. The building will be named the Dale and Betty Bumpers Vaccine Research Center.

Budget and Leadership

- NIH has increased funding for AIDS vaccine research by 100 percent since FY 1995. In FY 1999, funding for AIDS vaccine research increased by 30 percent over the previous year to about $194 million. The President's NIH budget request for FY 2000 includes $204 million for AIDS vaccine research.
- In May 1998, NIH Director Dr. Harold Varmus named Dr. Neal Nathanson as new director of the NIH Office of AIDS Research. Dr. Nathanson, a world-renowned

virologist from the University of Pennsylvania Medical Center, has a broad background in virology, epidemiology, and public health and is a member of the NIH AIDS Vaccine Research Committee chaired by Dr. David Baltimore.

- In September 1998, Dr. Margaret (Peggy) I. Johnston rejoined NIH to assume two key posts in AIDS vaccine research at the National Institute of Allergy and Infectious Diseases (NIAID). She is Assistant Director for HIV/AIDS Vaccines at NIAID, a newly created position; and Associate Director of the Vaccine and Prevention Research Program in NIAID's Division of AIDS. Dr. Johnston returned to NIH after serving two years as the top scientific administrator at the International AIDS Vaccine Initiative, a renowned not-for-profit organization whose mission is to foster the development of safe, effective, and accessible preventive HIV vaccines for use throughout the world.
- With the appointments of Drs. Nathanson and Johnston, and the establishment of an entirely new Vaccine Research Center led by Dr. Nabel, the NIH AIDS vaccine program has developed a strong leadership base and infrastructure for AIDS vaccine development.

NIH AIDS Vaccine Research Committee

- The AIDS Vaccine Research Committee, chaired by Nobel Laureate Dr. David Baltimore, was formed in early 1997 to improve coordination of NIH-supported AIDS vaccine activities. It has provided guidance to the NIH in developing a comprehensive research program aimed at developing a safe and effective AIDS vaccine. It has also advised the NIH about scientific opportunities, gaps in knowledge, and future directions of AIDS vaccine research, most notably contributing to the genesis and science of the Innovation Grant Program. A workshop co-sponsored by NIAID and the AVRC on May 3-5, 1999, brought together more than 700 researchers to discuss new research findings in HIV vaccine development.

Clinical Trials Progress

- Since 1987, more than 3,000 non-HIV-infected volunteers have enrolled in 52 NIAID-supported preventive vaccine studies (50 Phase 1 safety studies; two Phase 2 safety and immunogenicity studies) involving 27 vaccines. These trials have been conducted primarily at six university-based AIDS Vaccine Evaluation Group (AVEG) sites nationwide. NIAID's HIV Prevention Trials Network (HIVNET), which includes international as well as U.S. sites, and NIAID investigators in Bethesda have also led or helped conduct some of these trials.
- Earlier this year, NIAID opened the first AIDS vaccine trial in Africa, an important step for global vaccine development. This small study in Uganda will help determine if it is necessary to tailor-make vaccines for different parts of the world. The vaccine being tested is based on subtype B, the HIV variant most often found in the United States and Europe. The researchers will determine if the immunized volunteers develop immune responses that in laboratory experiments cross-react to the two other HIV subtypes, A and D, the cause of most infections in Uganda.
- NIAID has initiated clinical trials of several novel vaccine approaches in the past two years. One trial is testing novel routes of immunization. The vaccine is applied topically to the moist tissues lining the vagina, rectum, and other mucosal surfaces where most HIV infections are acquired. A second study employs a non-disease-causing form of *Salmonella* bacteria to present an HIV protein to the immune system. This is the first vaccine that NIAID has funded all the way from the laboratory to clinical trials without industry sponsorship. A third study is combining a new

adjuvant (GM-CSF) with an experimental vaccine to see if the adjuvant can enhance the immune responses stimulated by the vaccine.

- In June 1997, NIAID initiated its second intermediate-size AIDS vaccine trial and quickly completed enrollment of 420 volunteers. The Phase 2 trial is testing a combination of two different vaccines. This strategy offers the advantage of stimulating both components of the immune system. One vaccine, based on a harmless canarypox virus designed to carry genes coding for a few pieces of HIV, primarily stimulates cellular immune responses that kill HIV-infected cells. The other vaccine, a genetically engineered surface protein of HIV (gp120), primarily stimulates anti-HIV antibodies. Researchers are completing their analysis of the trial data. Trials that are ongoing and planned will assess modified versions of the canarypox-based vaccine to see if they stimulate better immune responses. The data from all these studies will form the basis for a future decision about proceeding to larger-scale efficacy trials that will determine if the vaccine protects against HIV infection.
- In June 1998, the first efficacy trial of an AIDS vaccine in the United States got underway. Although the trial is funded primarily by the vaccine manufacturer, VAXGEN, NIAID will collaborate with the company on ancillary studies of the samples they will collect. The trial, which is testing a bivalent subunit vaccine made from the gp120 surface protein of HIV, is expected to last three years and enroll 5,000 people in the United States, Canada, and the Netherlands.

NIAID's Restructured AIDS Vaccine Program

New initiatives have been launched by NIAID's Division of AIDS to enhance opportunities for vaccine discovery and to help move vaccine concepts from basic research through clinical trials. The overall objective is to increase the number of new, innovative and promising vaccine concepts flowing through the pipeline.

- *Innovation Grant Program for Approaches in HIV Vaccine Research*: In September 1997, NIAID announced the selection of the first 49 grantees for a new program to foster innovative research on AIDS vaccines. More grant awards have subsequently been made; the current total is 97. The Innovation Grant Program encourages early exploration of novel and innovative vaccine concepts and attempts to attract scientists currently working in other areas.
- *HIV Vaccine Research and Design Program*: This initiative supports traditional mid-stage, targeted research, including animal model studies, to help develop promising vaccine concepts.
- *Integrated Preclinical/Clinical Program:* This program funds the iterative processes of product development, optimization, and refinement, including clinical studies.
- Other programs that will be implemented in the near future include HIV Vaccine Design and Development Teams, which will advance vaccine concepts to the product stage, a program to encourage innovative research on improved technologies for evaluating immune responses, and resources to help advance products from preclinical to clinical research.
- NIAID has begun the process to restructure the AVEU and HIVNET networks. The reorganization will consolidate scientific responsibility and create two comprehensive networks for AIDS vaccine trials and non-vaccine HIV prevention research.

Recent Scientific Advances

- *Knowing Surface Structures Could Help Block Virus:* NIH-supported scientists have determined the 3-D crystal structures of two surface proteins of HIV, gp120 and gp41, which help the virus attach to cells. Studies of intermediate molecules formed

during virus-cell fusion are helping explain the step-by-step process by which HIV enters the cell, which could lead to new vaccine approaches for inducing antibodies to block its entry.

- *Removing Sugar Coating Improves Immunity*: The outer surface protein of HIV is coated with sugar molecules that may prevent it from being recognized by the immune system. An NIAID grantee has shown that selectively deleting certain of these sugar molecules from SIV, the monkey equivalent of HIV, can bring the mutant virus under immune control much faster than the normal virus. Hence, using similarly modified HIV molecules as potential vaccines may improve the immune response.
- *Testing New Vaccine Vectors*: A non-disease causing Venezuelan equine encephalitis (VEE) virus suitable for humans was modified to carry selected HIV genes. When given to mice, the vaccine induced both antibodies to the virus and immune responses that killed HIV-infected cells. These experiments, and additional experiments in monkeys, demonstrate the potential for VEE-based vaccines to stimulate both arms of the immune system and to control the level of virus. Another novel vector, a weakened form of vaccinia virus called MVA, has been developed and has been shown to induce good immune responses in rodents and monkeys.
- *Novel Form of HIV Induces Good Immunity:* Scientists have developed a novel vaccine based on HIV fusion molecules exposed only by freezing the virus in the act of infecting a cell. This virus-cell fusion mixture, when injected into mice genetically engineered to ignore key human proteins on the cells, made antibodies against the virus-cell fusion mixture. In laboratory tests, these antibodies were able to neutralize 23 of 24 strains of HIV representing a variety of different genetic subtypes and all isolated from infected individuals.
- *DNA Vaccine Protects Monkeys:* Several investigators have been pursuing research on DNA vaccines. Most recently, a chimeric DNA vaccine made from harmless genes of HIV and SIV, its monkey equivalent, has shown promise in monkey studies. The vaccine, when combined with "booster shots" made from a specially engineered virus carrying the same genes, seemed to protect animals later given doses of a live hybrid virus made from HIV and SIV. The vaccine did not keep the animals from getting infected but seemed to keep the hybrid virus under control, making it undetectable in the blood.
- *New Tests Developed to Measure Cellular Immunity:* During the past year, several new assays to measure cell-mediated immunity have been developed. These assays allow researchers to better compare the effectiveness of vaccine candidates in stimulating critical immune responses.

Other Federal Agencies

Within the federal government, several other agencies also have a role in AIDS vaccine research. For example, the Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD), and the Food and Drug Administration (FDA are some of the other federal agencies invested in AIDS vaccine development. The roles of these different agencies in AIDS vaccine development are related and complementary and span the spectrum from basic research to licensure and program implementation. For example, CDC conducts epidemiologic studies and surveillance needed to define health priorities, and develops recommendations for vaccine use. The FDA establishes standards for the processes, facilities, and pre- and post-licensing studies needed to insure the safety and effectiveness of vaccines. And the NIH supports most of the basic

and clinical research in fields such as immunology and microbiology that lead to vaccine development.

OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT
THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: Liz Symmy
FROM: Todd Summers
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DATE:
FAX NUMBER: 690-7755
TOTAL NO. OF PAGES INCLUDING COVER:
PHONE NUMBER:
RE:

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

I have yet to get any names from OPL (~~Sara~~ Jena Roscoe, Barbara Woolley or Richard Socarides). These are mine/Sandy's. Strong consideration should be given to inviting entire AIDS council – They're meeting on 6/7-6/8. Call Daniel for contact info (395-1445)

Todd

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Todd A. Summers
06/02/99 08:38:27 AM

Record Type: Record

To:

cc:
Subject: WH Invites for Bumpers Event

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Thurgood Marshall/CA
Elena Kagan/DPC
Cynthia Rice/DPC
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Dr. Paul Delay/USAID
Bob Hattoy/Interior

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Robert Fogel/Chair, International Subcommitte, PACHA
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E-mail: bgw2@cdc.gov

Zewdie, Debrework

Company: World Bank
Bus: (202) 473-9414

Front Page

Next Story

NIH RECORD

Michigan's Nabel To Head VRC

On the Front Page...

Dr. Gary Nabel

That new Vaccine Research Center director Dr. Gary Nabel's name is spelled almost like Nobel only seems to magnify the hope placed in him and the center being built for a staff of almost 100 workers he will name following his arrival from the University of Michigan on Apr. 11. It took nearly 2 years to find a VRC director, and NIH authorities are confident they found a good one.

Continued...

"Gary Nabel is a superb scientist who has excelled at the frontiers of virology, immunology, gene therapy and molecular biology," said NIH director Dr. Harold Varmus. "As a result of his experiences with clinical and laboratory research in academia and extensive interactions with industrial partners, he is remarkably well prepared to lead the complex, multidisciplinary and collaborative activities that will be required to develop an effective HIV vaccine. His recent work — on novel strategies for gene therapy for AIDS and for vaccines against cancer and Ebola virus — illustrates the imagination and drive that he will bring to the NIH Vaccine Research Center."

The center's initial focus is to develop candidate vaccines against HIV, though it is anticipated that other diseases such as malaria will also be targeted.

Nabel, who officially joins NIH on Apr. 11, comes from the University of Michigan in Ann Arbor, where he is the Henry Sewall professor of internal medicine and professor of biological chemistry; he also is a Howard Hughes Medical Institute investigator. Initial plans call for him to occupy temporary space in Bldg. 9, then move eventually to the A wing of Bldg. 10 until the VRC, now under construction, is complete.

The VRC receives joint funding from the National Institute of Allergy and Infectious Diseases and the National Cancer Institute and is spearheaded by those two institutes and the Office of AIDS Research.

In May 1997, President Clinton set a goal to develop an AIDS vaccine within 10 years. NIH responded by creating the VRC, a state-of-the-art biomedical research laboratory that will facilitate the development of vaccines. The center will stimulate multidisciplinary research, from basic and clinical immunology and virology through vaccine design and production. The VRC will integrate modern immunological science with a detailed understanding of how HIV disease develops, the creation of novel vaccine vectors and immunogens and new vaccination strategies.

"I'm honored and excited by the opportunity to contribute to vaccine development through this unique center at the NIH," Nabel said. "The development of an AIDS vaccine remains a formidable challenge and an urgent need, and the VRC hopes to drive the development of effective

vaccines with our partners in academia, industry and the public."

Currently, the VRC is a center without walls, involving a core group of NIH scientists with expertise in immunology, virology and vaccine development. Construction of a 5-story facility adjacent to Bldg. 37, which began in August 1998, is expected to be completed by mid-2000. When the VRC is fully operational, Nabel will oversee about 100 scientists and support staff.

A close look inside the "footprint" of the new Vaccine Research Center near Bldg. 37 shows workmen busy on the foundation of what will eventually be a 5-story structure. Completion is set for mid-2000 on the fast-track project that will eventually house new VRC director Dr. Gary Nabel and a staff of about 100 employees.

His interest in HIV gene therapy, supported by NIAID for the past 10 years, began with basic research and progressed to clinical studies. He and his colleagues developed Rev M10, a competitive inhibitor of the HIV Rev protein, which is required for HIV replication. The Rev M10 gene, when introduced into cells, makes a protein that prevents authentic REV from binding to the cell, thereby short-circuiting HIV's replication cycle. In 1996, they reported on the first HIV gene therapy trial, in which three HIV-infected patients had been infused with their own CD4+ T cells that had been modified with the Rev M10 antiviral gene. The scientists found that CD4+ T cells containing Rev M10 survive longer in the blood than unmodified cells, with no adverse side effects. His group continues work to improve this novel therapeutic strategy.

Nabel is also one of the first researchers to develop a DNA-based therapeutic vaccine against cancer. He and his colleagues have used direct gene transfer to introduce therapeutic proteins into patients with melanoma. Their clinical studies were among the first to demonstrate the feasibility and safety of this approach. NCI has supported this research for 8 years.

He also has applied his gene therapy expertise to the deadly Ebola virus. In late 1997, Nabel led a group of researchers who reported on their successful experiments in guinea pigs showing that a DNA-based vaccine could generate protective immune responses to Ebola virus.

Nabel graduated *magna cum laude* from Harvard College in 1975. He then entered the university's M.D.-Ph.D. program, completing his Ph.D. in 1980 and his M.D. 2 years later. He continued to divide his time between research and medical training. From 1980 to 1984, he worked as a postdoctoral research fellow in the laboratory of immunopatho-logy at Dana Farber Cancer Institute in Boston. Meanwhile, after completing his medical degree, he pursued an internship and residency training in internal medicine at Boston's Brigham and Women's Hospital. In 1985, he joined the laboratory of Dr. David Baltimore at the Whitehead Institute in Cambridge, working there for 2 years as a research associate. Baltimore, now president of California Institute of Technology, chairs the NIH AIDS vaccine research committee.

In 1987, Nabel became an assistant professor of internal medicine and assistant professor of biological chemistry at the University of Michigan. He also was named an assistant investigator of the Howard Hughes Medical Institute there.

Nabel has served on several NIH advisory committees, including the NIAID AIDS research advisory committee, which he chaired from 1996-1997.

Last year, he was elected a member of the Institute of Medicine of the National Academy of Sciences. In addition to his faculty positions, Nabel has been director of the Center for Gene Therapy at the University of Michigan Medical Center since 1997, and codirector of the University of Michigan Center for Molecular Medicine since 1994. He currently is associate editor of the *Journal of Virology* and the *Journal of Clinical Investigation* and serves on the editorial boards of several other journals.

His wife, Dr. Elizabeth G. Nabel, professor of internal medicine and physiology at Michigan, will join NHLBI as director of clinical branches.

Up to Top

Jewell Erickson

DRAFT – 9:00 am – May 26

Cornerstone Dedication Ceremony for the
Dale and Betty Bumpers Vaccine Research Center
June 9, 1999

Program of Events *[D R A F T]*

Pre-Program:

The event is to be located in a large tent situated outside the NIH Clinical Center in the vicinity of the construction site for the new building.

- While waiting for ceremony to begin, the general audience will be entertained by live music. We propose to include the following:
  - The World Children's Choir, a highly regarded group that has previously performed at similar events
  - A jazz musical ensemble, if available
- Beside the main tent, there will be a Holding Area with light refreshments in which speakers and guests of the Bumpers will wait with NIH Director Dr. Varmus and Secretary Shalala. We anticipate the President will first stop here when he arrives and greet the principals before entering the main tent.

Program:

We propose the following agenda:

1. Dr. Varmus – offers a brief welcome and introduces the Secretary 1
2. Sec. Shalala – delivers remarks, introduces the President 3-5
3. President – delivers remarks ~~8~~ 10
4. Unveiling of the cornerstone 5
5. Following the unveiling, a memento (cornerstone miniature) will be presented to the Bumpers 5
6. Dale Bumpers (and possibly Betty Bumpers) – to deliver remarks 3
7. Conclusion of ~~Ceremony:~~ some final remarks by Dr. Varmus will end with a song ~~by~~ the World Children's Choir 3

* Note - Senator Harkin, who initiated the effort to name the building, is being considered as a possible candidate to give remarks.

Pre-

~~Post~~-Ceremony Scientific Briefing:

NIH is proposing to provide a briefing on the AIDS vaccine. It will be held near the tent in the nearby Conte Building (Building 49) in the first floor conference room.

Proposed Briefing Relating to AIDS Vaccine Research
Building 49, NIH Campus
June 9, 1999

- Harold Varmus, NIH Director-- Overview/Introduction

- Anthony Fauci, NIAID Director–Need for an NIH vaccine, domestic and global levels; NIH successes in developing specific vaccines that have profound impact worldwide.

- Neal Nathanson, Director, Office of AIDS Research–The new Vaccine Research Center as part of NIH's broad strategy for developing an AIDS vaccine; coordination of intramural (on NIH campus) and extramural (grants around the country) efforts.

- David Baltimore (Caltech), head of NIH's AIDS Vaccine Research Committee–Innovative approaches for developing an AIDS vaccine; pipeline of scientific ideas and filling in the gaps in knowledge.

- Gary Nabel, new head of NIH's Vaccine Research Center–Vision for the new VRC.

Large, colorful posters will be used; no slides.

Additional people in attendance: Secretary Shalala, Sandra Thurman, the Bumpers(? where would their "event guests" go?), Arnold Levine (author of The Levine Report that called for more effort on vaccines), Gerry Keusch (head of NIH's Fogarty International Center), Bill Paul (former head of OAR), Richard Klausner (director of NCI), Michael Gottesman (NIH Deputy Director for Intramural Research), Peggy Johnston (NIAID, head of vaccine development), John LaMontagne (NIAID deputy director), Carole Heilman (NIAID), Jack Whitescarver (OAR).

AHS Chief of Staff

~~$3,000 - 4,000~~ ~~8-9~~

8.000

$10,000

SCHEDULE OF THE PRESIDENT
FOR
WEDNESDAY, JUNE 9, 1999

Draft Schedule

SCHEDULING DIRECTOR:	STEPHANIE STREETT
	HOME: 202-332-5651
	OFFICE: 202-456-2823
	WHCA PAGER: 4824
WEATHER:	WASHINGTON, D.C.

Schedule of the President
for
Wednesday, June 9, 1999
Draft Schedule

DOWN UNTIL 12:00 PM

12:00 pm- 12:15 pm		**MEETING** LOCATION TBD Staff Contact: John Podesta
TBD		**BRIEFING** LOCATION TBD Staff Contact: Thurgood Marshall, Jr.
12:30	pm	**THE PRESIDENT** departs The White House via motorcade en route Marriott Wardman Park Hotel [drive time: tbd]
12:40	pm	**THE PRESIDENT** arrives Marriott Wardman Park Hotel
12:45 pm- 1:45 pm		**REMARKS TO CIVIL RIGHTS LAW ENFORCEMENT ROUNDTABLE** LOCATION TBD Marriott Wardman Park Hotel Remarks: Staff Contact: Thurgood Marshall, Jr. Event Coordinator: **PRESS TBD**
1:55	pm	**THE PRESIDENT** departs Marriott Wardman Park Hotel via motorcade en route National Institute of Health Campus, Bethesda, Maryland [drive time: tbd]
2:25	pm	**THE PRESIDENT** arrives National Institute of Health Campus

2:30	pm-	**MEET AND GREET**
2:40	pm	ROOM TBD National Institute of Health Staff Contact: Event Coordinator: Laura Graham **CLOSED PRESS**
2:45	pm-	**DEDICATION CEREMONY FOR THE DALE AND BETTY BUMPERS**
3:30	pm	**VACCINE RESEARCH CENTER** OUTDOOR TENT National Institute of Health Campus Remarks: June Slow Staff Contact: Bruce Reed, Sandra Thurman Event Coordinator: Laura Graham **OPEN PRESS** **Note: There will be approximately 800 guests in attendance.**
3:40	pm	**THE PRESIDENT** departs National Institute of Health Campus via motorcade en route The White House [drive time: tbd]
4:10	pm	**THE PRESIDENT** arrives The White House
TBD		**HOLD FOR POSSIBLE CONGRESSIONAL MEETING** LOCATION TBD Staff Contact: Larry Stein

EVENING OFF

BC/HRC RON

THE WHITE HOUSE
WASHINGTON, DC

Gregory Roa
OCPL
Office of the Director
NIH
Tel. 301-496-5787
Fax301-496-0017
Email greg.roa@nih.gov

facsimile transmittal

To:	TODD SUMMERS	Fax:	202-456-2438
From:	Greg Roa , NIH/OD	Date:	05/26/99
Re:	**Seeking Approval of VRC Invitation Text**	Pages:	1
CC:	Todd Summers		

x Urgent x For Review Please Comment Please Reply ☐ Please Recycl

Mr. Summers, Anne Thomas asked me to send you the attached language for the VRC invitation. If you have any questions or comments, please contact me, Greg Roa, at

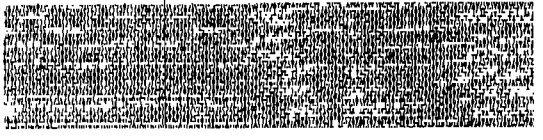
Tel 301-496-5787

Fax 301-496-0017

Email greg.roa@nih.gov

Many thanks.

NIH Event



Donna E. Shalala
Secretary of Health and Human Services
and
Harold Varmus
Director, National Institutes of Health
request the pleasure of your company
at the
Cornerstone Dedication Ceremony
for the
Dale and Betty Bumpers
Vaccine Research Center

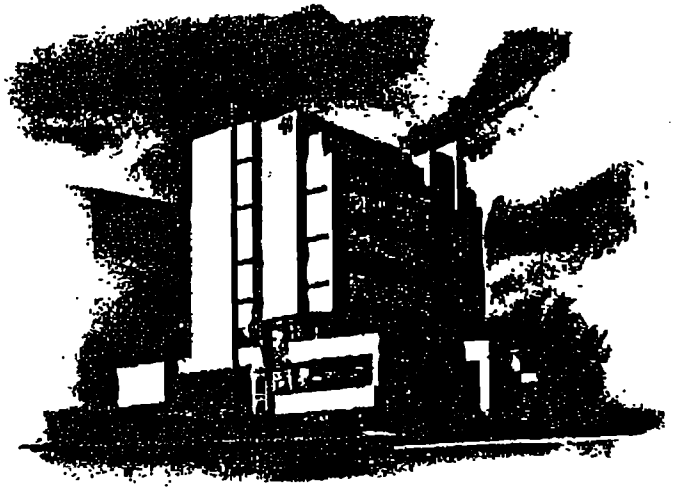
On the afternoon of
Wednesday, June 9, 1999

National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland

Please respond by Monday, June 7, to Ms. Judy Grosberg , 301/496-6756; this number will also provide a recorded message with the time of the ceremony. Please inform us of any special accommodation needs.

Guests must present this card to gain entrance to the ceremony tent.

Seating will begin one-and-a-half hours prior to the ceremony.



Harold Varmus
Director of the National Institutes of Health
requests the pleasure of your company
at the
CORNERSTONE DEDICATION CEREMONY
for the

DALE AND BETTY BUMPERS VACCINE RESEARCH CENTER

Thursday, April 29, 1999
10:00 A.M.
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland

Please respond by April 19 to Ms. Judy Grosberg • 301/496-6756
All guests must be seated by 9:50 A.M.
Please inform us of any special accommodation needs.

VACCINE RESEARCH CENTER EVENT

June 9, 1999

→ I. Invitations CIBOs

II. Program/Agenda

III. Scientific Briefing

IV. Logistics

V. Other Principals

FAX TRANSMISSION

NIH OFFICE OF AIDS RESEARCH
BUILDING 31, ROOM 4C02
BETHESDA, MD 20892
301-496-0357
FAX: 301-496-2119

To:	Todd Summers	**Date:**	May 20, 1999
Fax #:	202-456-2438	**Pages:**	6, including this cover sheet.
From:	Wendy Wertheimer		
Subject:	Status of AIDS Vaccine Research at NIH		

COMMENTS:

Todd,

Here is the background document prepared for you regarding the status of AIDS vaccine research. We can also send you the file via e-mail. Talk to you soon.

May 1999
STATUS OF AIDS VACCINE RESEARCH AT NIH

Background
In his commencement address at Morgan State University on May 18, 1997, President Clinton asked the nation to commit to creating a vaccine against AIDS within 10 years. To accelerate this quest, he announced that a new Vaccine Research Center would be established at the National Institutes of Health (NIH).

Last year, AIDS vaccine advocates marked the anniversary of this announcement by designating May 18 as AIDS Vaccine Awareness Day. Communities nationwide organized teach-ins and other activities to educate people about AIDS vaccine research and to honor the several thousand U.S. volunteers who have already participated in clinical trials of experimental AIDS vaccines. The National Institute of Allergy and Infectious Diseases (NIAID) supported their efforts by coordinating national media contacts. Similar events are planned again this year to mark this anniversary.

This document summarizes progress in NIH-sponsored AIDS vaccine research in the two years since the President's commencement address at Morgan State University.

Vaccine Research Center at the NIH
- Since the announcement of the new Vaccine Research Center, and even before building began, a core group of NIH scientists with expertise in immunology, virology, and vaccine development has met regularly to help develop the concept of the "Center without walls."
- Construction of the $30 million, 50,000-square-foot Center building started in August 1998 and is expected to be completed in mid-2000. When fully operational, the state-of-the-art facility will house around 100 scientists and support staff. The scientists will be able to take a vaccine from concept through vaccine design and pilot-lot production.
- On April 11, 1999, Dr. Gary Nabel of the University of Michigan was named the Center's first director. Dr. Nabel has begun recruiting scientific staff and charting the Center's research course. He is a superb scientist who has excelled at the frontiers of virology, immunology, gene therapy, and molecular biology. His research career has focused on developing gene therapy for AIDS and novel vaccine strategies against cancer and the Ebola virus.
- This summer, the NIH will dedicate the cornerstone of the Center building. The event is being planned to include the President and Health and Human Services Secretary Donna E. Shalala as well as former U.S. Senator Dale Bumpers and his wife Betty Bumpers. The building will be named the Dale and Betty Bumpers Vaccine Research Center.

Budget and Leadership
- NIH has increased funding for AIDS vaccine research by 100 percent since FY 1995. In FY 1999, funding for AIDS vaccine research increased by 30 percent over the previous year to about $194 million. The President's NIH budget request for FY 2000 includes $204 million for AIDS vaccine research.

- In May 1998, NIH Director Dr. Harold Varmus named Dr. Neal Nathanson as new director of the NIH Office of AIDS Research. Dr. Nathanson, a world-renowned virologist from the University of Pennsylvania Medical Center, has a broad background in virology, epidemiology, and public health and is a member of the NIH AIDS Vaccine Research Committee chaired by Dr. David Baltimore.
- In September 1998, Dr. Margaret (Peggy) I. Johnston rejoined NIH to assume two key posts in AIDS vaccine research at the National Institute of Allergy and Infectious Diseases (NIAID). She is Assistant Director for HIV/AIDS Vaccines at NIAID, a newly created position; and Associate Director of the Vaccine and Prevention Research Program in NIAID's Division of AIDS. Dr. Johnston returned to NIH after serving two years as the top scientific administrator at the International AIDS Vaccine Initiative, a renowned not-for-profit organization whose mission is to foster the development of safe, effective, and accessible preventive HIV vaccines for use throughout the world.
- With the appointments of Drs. Nathanson and Johnston, and the establishment of an entirely new Vaccine Research Center led by Dr. Nabel, the NIH AIDS vaccine program has developed a strong leadership base and infrastructure for AIDS vaccine development.

NIH AIDS Vaccine Research Committee

- The AIDS Vaccine Research Committee, chaired by Nobel Laureate Dr. David Baltimore, was formed in early 1997 to improve coordination of NIH-supported AIDS vaccine activities. It has provided guidance to the NIH in developing a comprehensive research program aimed at developing a safe and effective AIDS vaccine. It has also advised the NIH about scientific opportunities, gaps in knowledge, and future directions of AIDS vaccine research, most notably contributing to the genesis and science of the Innovation Grant Program. A workshop co-sponsored by NIAID and the AVRC on May 3-5, 1999, brought together more than 700 researchers to discuss new research findings in HIV vaccine development.

Clinical Trials Progress

- Since 1987, more than 3,000 non-HIV-infected volunteers have enrolled in 52 NIAID-supported preventive vaccine studies (50 Phase 1 safety studies; two Phase 2 safety and immunogenicity studies) involving 27 vaccines. These trials have been conducted primarily at six university-based AIDS Vaccine Evaluation Group (AVEG) sites nationwide. NIAID's HIV Prevention Trials Network (HIVNET), which includes international as well as U.S. sites, and NIAID investigators in Bethesda have also led or helped conduct some of these trials.
- Earlier this year, NIAID opened the first AIDS vaccine trial in Africa, an important step for global vaccine development. This small study in Uganda will help determine if it is necessary to tailor-make vaccines for different parts of the world. The vaccine being tested is based on subtype B, the HIV variant most often found in the United States and Europe. The researchers will determine if the immunized volunteers develop immune responses that in laboratory experiments cross-react to the two other HIV subtypes, A and D, the cause of most infections in Uganda.
- NIAID has initiated clinical trials of several novel vaccine approaches in the past two years. One trial is testing novel routes of immunization. The vaccine is applied topically to the moist tissues lining the vagina, rectum, and other mucosal surfaces

where most HIV infections are acquired. A second study employs a non-disease-causing form of *Salmonella* bacteria to present an HIV protein to the immune system. This is the first vaccine that NIAID has funded all the way from the laboratory to clinical trials without industry sponsorship. A third study is combining a new adjuvant (GM-CSF) with an experimental vaccine to see if the adjuvant can enhance the immune responses stimulated by the vaccine.

- In June 1997, NIAID initiated its second intermediate-size AIDS vaccine trial and quickly completed enrollment of 420 volunteers. The Phase 2 trial is testing a combination of two different vaccines. This strategy offers the advantage of stimulating both components of the immune system. One vaccine, based on a harmless canarypox virus designed to carry genes coding for a few pieces of HIV, primarily stimulates cellular immune responses that kill HIV-infected cells. The other vaccine, a genetically engineered surface protein of HIV (gp120), primarily stimulates anti-HIV antibodies. Researchers are completing their analysis of the trial data. Trials that are ongoing and planned will assess modified versions of the canarypox-based vaccine to see if they stimulate better immune responses. The data from all these studies will form the basis for a future decision about proceeding to larger-scale efficacy trials that will determine if the vaccine protects against HIV infection.
- In June 1998, the first efficacy trial of an AIDS vaccine in the United States got underway. Although the trial is funded primarily by the vaccine manufacturer, VAXGEN, NIAID will collaborate with the company on ancillary studies of the samples they will collect. The trial, which is testing a bivalent subunit vaccine made from the gp120 surface protein of HIV, is expected to last three years and enroll 5,000 people in the United States, Canada, and the Netherlands.

NIAID's Restructured AIDS Vaccine Program

New initiatives have been launched by NIAID's Division of AIDS to enhance opportunities for vaccine discovery and to help move vaccine concepts from basic research through clinical trials. The overall objective is to increase the number of new, innovative and promising vaccine concepts flowing through the pipeline.

- *Innovation Grant Program for Approaches in HIV Vaccine Research*: In September 1997, NIAID announced the selection of the first 49 grantees for a new program to foster innovative research on AIDS vaccines. More grant awards have subsequently been made; the current total is 97. The Innovation Grant Program encourages early exploration of novel and innovative vaccine concepts and attempts to attract scientists currently working in other areas.
- *HIV Vaccine Research and Design Program*: This initiative supports traditional mid-stage, targeted research, including animal model studies, to help develop promising vaccine concepts.
- *Integrated Preclinical/Clinical Program:* This program funds the iterative processes of product development, optimization, and refinement, including clinical studies.
- Other programs that will be implemented in the near future include HIV Vaccine Design and Development Teams, which will advance vaccine concepts to the product stage, a program to encourage innovative research on improved technologies for evaluating immune responses, and resources to help advance products from preclinical to clinical research.

- NIAID has begun the process to restructure the AVEU and HIVNET networks. The reorganization will consolidate scientific responsibility and create two comprehensive networks for AIDS vaccine trials and non-vaccine HIV prevention research.

Recent Scientific Advances

- *Knowing Surface Structures Could Help Block Virus:* NIH-supported scientists have determined the 3-D crystal structures of two surface proteins of HIV, gp120 and gp41, which help the virus attach to cells. Studies of intermediate molecules formed during virus-cell fusion are helping explain the step-by-step process by which HIV enters the cell, which could lead to new vaccine approaches for inducing antibodies to block its entry.
- *Removing Sugar Coating Improves Immunity:* The outer surface protein of HIV is coated with sugar molecules that may prevent it from being recognized by the immune system. An NIAID grantee has shown that selectively deleting certain of these sugar molecules from SIV, the monkey equivalent of HIV, can bring the mutant virus under immune control much faster than the normal virus. Hence, using similarly modified HIV molecules as potential vaccines may improve the immune response.
- *Testing New Vaccine Vectors:* A non-disease causing Venezuelan equine encephalitis (VEE) virus suitable for humans was modified to carry selected HIV genes. When given to mice, the vaccine induced both antibodies to the virus and immune responses that killed HIV-infected cells. These experiments, and additional experiments in monkeys, demonstrate the potential for VEE-based vaccines to stimulate both arms of the immune system and to control the level of virus. Another novel vector, a weakened form of vaccinia virus called MVA, has been developed and has been shown to induce good immune responses in rodents and monkeys.
- *Novel Form of HIV Induces Good Immunity:* Scientists have developed a novel vaccine based on HIV fusion molecules exposed only by freezing the virus in the act of infecting a cell. This virus-cell fusion mixture, when injected into mice genetically engineered to ignore key human proteins on the cells, made antibodies against the virus-cell fusion mixture. In laboratory tests, these antibodies were able to neutralize 23 of 24 strains of HIV representing a variety of different genetic subtypes and all isolated from infected individuals.
- *DNA Vaccine Protects Monkeys:* Several investigators have been pursuing research on DNA vaccines. Most recently, a chimeric DNA vaccine made from harmless genes of HIV and SIV, its monkey equivalent, has shown promise in monkey studies. The vaccine, when combined with "booster shots" made from a specially engineered virus carrying the same genes, seemed to protect animals later given doses of a live hybrid virus made from HIV and SIV. The vaccine did not keep the animals from getting infected but seemed to keep the hybrid virus under control, making it undetectable in the blood.
- *New Tests Developed to Measure Cellular Immunity:* During the past year, several new assays to measure cell-mediated immunity have been developed. These assays allow researchers to better compare the effectiveness of vaccine candidates in stimulating critical immune responses.

Other Federal Agencies

Within the federal government, several other agencies also have a role in AIDS vaccine research. For example, the Centers for Disease Control and Prevention (CDC), the

Department of Defense (DoD), and the Food and Drug Administration (FDA are some of the other federal agencies invested in AIDS vaccine development. The roles of these different agencies in AIDS vaccine development are related and complementary and span the spectrum from basic research to licensure and program implementation. For example, CDC conducts epidemiologic studies and surveillance needed to define health priorities, and develops recommendations for vaccine use. The FDA establishes standards for the processes, facilities, and pre- and post-licensing studies needed to insure the safety and effectiveness of vaccines. And the NIH supports most of the basic and clinical research in fields such as immunology and microbiology that lead to vaccine development.

FACSIMILE

DATE: 3/12/99
Deborah Adler

TO: Todd Summers
456-~~6777~~ 5657

FAX #: 456-2438

FROM: Rebecca Werbel
Office of the Chief of Staff
Department of Health and Human Services

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

Per my voice mail/e-mail, let me know if you have any questions or comments.

_____Pages [including this cover]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

MAR 11 1999

MEMORANDUM FOR THURGOOD MARSHALL, JR.

I am requesting that the President join Secretary Shalala in participating in an event to dedicate the cornerstone of the Vaccine Research Center (VRC) building now under construction at the National Institutes of Health (NIH). The event will be held on Thursday, April 29, 1999, at the building site on the NIH campus beginning at 10:00 a.m. The Honorable and Mrs. Dale Bumpers will attend the event. The VRC Building is named the Dale and Betty Bumpers Vaccine Research Facility.

The President announced in his commencement address at Morgan State University in May 1997 that he would establish an AIDS vaccine research center at the NIH and summoned the nation's scientific and business community to make an AIDS vaccine "the first great triumph" of the 21st century. Plans were immediately launched to erect a building for this dedicated research facility, and construction of the VRC building on the NIH campus is progressing on schedule with a projected completion date of May 2000.

Attendees at the event will include patient advocacy group representatives, members of Congress, distinguished scientists, industry executives, and members of the press. Attendance is estimated at about 800 people.

The President's presence at this special event would further demonstrate his commitment to the fight against AIDS and reinforce his challenge to scientists and industry to develop a vaccine that would prevent further spread of this dreaded disease throughout the world.

Thank you for your assistance.

Mary Beth Donahue
Chief of Staff

Attachment

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 11 1999

MEMORANDUM FOR THE PRESIDENT

An event to dedicate the cornerstone of the Dale and Betty Bumpers Vaccine Research Facility at the National Institutes of Health (NIH) will be held on Thursday, April 29, 1999, 10:00 a.m., at the construction site on the NIH campus. Guests in attendance at the event will be Senator and Mrs. Dale Bumpers, members of Congress, distinguished scientists, industry executives, members of patient advocacy groups, and members of the press. Approximately 800 people are expected to attend.

The construction of this important "state of the art" research building began as a result of your announcement in the Morgan State University Commencement Address in May 1997 that a vaccine research center be established at the NIH initially dedicated to developing a vaccine against AIDS. The building is scheduled for completion in May 2000. Important scientific achievements have been made since the development of an AIDS vaccine became a high priority at the NIH. Though there are many scientific hurdles yet to surmount, there is greater hope now than ever before that a vaccine against this dreaded disease can be developed.

Your presence as a participant at this special event would underscore your support and commitment to the fight against AIDS worldwide and would serve to reaffirm your call to members of the G-8 to provide the necessary support to accelerate AIDS vaccine research.

Donna E. Shalala

SCHEDULE PROPOSAL TODAY'S DATE: 3/12/99

_____ ACCEPT _____ REGRET _____ PENDING

TO: Stephanie Streett
Assistant to the President and
Director of Scheduling

FROM: Thurgood Marshall, Jr.
Secretary to the Cabinet

REQUEST: Invitation for the President to participate in the dedication of the cornerstone for the Dale and Betty Bumpers Vaccine Research Facility at the National Institutes of Health Campus in Bethesda, Maryland.

PURPOSE: The President's participation in this event would provide an opportunity for the President to further demonstrate his commitment to the fight against AIDS and to reinforce his challenge to scientists and industry to develop a vaccine that would prevent further spread of HIV.

BACKGROUND: In his Morgan State University Commencement Address in May of 1997, the President challenged the scientific and business communities of the nation to develop a vaccine against HIV within the next ten years. On March 11, 1999, the President joined Secretary Shalala in announcing the appointment of Dr. Gary Nabel as the Director of the Vaccine Research Center at NIH.

PREVIOUS PARTICIPATION: None

DATE AND TIME:	Thursday, April 29, 1999, 10:00 a.m. (If this date or time conflicts with the President's schedule, other options can be discussed.)
BRIEFING TIME:	None
DURATION:	45 minutes
LOCATION:	NIH Campus, Bethesda, Maryland
PARTICIPANTS:	The President, Secretary Shalala, Senator and Mrs. Bumpers, Harold Varmus, Sandy Thurman, members of Congress, patient advocacy groups, distinguished scientists, industry executives, and members of the press. Approximately 800 people will attend.
OUTLINE OF EVENTS:	The program will be determined based on the availability of the participants.
REMARKS REQUIRED:	Yes, 10 minutes.
MEDIA COVERAGE:	Yes
VICE PRESIDENT'S ATTENDANCE:	If available.
FIRST LADY'S ATTENDANCE:	No
MRS. GORE'S ATTENDANCE:	No
RECOMMENDED BY:	Secretary Donna E. Shalala
CONTACT:	Jon Jennings Office of Cabinet Affairs (202)456-2572 fax: (202) 456-6704
ORIGIN OF PROPOSAL:	External

FACSIMILE

DATE: 4/5/99

TO: Todd Summers

FAX #: 456-2438

FROM: Rebecca Werbel / Liz Summy
Office of the Chief of Staff
Department of Health and Human Services

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

Per your conversation with Liz, the following is the agenda from Mrs. Clinton's last visit to NIH. If you can give us an idea of what she might like to do, HHS/NIH would be happy to put something together. Please let Liz or me know what your thoughts are.

Thanks

_____Pages [including this cover]

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Example

A 1 (2.5 HRS.) February 17, 1994

Visit of the First Lady,
Mrs. Hilary Clinton,
to the National Institutes of Health

10:00 Arrive front of the NIH Clinical Center
Greeted by Dr. Harold Varmus, NIH Director

10:03 Proceed to 2nd Floor

10:08 Tour Cancer Research Labs and Patient Ward with and Dr. Samuel Broder, Director, National Cancer Institute and Dr. Steven Rosenberg, Chief, Surgery Branch, (meet with patients?)

10:23 Proceed to 7th Floor

10:28 Tour Heart Research Labs and Patient Ward with Dr. Claude Lenfant, Director, National Heart, Lung, and Blood Institute and Dr. Stephen Epstein, Chief, Cardiology Branch, (meet with patients?)

10:43 Proceed to 11th Floor

10:48 Tour AIDS Research Labs and Patient Ward with Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Disease (meet with patients?)

11:03 Proceed to 13th Floor

11:08 Tour Pediatric Ward with Dr. Broder and Dr. Philip Pizzo, Chief, Pediatric Branch (meet with patients?)

11:18 Proceed to NIH Library

11:23 Meet with ICD Directors and OD Senior Staff

11:43 Proceed to Masur Auditorium

11:48 Speak at Masur

12:18 Depart rear of Clinical Center

12:23 Visit Children's Inn at NIH

12:33 Depart NIH

National Institute of Allergy and Infectious Diseases
National Institutes of Health

OFFICE OF COMMUNICATIONS AND PUBLIC LIAISON

DATE: 6-4-99 **TIME:** 3:20 pm

TO: Todd Summers

ORGANIZATION:

FAX # 202-456-2438

NO. OF PAGES INCLUDING COVER SHEET: Thanx

COMMENTS: Todd: Wendy Wertheimer asked that I send materials to prep the speechwriter for Wednesday's VRC event. Please call if you need more.

FROM: Leslie Fink

NIAID Office of Communications and Public Liaison
National Institutes of Health
Bldg. 31, Room 7A50
Bethesda, MD 20892

Tel. #: (301) 496-5717 (public) 402-1663 (media)
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DALE BUMPERS AND BETTY BUMPERS

The Dale and Betty Bumpers Vaccine Research Center is named in honor of two accomplished and tireless advocates of immunization who recognized it as a key to public health in the United States and around the world.

Dale Bumpers is best known for his long and distinguished career in public service in the U.S. Senate and his home state of Arkansas. His father, a member of the state legislature, instilled in him from an early age an interest in politics and government, and a deep sense of civic responsibility; discussions of local and national affairs were the centerpiece of the family dinner table. Early on, Dale Bumpers worked as a small-town attorney, owned and operated a hardware store, raised cattle, and became active in community affairs. He served in the Marines during World War II and returned to finish his education at the University of Arkansas and Northwestern University Law School. He ran for governor of Arkansas in 1970, defeating a former governor in the Democratic primary, and went on to serve two terms. During his first term, he became interested in the cause of childhood vaccination, thanks to his wife, Betty.

Dale Bumpers was elected to the U.S. Senate as an Arkansas Democrat in 1974 and was eventually reelected three more times. He became especially known, on Capitol Hill and throughout the nation, as a compelling orator and for his brilliant leadership on issues close to Americans' lives, such as health care, medical research (he has been a great friend of the NIH), education, homelessness, preservation of the environment, and the U.S. defense budget and strategy in the post-Cold War era.

Betty Bumpers has also enjoyed a long and distinguished career in service to the people of Arkansas, to the United States, and to the cause of child immunization. A former art teacher, she attended Iowa State University, the University of Arkansas, and the Chicago Academy of Fine Arts. Being a devoted mother of three children, she said, led her to dedicate her life to issues affecting children's health. She first became interested in child immunization when her husband

was a new governor. To maximize the promise of newly developed vaccines, The Centers for Disease Control asked all state First Ladies to lend their efforts to childhood immunization in their states. At the time, Arkansas had one of the lowest immunization rates in the United States. After Mrs. Bumpers set up a model system to immunize Arkansas children, the state eventually achieved one of the highest immunization rates and became a national model for other states. As she advocate for the immunization cause, she developed an expertise in working with public health officials and the political community to get the vaccination message out and put delivery systems into place. These skills served her well when she and Senator Bumpers came to Washington, DC.

In Washington, Mrs. Bumpers worked on immunization issues with other state governors' wives, including Rosalynn Carter of Georgia. When Jimmy Carter was elected president, Mrs. Bumpers contacted the new administration, explained the deficits in our country's immunization program, and urged that something be done to improve it. Her advocacy, and Mrs. Carter's, led to the 1977 National Childhood Immunization Initiative. Mrs. Bumpers and Mrs. Carter have also been credited with the existence of laws, now in every state, pertaining to vaccination at entry into school. As a result of these laws, over 95% of American children are immunized by the time they enter school.

Dale Bumpers worked tirelessly during his Senate career to bring vaccines and vaccine research to the attention of his colleagues and the American public. He became so well informed on issues surrounding immunization and vaccine-preventable diseases that Walter Orenstein, M.D., director of the National Immunization Program at the Centers for Disease Control, terms him a colleague and a world-class expert. The Senator consistently worked for the control and elimination of measles, and of polio; his efforts are one important reason that polio will soon be eliminated from the earth. In other efforts, he supported the purchase of *Haemophilus influenzae* type b vaccine. He convinced his colleagues that vaccines save money; for example, it is estimated that for every dollar spent on diphtheria-tetanus-pertussis vaccine, more than $30 is

saved in direct medical care costs. He obtained federal funding for state outreach programs to buy and administer vaccines. During lean times for domestic programs in the 1980s, he made sure funding levels of the national immunization program were maintained. He led efforts to establish a program to reward states, through grant incentives, for high immunization levels. He advocated preparing for outbreaks of vaccine-preventable diseases by establishing a stockpile of vaccines and supported their emergency purchase. He co-sponsored the first bill on Federal compensation for vaccine-related injuries.

Dale Bumpers also recognized that the public–health infrastructure was eroding, and had the foresight to provide a way to reverse that trend. The infrastructure resources that he helped put into place represent the operational heart of every current immunization program in the United States. On the Senate Appropriations Committee, he consistently supported both laboratory research and epidemiological studies in the control and prevention of disease, and saw the wisdom of coordinating U.S. national immunization efforts with other government programs, such as the Women, Infants and Children program.

Betty Bumpers, too, has gone on to more achievements on immunization issues. In 1991, she and Rosalynn Carter started a campaign called "Every Child By Two," spurred, in part, by a measles epidemic in 1989-1991 which brought the issue of childhood vaccination home to Americans. Over 55,000 cases of measles were reported to the Centers for the Disease Control; more than half were in non-immunized youngsters of preschool age. One hundred twenty-three people died of the disease. For the past eight years, Every Child By Two has worked toward the goals of ensuring that all children in America – including those who are medically underserved, have no or inadequate health insurance, are undocumented residents, or live in high-risk areas – are immunized on schedule from birth to age two, and that immunization delivery is institutionalized nationwide. Mrs. Bumpers travels the United States, meeting with grassroots immunization workers and encouraging and facilitating public-private and managed-care partnerships and school-based immunization clinics.

In recent years, Mrs. Bumpers has also worked on the global campaign to eradicate polio. In March 1998, she was invited to travel with a delegation to Cote d'Ivoire and Zimbabwe as part of the "Kick Polio Out of Africa" campaign and Africa's annual "National Immunization Days." She met with African health leaders and other diplomats, mingled with citizens, and even administered oral vaccines to children.

Mrs. Bumpers has served on the National Vaccine Advisory Committee and as a longtime member of several boards, including the National League for Nursing. In 1982, she founded Peace Links, today a national, non-profit organization that mobilizes citizens to work for violence prevention and peace building in their communities and around the world.

Dale and Betty Bumpers have received many national awards and honorary doctorates. Together, they have received the March of Dimes Citizen of the Year Award, the Excellence in Public Service Award from the American Academy of Pediatrics, and the Maxwell Finland Award from the National Foundation for Infectious Diseases.

Dale Bumpers retired from the Senate in 1998. Today, he is director of the Center for Defense Information in Washington, DC. In February 1998, he commented, in the wake of an Appropriations Committee hearing on measles and polio eradication, "We live at a time when government and politicians are the targets of great criticism... While the U.S. effort to support smallpox eradication, polio eradication, child health and child immunization is a consequence of enlightened self-interest, it also expresses our understanding, as Americans, of a responsibility to the world and to the future. It is the U.S. government at its very best." Dale and Betty Bumpers are the U.S. citizenry at its very best. The National Institutes of Health is proud to name its new Vaccine Research Center in their honor.

SENATOR DALE BUMPERS

A BIOGRAPHICAL SKETCH

First elected to the United States Senate in 1974, U.S. Senator Dale Bumpers is serving his fourth term as a Democratic Senator from Arkansas. He was re-elected in 1992 with more than 60 percent of the vote.

Before joining the U.S. Senate, Bumpers served two terms as Governor of Arkansas, where he reorganized state government and trimmed the number of state agencies from 69 to 13; doubled the number of State Parks; started the State Kindergarten Program and launched an initiative that doubled the number of doctors trained at Arkansas' only medical school.

Before entering politics, Bumpers lived in his home town of Charleston, where he practiced law; operated a small hardware, furniture, and appliance store; raised cattle; and pursued several other business interests. During those years, Bumpers was active also in community affairs, serving as city attorney, school board president, and president of the Chamber of Commerce.

After serving in the U.S. Marine Corps for three years in the South Pacific during World War II, Senator Bumpers returned to continue his undergraduate work at the University of Arkansas, and later received his law degree from Northwestern University.

Bumpers is married to the former Betty Flanagan of Charleston. They are the parents of three children, Brent, Bill, and Brooke, and they have six grandchildren.

A champion of the taxpayer and a foe of government waste, Senator Bumpers fought for a balanced budget long before it became a publicized national issue. He led the successful battle to cancel the $12 billion Superconducting Super Collider, and he is continuing his efforts to ground the $100 billion space station, a boondoggle he contends offers few, if any, scientific benefits. While supporting a strong but not bloated defense, Senator Bumpers has fought to eliminate Star Wars, a pipe dream that would make the heavens a battlefield and cost citizens hundreds of billions of dollars for an illusion of security; and the F-22, an unneeded fighter plane that sports a price tag of $180 million each.

From his position as the ranking member of the Senate Energy and Natural Resources Committee, Bumpers also fights policies that attack the common good. Calling it "the biggest ongoing scam in America," Senator Bumpers has, for nine years, sought to stop the giveaway of America's public lands. Since 1872, mining interests, many of them foreign-owned, have paid as little as $2.50 an acre for mineral-rich public lands and extracted billions of dollars worth of gold, silver, platinum and palladium while paying not a penny in royalties to American taxpayers. "Mining companies get the gold and the taxpayers get the shaft," he says of this staggering abuse of public assets.

Also, he has fought for nearly 20 years to bring competition to the operation of concessions in National Parks, which, because of preferential treatment for contracts, rake in about $700 million a year but offer taxpayers a meager 2.4 percent return on the use of their land.

Senator Bumpers was one of only three Senators to vote for the 1981 Reagan budget cuts but against the reckless 1981 tax cuts. Had a majority adopted his positions, federal budget deficits would have been eliminated by 1985.

A student of history with a profound respect for the intelligence, ideals and vision of the country's founders and a healthy skepticism of passing fads in economic and social theory, Senator Bumpers is hesitant to change the Constitution, which he calls a "sacred document."

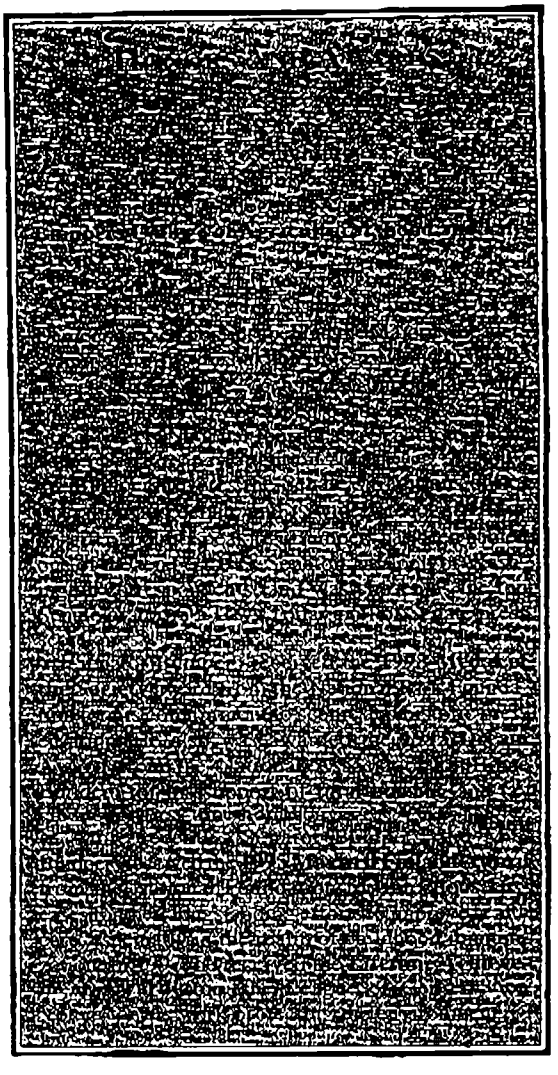
As a Senator from a rural state and the top ranking Democrat on the Senate Appropriations Subcommittee on Agriculture, Dale Bumpers has fought to protect family farmers, to expand rural housing and to promote rural development, especially the water and sewer programs that improve the quality of life and help bring jobs to rural areas.

A dedicated environmentalist, Senator Bumpers believes we must preserve America's natural heritage and warns that America's fate may hinge on stopping and preventing threats to our air, land, water and habitats. And he has played a crucial role in protecting the integrity of national historic sites, such as the Manassas Battlefield in Virginia.

Senator Bumpers and his wife Betty have long been national leaders in protecting the health of children by promoting childhood immunization. Their efforts have helped America reach a record high level of immunizations. Since 1991, Mrs. Bumpers and Rosalyn Carter have been actively involved in "Every Child by Two," a program dedicated to fully immunize every American child by the age of two.

In January, 1997, Senator Bumpers became the highest ranking Democratic member of the Senate Energy and Natural Resources Committee, and also in 1997 introduced the first comprehensive legislation of the 105th Congress to deregulate the electricity industry, which could save consumers billions of dollars. He also sits on the powerful Senate Appropriations Committee and is a member of the Small Business Committee.

During his tenure in the Senate, Bumpers has kept in close touch with the people of Arkansas, making more than 100 appearances in the state annually.



Center for Defense Information
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BIOGRAPHICAL DATA

Senator Dale Bumpers

Senator Dale Bumpers was first elected to the U.S. Senate in 1974. He served four terms as a Democratic Senator from Arkansas before he retired from the Senate at the end of 1998. Before joining the Senate, Bumpers served two terms as Governor of Arkansas, where he reorganized state government and trimmed the number of state agencies from 69 to 13; doubled the number of state parks; started the State Kindergarten Program and launched an initiative that doubled the number of doctors trained at Arkansas' only medical school.

Before entering politics, Bumpers lived in Charleston, Arkansas, where he practiced law; operated a small hardware, furniture and appliance store; and raised cattle. After serving in the U.S. Marine Corps for three years in the South Pacific during World War II, Senator Bumpers completed his undergraduate studies at the University of Arkansas and later received his law degree from Northwestern University.

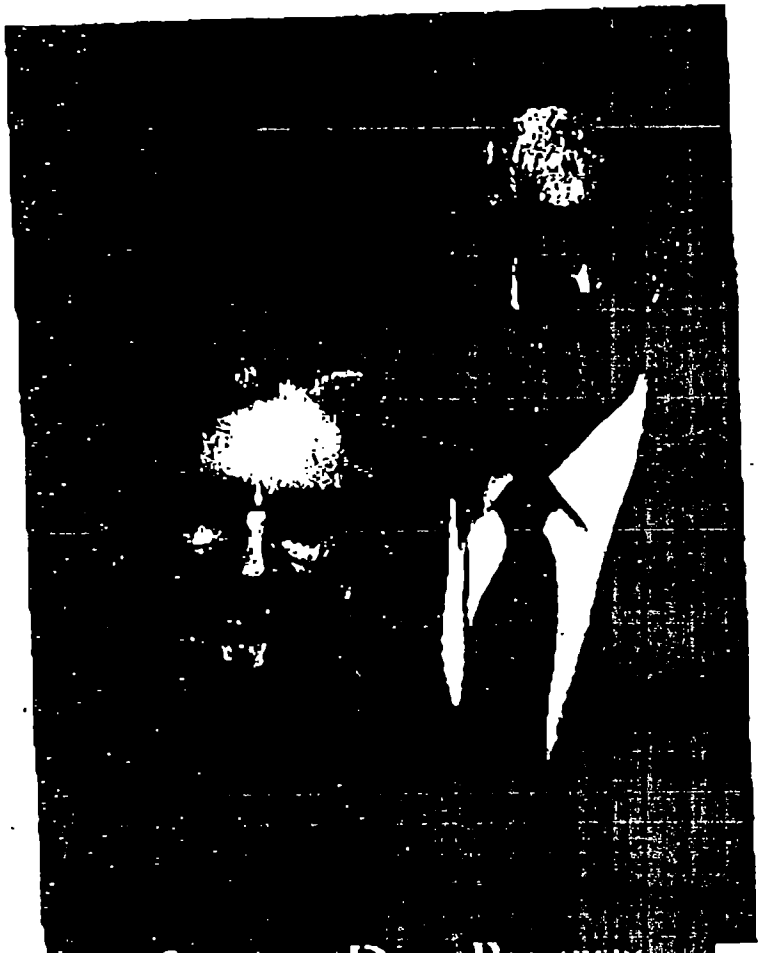
While in the Senate Bumpers advocated a strong but sane defense budget. He fought to eliminate President Reagan's Star Wars proposal, which he called a pipe dream that would make the heavens a battlefield and cost citizens hundreds of billions of dollars for an illusion of security. He also opposed the F-22, an unneeded fighter plane that sports a price tag of close to $200 million each. A champion of the taxpayer and a foe of government waste, Senator Bumpers fought for a balanced budget long before it became a national issue. He was one of only three Senators to vote for the 1981 Reagan budget cuts but against the1981 tax cuts. Had a majority adopted his positions, federal budget deficits would have been eliminated by 1985.

A student of history with a profound respect for the intelligence, ideals and vision of the country's founders and a healthy skepticism of passing fads in economic and social theory, Senator Bumpers consistently opposed irresponsible and ill-conceived proposals to change the Constitution, which he calls a "sacred document."

A dedicated environmentalist, Senator Bumpers believes we must preserve America's natural heritage and warns that America's fate may hinge on stopping and preventing further degradation of our natural resources, stopping global climate changes and arresting population growth around the world.

Bumpers was named one of the ten best U.S. Senators in a poll of Washington correspondents and was chosen as the top Senate orator in a USA Today poll of Senate press secretaries. He was described by the political weekly National Journal as a Senator to whom "other Senators pay attention."

Senator Bumpers joined the Center for Defense Information as Director in January, 1999. In that position he continues his advocacy for a defense budget that is based on national security considerations rather than political or economic considerations.



SENATOR DALE BUMPERS
AND MRS. BETTY F. BUMPERS

Maxwell Finland Award Recipients
1995

from the

National Foundation for Infectious Diseases

For 25 years the husband and wife team of Dale and Betty Bumpers have worked together to build protection against infectious childhood diseases.

"It was in 1971 when my husband was governor of Arkansas that I really got interested in children's immunization," Mrs. Bumpers recalls. The Centers for Disease Control and Prevention (CDC) had just asked all state governor's wives to participate in childhood immunization efforts for the childhood vaccines that were becoming available. Campaigns for immunization against poliomyelitis had been developed in the 1960s when measles vaccine was also licensed. A few years later came protection against mumps and rubella.

As the state's first lady and a board member of the Arkansas visiting nurse association, Betty Bumpers set up a model system to immunize children. "I made it my cause," she says. As she pursued this vigorously, the immunization rates in Arkansas children rose.

She learned how to work with public health officials, and discovered that getting political circles interested was the key to galvanizing programs. These lessons stood her in good stead when she came to Washington in 1975 as the wife of the newly elected senator from Arkansas.

It is hard today to appreciate what the attitude towards preventable childhood diseases was 20 years ago. "In fiscal year 1976, the budget for immunization was reduced to $4.96 million from $6.2 million," recalls Dr. Walter A. Orenstein, now director of CDC's National Immunization Program. "We were in the midst of a major measles epidemic with over 57,000 cases."

Immunization of children had not been organized, and interest was concentrated on each new vaccine as it appeared. Dr. Orenstein recalls: "We had data which showed that as federal funds for measles vaccination went up, measles cases went down. When funding fell, the cases went up." Former CDC official Dr. Bill Watson notes that "you could track immunization levels in the country by what was happening to the federal funds."

Mrs. Bumpers pursued her cause with other state governor's wives. One was Rosalynn Carter whose husband was the governor of Georgia. So, in 1977, when the Carters came to Washington as president and first lady, Mrs. Bumpers moved quickly to take advantage of this.

"Almost singlehandedly, Betty Bumpers was responsible for the remarkable improvement in immunization levels against childhood diseases in the United States."

She went to Mrs. Carter and, according to Dr. Alan R. Hinman, former director of the Immunization division at CDC, she said to the first lady: "You know it's a crying shame that the children in this country are not well-immunized." Mrs. Carter agreed and mentioned it to her husband. He in turn called it to the attention of his secretary of health, education and welfare, Joseph A. Califano, suggesting the secretary might do something about it.

Mr. Califano is not a man to ignore a good idea, especially when it comes from his president. The result was the Childhood Immunization Initiative of 1977. The program had two targets: the first was to raise to 90 percent the immunization levels in school children and the second was to put in place a mechanism to

maintain those levels. The Carter administration increased federal funds to about $13 million. "To us it seemed an incredible amount of money," says Dr. Hinman.

Almost singlehandedly, continues Dr. Hinman, Betty Bumpers was responsible for the remarkable improvement in immunization levels against childhood diseases in the United States.

"When Dale Bumpers came to Washington in 1977, he made childhood immunization one of his priorities. He convinced his congressional colleagues that vaccines were cost-effective."

Meanwhile the senator was also playing a vital role. When Dale Bumpers came to Washington in 1977, he made childhood immunization one of his priorities. He convinced his congressional colleagues that vaccines were cost-effective, according to one of his former staff assistants, Melissa Skolfield. For every dollar spent there was $10 or $15 saved on the medical costs of treating preventable illnesses. Senator Bumpers got federal grants for state outreach programs, which were funds to enable states to hire clinic nurses and to help buy vaccines.

While the senator pushed funding in Congress, Betty Bumpers, along with Mrs. Carter and the governor's wives network, was working to get all 50 states to require that children be vaccinated by the time they entered school. This mechanism is still in place today, and because of it 95 percent of our children are immunized by the age [illegible]ve and vaccine preventable diseases have sunk to record low levels. Mr. Calfano likes to tell how his daughter was once sent home from school because she did not have an adequate record of immunizations.

But these regulations were not enough. There was no mechanism to assure that children under the age of five were also protected. In 1989 measles started increasing again. By 1990 there was a full-blown epidemic. Cases had risen from 1,500 in 1983 to almost 28,000. By 1991, over 55,000 cases, including 160 deaths, were reported to the CDC. Nearly half of these cases occurred among pre-school children who had not been immunized. The lesson was clear. If vaccine preventable diseases were to be reduced, a program had to be set up to immunize these youngsters.

"No two people have influenced the effort to immunize children more than the senator and Betty Bumpers, whether it's through political leadership, interesting the right groups or in getting people to work together towards a common goal."

In January 1991, the then-chairman of the National Vaccine Advisory Committee, Dr. Vincent A. Fulginiti, went to the assistant secretary for health with a report that spelled out the barriers to preschool immunization such as insufficient personnel, limited clinic hours and too few clinic locations. The report pointed out that 80 percent of measles cases among children aged 16 months to five years could have been prevented if they had been immunized in a timely manner. So, that same year, public health officials mounted a major campaign to deal with missed opportunities for protecting children, creating a demand for preschool immunization.

Betty Bumpers and Rosalynn Carter, who were also aware of the situation, mounted a parallel campaign entitled Every Child by Two. This drew attention to the need; enlisted the help of national and local organizations; encouraged health care providers; and promoted national and local programs to institutionalize the immunization of every child by the age of two.

"What's going to save us are local health workers, both public and private, who are out in the field and doing their jobs as best they can," says Dr. Orenstein. "When Mrs. Bumpers visits them and tells them that what they are doing is important, it stimulates their interest and they feel their efforts are being rewarded. She has been invaluable."

Dale Bumpers' grasp of the subject impresses Dr. Orenstein. "Here's a US senator who has so many things for which he is responsible, and yet he has made himself into a technical expert on immunization. He really understands the immunization program and issues. I can talk to him as if he were a professional colleague. It's invaluable having someone that knowledgeable in the Senate.

"You have to respect what he says about immunization. It is always well thought through. He doesn't shoot from the hip and he's innovative." For example, the senator developed a program wherein states are awarded money based on how well they immunize their children. The better they do, the more money they earn.

There was less enthusiasm for funding immunization when Ronald Reagan and George Bush were in the White House. But Senator Bumpers never stopped working for childhood immunization. "In those years he may not have gotten much in the way of increases," his wife comments, "but he never let the level of funds drop.

"No two people have influenced the effort to immunize children more than the senator and Betty Bumpers," Dr. Orenstein sums up, "whether it's through political leadership, interesting the right groups or in getting people to work together towards a common goal."

"Here's a US senator who has so many things for which he is responsible, and yet he has made himself into a technical expert on immunization. He really understands the immunization program and issues. . . . It's invaluable having someone that knowledgeable in the Senate."

By keeping himself informed, Senator Bumpers has made it easier for public health officials to discuss issues with him. It has also paid off with his political colleagues. What Senator Bumpers says on immunization continues to be listened to with respect by both sides of the aisle.

According to Betty Bumpers, being a former governor's wife and a senator's spouse "gives you credibility. This helps a great deal. Most first ladies catch on very quickly and thoroughly enjoy sponsoring a good program that especially benefits children—and there are no negatives to that in the [illegible]te."

HIGHLIGHTS OF SEN. DALE BUMPERS' AND MS. BETTY BUMPERS' ADVOCACY OF VACCINES AND VACCINE RESEARCH

- July 1997: Chaired Senate Committee on Appropriations Subcommittee on Labor, Health and Human Services, and Education hearing on the subject of "National Immunization Program" examining the development of new vaccines and the challenges these products present for providers and states as they develop or revise immunization strategies. In his opening remarks, Senator Bumpers described the hearing as an opportunity to celebrate breakthroughs on several fronts, including the highest coverage rates in U.S. history and the development of new vaccines including one to prevent rotoviruses. He stated that he hoped the hearing would focus on how these breakthroughs have presented new challenges to public health officials including: the maintenance of high coverage levels; the distribution of products in a timely fashion; and the accommodation of increased costs.

- September 1998: Chaired Senate Committee on Appropriations Subcommittee on Labor, Health and Human Services, and Education hearing on the subject of "the Global Eradication of Polio and Measles."

- Since his Senate career began, he has been tireless in supporting the control and elimination of measles. He supported the purchase of Haemophilus influenzae b vaccine, recognized that the public sector infrastructure was eroding, and had the foresight to provide a way to reverse that trend. The infrastructure resources that the Senator ensured represent the operational heart of every current immunization program in the Country.

- Led efforts to establish a program to reward States through grant incentives that has been successful in preventing unnecessary disease by obtaining and maintaining high immunization levels.

- Led efforts to prepare for outbreaks of vaccine-preventable diseases by establishing a stockpile of vaccines and supported the emergency purchase of vaccines.

- When appropriations were tight and retrenchment was the order of the day, Sen. Bumpers ensured the continuation of the national immunization program.

- Sen. Bumpers has consistently supported the global eradication of polio. There has not been a case of wild virus polio in the United States for 19 years. Due to his support, and that of international organizations such a Rotary International, it now appears likely that a second disease--polio--will be eliminated from the earth.

- Through his service on the Appropriations Committee, Sen. Bumpers consistently supported both laboratory research and epidemiological studies in the control and prevention of disease, as well as the coordination of U.S. immunization efforts with other programs, such as WIC, to improve effectiveness and efficiency.

- Sen. Bumpers understood that not all vaccines are totally safe, and that a compensation program was essential to the overall success in averting vaccine-preventable diseases. Toward this end, he co-sponsored the National Childhood Vaccine Improvement Act of 1986, which would have established the National Vaccine-Injury Compensation Program as an elective alternative remedy to judicial action for vaccine-related injuries. A similar bill, creating a federal no-fault compensation program for vaccine-injured children, became law later that year.

- The Senator's wife, Betty, first peaked his interest in immunization when he was the Governor of Arkansas. In 1971, the CDC had just asked all state governors' wives to participate in childhood immunization efforts for the childhood vaccines that were becoming available. Campaigns for immunization against polio had been developed in the 1960s when measles vaccine was also licensed. A few years later came protection against mumps and rubella. In 1972, as Arkansas's first lady and a board member of the visiting nurse association, Betty Bumpers set up a model system to immunize children, succeeding in getting increased support for immunizations and improved immunization levels in Arkansas. As a result, the Bumper's family legacy was to convert a State with the Nation's lowest immunization levels and one of its highest measles rates, into a State with one of the highest immunization levels and one of the lowest measles rates. After Senator Bumpers was elected to the United States Senate, and Jimmy Carter was elected President in 1976, Betty contacted the new administration. She explained the deficits in our country's childhood immunization program, and urged that something be done to improve it. This produced the 1977 National Childhood Immunization Initiative and the beginning of an unparalleled record of support from the Senator and Betty Bumpers.

Shots by age two if they're important to you.

Every Child By Two

The Carter/Bumpers Campaign For Early Immunization

Betty Bumpers

Betty Bumpers is the co-founder of *Every Child by Two* along with Former First Lady Rosalynn Carter. Betty Bumpers is the wife of Senator Dale Bumpers (retired), a mother of three children, and a former art teacher. Bumpers received her education at Iowa State University, the University of Arkansas, and the Chicago Academy of Fine Arts.

During her husband's tenure as Governor of Arkansas, Betty Bumpers was the leader of a successful statewide immunization program for children, which was later used by the Centers for Disease Control as a national model for other states. During the presidency of Jimmy Carter, she worked with First Lady Rosalynn Carter to implement immunization programs state-by-state. She and Rosalynn Carter have been credited with the passage of laws mandating vaccination at school entry which now exist in every state. As a result of these laws, the United States has a 95% plus immunization rate for school enterers. Realizing the need to immunize our pre-school age children and the need to increase the immunization rates for our nation's un-insured, under-insured and un-documented children, they have continued their efforts through the Every Child By Two Program.

Betty Bumpers has served on the National Vaccine Advisory Committee and as a member of the Board for the National League for Nursing for six years, the All Kids Count Advisory Board, and the Family Place Project Advisory Committee for Libraries for Our Future.

In addition to her vigilant efforts to eliminate preventable diseases in our children, Betty Bumpers founded Peace Links, Women Against Nuclear War, in 1982. Peace Links, an international peace education group for women was a major force in ending the Nuclear Arms race and is still active in all fifty states. As we move away from the Cold War, they have re-focused their goal towards attaining peace within our communities by taking part in discussions with women and children throughout the world who strive to create a better place for our children to live.

Awards and Recognitions:

- 1998, Rotary International's Polio Eradication Champion award for extraordinary effort on behalf of all the children of the world to eradicate Polio.
- 1998, March of Dimes Citizen of the Year Award, presented to Senator and Betty Bumpers for a lifetime commitment to children's health and the eradication of Polio.
- 1997, National League for Nursing Isaac K. Beckes Award for service to the NLN by a non-nurse of national stature.
- 1997, Caring for Kids Award presented by Bell Atlantic.

Co-Founders:
Rosalynn Carter
Betty F. Bumpers

Executive Director:
Amy A. Pisani, MS

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E-mail: info@ecbt.org
Website: www.ecbt.org

•1993, Healthy Community National Award, The Community Foundations

•1993, The Surgeon General's Medallion, presented by US Surgeon General Antonia C. Novello

•1993, National Immunization Program Award, Centers for Disease Control

•1993, Friend of the Children Award, Southern Early Childhood Association

•1993, National Council of Jewish Women Award

•1992, Pediatric Nursing Humanitarian Award

•1987, Distinguished Citizen Award, presented by the Governor of Arkansas, the Arkansas Office of Volunteerism and KARK-TV, Channel 4.

•Honorary Doctor of Laws degrees from Hendrix College and the University of Arkansas at Little Rock.

•Excellence in Public Service Award presented by the American Academy of Pediatrics (jointly with Senator Bumpers) for child advocacy.

DRAFT

National Institute of Allergy and Infectious Diseases

National Institutes of Health

June 1999

~~NIH~~ Vaccine Research at NIH

Vaccines provide safe, cost effective and efficient means of preventing illness, disability and death from infectious diseases. Indeed, vaccines are the only human interventions that have actually eradicated diseases: the last case of smallpox on earth occurred in 1977, and polio has been eradicated from the western hemisphere, the western Pacific region, and virtually all of Europe. The complete elimination of polio, and perhaps other, vaccine-preventable diseases, is within our grasp. In the United States, the progress against many infectious diseases has been dramatic:

The impact of vaccines in the United States		
Disease	Peak incidence (year)	1998 cases (preliminary data)
Diphtheria	206,939 (1921)	1
Measles	894,134 (1941)	89
Mumps	152,209 (1968)	606
Pertussis	265,269 (1934)	6,279
Polio, paralytic (wild poliovirus)	21,269 (1952)	0
Rubella (German measles)	57,686 (1969)	345
Rubella, congenital syndrome	20,000 (1964-5)	5

The National Institutes of Health (NIH) supports much of the basic and clinical research that leads to vaccine development. The National Institute of Allergy and Infectious Diseases, whose core scientific disciplines – immunology, microbiology and infectious diseases – underpin vaccine development, leads the NIH vaccine research effort. Other NIH Institutes involved in vaccine research include the National Cancer Institute, National Center for Research Resources, National Eye Institute, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Child Health and Human Development, National Institute of Dental and Craniofacial Disorders, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute on Drug Abuse, and National Institute of General Medical Sciences. This document summarizes recent progress and ongoing challenges in NIH vaccine research.

Recent Successes

Infant diarrhea
NIH research spanning 25 years recently culminated in the licensure of a vaccine against rotavirus, a leading cause of life-threatening childhood diarrhea. Widespread use of the rotavirus vaccine promises to reduce the 160,000 emergency room visits and 50,000 hospitalizations caused by rotavirus infections each year in this country. Global use of the vaccine could significantly lessen the impact of rotavirus diarrhea, which affects 130 million infants and children each year, resulting in more than 870,000 deaths.

Meningitis
After decades of research by scientists at NIH and in private industry, three new vaccines were licensed in the late 1980s to protect young children from the bacterium *Haemophilus influenzae* type B (Hib), a microbe that causes meningitis, deafness and approximately 400,000 deaths worldwide each year. The new vaccines use conjugate vaccine technology, in which Hib's polysaccharide coat is linked to a protein that acts to boost immunity in infants. More than 35 countries, including the United States, have added these vaccines to their immunization programs. Hib disease has been dramatically reduced wherever the vaccine has been used.

Whooping cough
Pertussis, or whooping cough, is a highly contagious respiratory disease that affects more than 50 million people worldwide and causes an estimated 350,000 deaths each year, primarily among infants. In the early 1990s, NIH-sponsored clinical trials conclusively demonstrated that acellular pertussis vaccines, which use only part of the pertussis bacterium, were highly effective in protecting infants against whooping cough, with fewer side-effects than the whole-cell pertussis vaccine that had been in use for many years.

Hepatitis A
Worldwide, more than 1.4 million cases of hepatitis A virus infection occur each year, mostly in countries with poor sanitation. This food- and water-borne disease also accounts for one-third to one-half of all hepatitis cases in this country. Although only about 25,000 cases are actually reported, as many as 130,000 cases of hepatitis A infection are estimated to occur each year in the United States. A strain of hepatitis A virus (HAV) developed by NIH scientists led to the production of the first commercially available hepatitis A vaccine in 1995. A single dose of the vaccine is protective. With a booster in 6 to 12 months, the vaccine is expected to protect against hepatitis A for up to 10 years. The new HAV vaccine is now available in 45 countries.

Lyme Disease
Late last year, the Food and Drug Administration approved the first vaccine against Lyme disease. In 1981, NIH scientists discovered *Borrelia burgdorferi*, the microbe that later would be identified as the cause of Lyme disease. In the mid-1980s, NIH-supported and other researchers identified a protein, OspA, on the outer surface of the microbe that caused an immune response in humans. In the early 1990s, NIH-supported researchers developed an OspA-based vaccine that protected mice from infection. The recently approved vaccine also is based on the OspA protein.

New Vaccine Strategies

Nasal Spray Vaccine for Influenza

In a large clinical trial supported in part by NIH, an experimental nasal spray vaccine tested in children provided 93 percent protection against the flu and, unexpectedly, 98 percent protection against ear infection, a common complication of the flu. Children experience the highest incidence of flu, two to 10 times that seen in adults, and are a common source of its spread to adults and to other children. The vaccine is made from live but weakened influenza viruses adapted to grow only at cooler temperatures, such as those found in the nasal passages, but not in such warm respiratory environments as the lungs. Thus, it induces immunity without actually causing disease.

Edible Vaccines

In 1998, researchers demonstrated that an edible vaccine can safely trigger significant immune responses in people. Volunteers in the NIH-supported study ate bite-sized pieces of raw potato that had been genetically engineered to produce a protein secreted by *Escherichia coli*, a bacterium that causes diarrhea. NIH-supported scientists are using this technique to develop edible vaccines targeted against intestinal pathogens such as Norwalk virus, a common cause of diarrhea, and hepatitis B virus. Edible vaccines would be particularly useful in developing countries, where storing and administering traditional vaccines are often major problems.

DNA Vaccines

Perhaps the most exciting new experimental vaccine technique, DNA vaccination involves the injection of DNA from a disease-causing organism directly into the body. The DNA is used by the body's own cells to make the "foreign" proteins, which then stimulate an immune response. The DNA can potentially result in lifelong protection. And since the vaccine contains only a fragment of the organism's genetic material, it will not cause disease. DNA vaccines are inexpensive, easy to make, and don't need refrigeration, qualities that make feasible their widespread use in developing countries. DNA vaccines for malaria, influenza, and HIV have been tested in humans and NIH researchers recently developed a DNA vaccine that protected monkeys from rabies.

Genome Sequencing

Numerous projects are underway to sequence the genetic instructions, or genomes, of disease-causing microbes. These initiatives promise to speed vaccine and drug development. In 1998 alone, NIH-supported researchers reported the complete genomic sequence of three important pathogens: the agents of chlamydia, syphilis and tuberculosis, as well as the sequence of one of the chromosomes of the malaria parasite *Plasmodium falciparum*. The new genomic sequence data promise to provide important insights regarding the components of these organisms that might be incorporated into candidate vaccines.

Ongoing Challenges

Tuberculosis

Last year, tuberculosis (TB) claimed the lives of nearly 3 million people, more than any other single infectious disease. Clearly, an effective TB vaccine is needed. NIH is using a two-tiered approach to develop a TB vaccine: basic research into the cellular events that occur during

disease and the host immune response to infection with the TB bacterium; and applied research into vaccine candidates. Several experimental vaccine approaches appear promising, and the NIH recently joined forces with public- and private-sector health agencies to formulate a "blueprint" to speed TB vaccine development.

Malaria

Between 300 million and 500 million cases of malaria occur worldwide each year and every 20 seconds, a child dies of the disease. As part of the Multilateral Initiative on Malaria coalition, NIH works with research organizations and agencies from around the world to enhance international collaborations, encourage the involvement of scientists from malaria-endemic countries, and identify additional malaria research resources. NIH recently bolstered its long-term commitment to malaria research with a multi-year research plan designed to accelerate the development of a malaria vaccine. The plan includes: establishing a repository of well-characterized malaria reagents to improve worldwide access to malaria research materials; expanding efforts to sequence the genomes of malaria parasites; and expanding current malaria vaccine production and evaluation efforts through collaborations between NIH scientists and grantees.

HIV/AIDS

The development of a safe and effective vaccine for HIV infection remains the "holy grail" of AIDS research. NIH funding for HIV/AIDS vaccine research increased by nearly 80 percent between FY 1995 and FY 1999. As part of this expanded effort, NIH has awarded numerous grants to foster innovative research on HIV vaccines, and is invigorating and reorganizing its vaccine clinical trials effort. In addition, NIH has established a Vaccine Research Center on the NIH campus to stimulate multidisciplinary vaccine research.

Recent studies supported by the NIH have assessed so-called "vectored vaccines": harmless viruses which are genetically altered to make HIV proteins. These vaccines have been administered to volunteers in combination with a separate vaccine made of a purified HIV protein. Results have been encouraging: in phase I and phase II studies, the combination approach has appeared safe and evoked several types of immune responses that may have a role in protection from HIV. NIH-funded researchers are now comparing three different vectors, as well as other HIV proteins to determine which combination produces the most robust immune response. Meanwhile, a large-scale study of a vaccine based on the surface proteins of two HIV strains was recently undertaken in the United States by a private company, with an additional phase III study to be conducted in Thailand. NIH will collaborate with the company in evaluating the immunological responses to the vaccine.

Sexually Transmitted Diseases

Sexually transmitted diseases (STDs) affect an estimated 13 million people in the United States and many millions more worldwide each year. More than 20 STDs have now been identified but so far, a vaccine against only one of them, hepatitis B, has been developed. NIH supports ongoing basic research directed towards STD vaccine development, particularly for chlamydia, gonorrhea, syphilis, human papillomavirus, and herpes. This research includes several major projects investigating the molecular immunology of STD infections to identify new antigens as potential vaccine candidates. NIH also supports projects to sequence the genomes of a variety of STD pathogens. Within the past year, scientists have reported the complete genome sequences

of the chlamydia and syphilis pathogens. This information should provide new insights into STD and could also identify new vaccine candidates.

Streptococcal Infections

Streptococcus pneumoniae infections are among the leading causes worldwide of illness and death in young children, persons with underlying chronic medical conditions, and the elderly. In the United States, these bacteria are the most common cause of community-acquired pneumonia. They also cause infections of the bloodstream, central nervous system and upper respiratory system. NIH supports research aimed at developing safe and effective streptococcal vaccines. The most active area is the development and clinical evaluation of conjugate vaccines, but NIH actively supports research to develop alternative vaccines that might provide immunity at an earlier age, or might be more broadly protective than the conjugate vaccines.

Cancer

Continuing insight into how the immune system works at the molecular level has spurred research on vaccines against cancer. Unlike conventional vaccines, which are used to prevent illness, cancer vaccines seek to mobilize the body's immune defenses against cancerous tissue. So far, cancer vaccine research has focused largely on melanoma, a potentially deadly skin cancer. However, NIH scientists and grantees are conducting basic research that may lead to the development of candidate vaccines for prostate, lung, colon, lymphoma, and other cancers. One experimental approach uses whole tumor cells from a cancer patient's own tumor as a vaccine. These whole-cell vaccine preparations stimulate an immune response when injected back into the patient. To heighten that response, researchers usually link the cells with an immune-boosting protein. Another cancer vaccine strategy involves identifying immune-stimulating antigens on tumor cells. These molecules may be unique to individual tumors, shared by several tumor types, or expressed by the normal tissue from which a tumor arises.

Immunologic Diseases

Scientists have begun to investigate the development of vaccines designed to tolerize – or turn off – the wayward immune responses characteristic of autoimmune and allergic diseases. Autoimmune diseases, in which a person's immune system attacks its own tissues and organs, affect nearly 5 percent of adults in North America and Europe and allergic diseases affect an estimated 15 percent of children and adults. The activation of the immune system's T cells is central to virtually all autoimmune diseases. Scientists are pursuing a variety of experimental approaches for inducing T cell tolerance and some of these approaches are now being developed as candidate vaccines.

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U.S. Department of Health and Human Services

National Institute of Allergy and Infectious Diseases
National Institutes of Health

May 1999

Status of AIDS Vaccine Research at NIH

Background

In his commencement address at Morgan State University on May 18, 1997, President Clinton asked the nation to commit to creating a vaccine against AIDS within 10 years. To accelerate this quest, he announced that a new Vaccine Research Center would be established at the National Institutes of Health (NIH).

Last year, AIDS vaccine advocates marked the anniversary of this announcement by designating May 18 as AIDS Vaccine Awareness Day. Communities nationwide organized teach-ins and other activities to educate people about AIDS vaccine research and to honor the several thousand U.S. volunteers who have already participated in clinical trials of experimental AIDS vaccines. The National Institute of Allergy and Infectious Diseases (NIAID) supported their efforts by coordinating national media contacts. Similar events are planned again this year to mark this anniversary.

This document summarizes progress in NIH-sponsored AIDS vaccine research in the two years since the President's commencement address at Morgan State University.

Vaccine Research Center at the NIH

- Since the announcement of the new Vaccine Research Center, and even before building began, a core group of NIH scientists with expertise in immunology, virology, and vaccine development has met regularly to help develop the concept of the "Center without walls."

- Construction of the $30 million, 50,000-square-foot Center building started in August 1998 and is expected to be completed in mid-2000. When fully operational, the state-of-the-art facility will house approximately 100 scientists and support staff. The scientists will be able to take a vaccine from concept through vaccine design and pilot-lot production.

- On April 11, 1999, Dr. Gary Nabel of the University of Michigan was named the Center's first director. Dr. Nabel has begun recruiting scientific staff and charting the Center's research course. He is a superb scientist who has excelled at the frontiers of virology, immunology, gene therapy, and molecular biology. His research career has focused on developing gene therapy for AIDS, and novel vaccine strategies against cancer and the Ebola virus.

Budget and Leadership

- The Clinton/Gore Administration has doubled the NIH funding for AIDS vaccine research by 100 percent since FY 1995. In FY 1999, funding for AIDS vaccine research increased by 30 percent over the previous year to about $194 million. The President's NIH budget request for FY 2000 includes $204 million for AIDS vaccine research.

- In May 1998, NIH Director Dr. Harold Varmus named Dr. Neal Nathanson as the new director of the NIH Office of AIDS Research. Dr. Nathanson, a world-renowned virologist from the University of Pennsylvania Medical Center, has a broad background in virology, epidemiology, and public health and is a member of the NIH AIDS Vaccine Research Committee chaired by Dr. David Baltimore.

- In September 1998, Dr. Margaret (Peggy) I. Johnston rejoined NIH to assume two key posts in AIDS vaccine research at the National Institute of Allergy and Infectious Diseases (NIAID). She is Assistant Director for HIV/AIDS Vaccines at NIAID, a newly created position; and Associate Director of the Vaccine and Prevention Research Program in NIAID's Division of AIDS. Dr. Johnston returned to NIH after serving two years as the top scientific administrator at the International AIDS Vaccine Initiative, a renowned not-for-profit organization whose mission is to foster the development of safe, effective, and accessible preventive HIV vaccines for use throughout the world.

- With the appointments of Drs. Nathanson and Johnston, and the establishment of an entirely new Vaccine Research Center led by Dr. Nabel, the NIH AIDS vaccine program has developed a strong leadership base and infrastructure for AIDS vaccine development.

NIH AIDS Vaccine Research Committee

- The AIDS Vaccine Research Committee, chaired by Nobel Laureate Dr. David Baltimore, was formed in early 1997 to improve coordination of NIH-supported AIDS vaccine activities. It has provided guidance to the NIH in developing a comprehensive research program aimed at developing a safe and effective AIDS vaccine. It has also advised the NIH about scientific opportunities, gaps in knowledge, and future directions of AIDS vaccine research, most notably contributing to the genesis and science of the Innovation Grant Program. A workshop co-sponsored by NIAID and the AVRC on May 3-5, 1999, brought together more than 700 researchers to discuss new research findings in HIV vaccine development.

Clinical Trials Progress

- Since 1987, more than 3,200 non-HIV-infected volunteers have enrolled in 52 NIAID-supported preventive vaccine studies (50 Phase 1 safety studies; two Phase 2 safety and immunogenicity studies) involving 27 vaccines. These trials have been conducted primarily at six university-based AIDS Vaccine Evaluation Group

(AVEG) sites nationwide. NIAID's HIV Prevention Trials Network (HIVNET), which includes international as well as U.S. sites, and NIAID investigators in Bethesda have also led or helped conduct some of these trials.

- Earlier this year, NIAID opened the first AIDS vaccine trial in Africa, an important step for global vaccine development. This small study in Uganda will help determine if it is necessary to tailor-make vaccines for different parts of the world. The vaccine being tested is based on subtype B, the HIV variant most often found in the United States and Europe. The researchers will determine if the immunized volunteers develop immune responses that in laboratory experiments cross-react to the two other HIV subtypes, A and D, the cause of most infections in Uganda.

- NIAID has initiated clinical trials of several novel vaccine approaches in the past two years. One trial is testing novel routes of immunization. The vaccine is applied topically to the moist tissues lining the vagina, rectum, and other mucosal surfaces where most HIV infections are acquired. A second study employs a non-disease-causing form of *Salmonella* bacteria to present an HIV protein to the immune system. This is the first vaccine that NIAID has funded all the way from the laboratory to clinical trials without industry sponsorship. A third study is combining a new adjuvant (GM-CSF) with an experimental vaccine to see if the adjuvant can enhance the immune responses stimulated by the vaccine.

- In June 1997, NIAID initiated its second intermediate-size AIDS vaccine trial and quickly completed enrollment of 420 volunteers. The Phase 2 trial is testing a combination of two different vaccines. This strategy offers the advantage of stimulating both components of the immune system. One vaccine, based on a harmless canarypox virus designed to carry genes coding for a few pieces of HIV, primarily stimulates cellular immune responses that kill HIV-infected cells. The other vaccine, a genetically engineered surface protein of HIV (gp120), primarily stimulates anti-HIV antibodies. Researchers are completing their analysis of the trial data. Trials that are ongoing and planned will assess modified versions of the canarypox-based vaccine to see if they stimulate better immune responses. The data from all these studies will form the basis for a future decision about proceeding to larger-scale efficacy trials that will determine if the vaccine protects against HIV infection.

- In June 1998, the first efficacy trial of an AIDS vaccine in the United States got underway. Although the trial is funded primarily by the vaccine manufacturer, VAXGEN, NIAID will collaborate with the company on ancillary studies of the samples they will collect. The trial, which is testing a bivalent subunit vaccine made from the gp120 surface protein of HIV, is expected to last three years and enroll 5,000 people in the United States, Canada, and the Netherlands.

NIAID's Restructured AIDS Vaccine Program

New initiatives have been launched by NIAID's Division of AIDS to enhance opportunities for vaccine discovery and to help move vaccine concepts from basic research through clinical trials. The overall objective is to increase the number of new, innovative and promising vaccine concepts flowing through the pipeline.

- *Innovation Grant Program for Approaches in HIV Vaccine Research*: In September 1997, NIAID announced the selection of the first 49 grantees for a new program to foster innovative research on AIDS vaccines. More grant awards have subsequently been made; the current total is 97. The Innovation Grant Program encourages early exploration of novel and innovative vaccine concepts and attempts to attract scientists currently working in other areas.

- *HIV Vaccine Research and Design Program*: This initiative supports traditional mid-stage, targeted research, including animal model studies, to help develop promising vaccine concepts.

- *Integrated Preclinical/Clinical Program:* This program funds the iterative processes of product development, optimization, and refinement, including clinical studies.

- Other programs that will be implemented in the near future include HIV Vaccine Design and Development Teams, which will advance vaccine concepts to the product stage, a program to encourage innovative research on improved technologies for evaluating immune responses, and resources to help advance products from preclinical to clinical research.

- NIAID has begun the process to restructure the AVEU and HIVNET networks. The reorganization will consolidate scientific responsibility and create two comprehensive networks for AIDS vaccine trials and non-vaccine HIV prevention research.

Recent Scientific Advances

- *Knowing Surface Structures Could Help Block Virus:* NIH-supported scientists have determined the 3-D crystal structures of two surface proteins of HIV, gp120 and gp41, which help the virus attach to cells. Studies of intermediate molecules formed during virus-cell fusion are helping explain the step-by-step process by which HIV enters the cell, which could lead to new vaccine approaches for inducing antibodies to block its entry.

- *Removing Sugar Coating Improves Immunity*: The outer surface protein of HIV is coated with sugar molecules that may prevent it from being recognized by the immune system. An NIAID grantee has shown that selectively deleting certain of these sugar molecules from SIV, the monkey equivalent of HIV, can bring the mutant virus under immune control much faster than the normal virus. Hence, using similarly modified HIV molecules as potential vaccines may improve the immune response.

- *Testing New Vaccine Vectors*: A non-disease causing Venezuelan equine encephalitis (VEE) virus suitable for humans was modified to carry selected HIV genes. When given to mice, the vaccine induced both antibodies to the virus and immune responses that killed HIV-infected cells. These experiments, and additional experiments in monkeys, demonstrate the potential for VEE-based vaccines to stimulate both arms of

the immune system and to control the level of virus. Another novel vector, a weakened form of vaccinia virus called MVA, has been developed and has been shown to induce good immune responses in rodents and monkeys.

- *Novel Form of HIV Induces Good Immunity:* Scientists have developed a novel vaccine based on HIV fusion molecules exposed only by freezing the virus in the act of infecting a cell. This virus-cell fusion mixture, when injected into mice genetically engineered to ignore key human proteins on the cells, made antibodies against the virus-cell fusion mixture. In laboratory tests, these antibodies were able to neutralize 23 of 24 strains of HIV representing a variety of different genetic subtypes and all isolated from infected individuals.

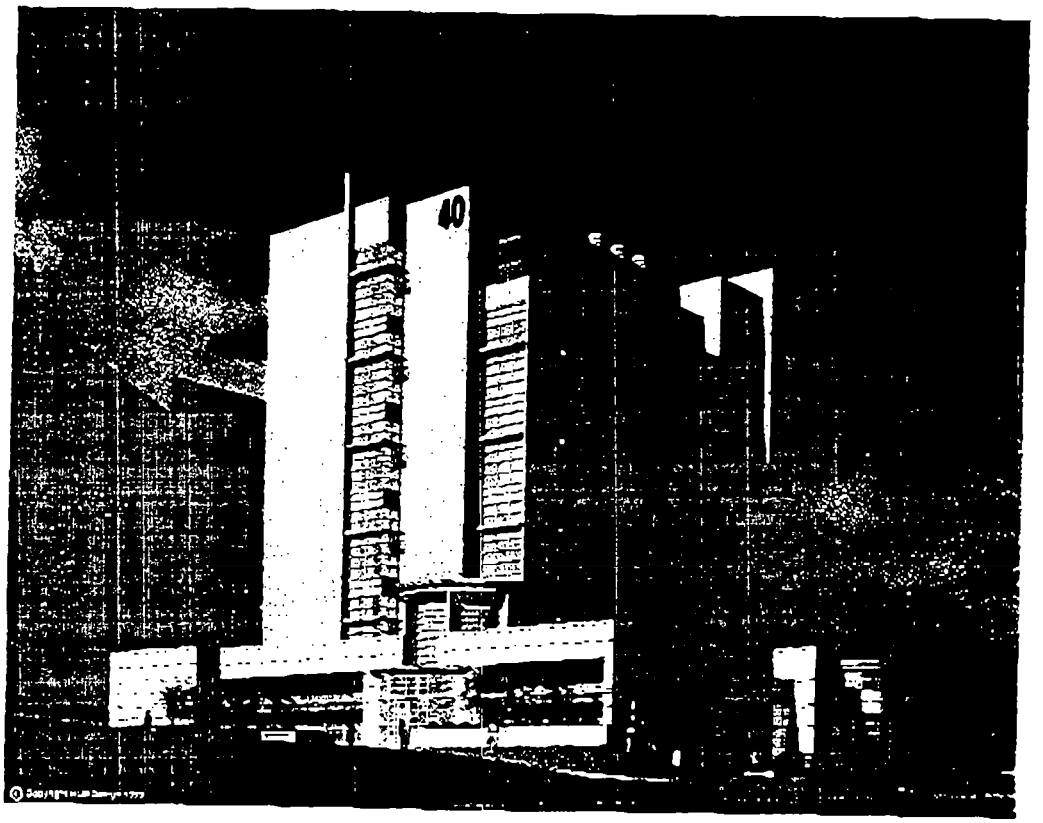
- *DNA Vaccine Protects Monkeys:* Several investigators have been pursuing research on DNA vaccines. Most recently, a chimeric DNA vaccine made from harmless genes of HIV and SIV, its monkey equivalent, has shown promise in monkey studies.

  The vaccine, when combined with "booster shots" made from a specially engineered virus carrying the same genes, seemed to protect animals later given doses of a live hybrid virus made from HIV and SIV. The vaccine did not keep the animals from getting infected but seemed to keep the hybrid virus under control, making it undetectable in the blood.

- *New Tests Developed to Measure Cellular Immunity:* During the past year, several new assays to measure cell-mediated immunity have been developed. These assays allow researchers to better compare the effectiveness of vaccine candidates in stimulating critical immune responses.

Other Federal Agencies

Within the federal government, several other agencies also have a role in AIDS vaccine research, including the Centers for Disease Control and Prevention (CDC); the Department of Defense (DoD); and the Food and Drug Administration (FDA). The roles of these different agencies in AIDS vaccine development are related and complementary, and span the spectrum from basic research to licensure and program implementation. For example, CDC conducts epidemiologic studies and surveillance needed to define health priorities, and develops recommendations for vaccine use. The FDA establishes standards for the processes, facilities, and pre- and post-licensing studies needed to insure the safety and effectiveness of vaccines. And the NIH supports most of the basic and clinical research in fields such as immunology and microbiology that lead to vaccine development.



National Institutes of Health

Dale and Betty Bumpers
Vaccine Research Center

CORNERSTONE DEDICATION
date TBD

Thirty-six years ago, President Kennedy looked to the heavens and proclaimed that the flag of peace and democracy, not war and tyranny, must be the first to be planted on the moon. He gave us a goal of reaching the moon, and we achieved it ahead of time . . .

Let us today set a new national goal for science in the age of biology. Today, let us commit ourselves to developing an AIDS vaccine within the next decade . . .

If America commits to find an AIDS vaccine and we enlist others in our cause, we will do it. I am prepared to do all I can to make it happen.

Today, I am pleased to announce the National Institutes of Health will establish a new AIDS vaccine research center dedicated to this crusade. And next month at the Summit of the Industrialized Nations in Denver, I will enlist other nations to join us in a worldwide effort to find a vaccine to stop one of the world's greatest killers. We will challenge America's pharmaceutical industry, which leads the world in innovative research and development, to work with us to make the successful development of an AIDS vaccine part of its basic mission. My fellow Americans, if the 21st century is to be the century of biology, let us make an AIDS vaccine its first great triumph.

President William J. Clinton
Commencement Address
Morgan State University
Baltimore, Maryland
May 18, 1997

PROJECT DATA

Building Owner:	The National Institutes of Health
Building Location:	Bethesda, Maryland
Building Function:	Biomedical Research Laboratory
Project Start:	November 1997
Project Completion:	September 2000
Building GSF:	82,500-square-feet
Building NSF:	78,950-square-feet
Typical Floor:	11,785-square-feet
Building Population:	160
NIH Project Officer:	Nancy Boyd
NIH Contracting Officer:	Jean Riddle
NIH Science / Design Coordinator:	Cyrena Simons
Design / Construction Team:	Spaulding & Slye *development manager* HLM Design *architecture / structural engineering* RMF Engineering, Inc. *MEP Engineering* sst planners *laboratory planning / programming* A. Morton Thomas & Associates *civil engineering* Schnabel Engineering Associates *geotechnical engineering* Rolf Jensen & Associates, Inc. *fire protection / life safety* Polysonics, Inc. *acoustic & vibration control* Lerch Bates & Associates, Inc. *vertical transportation* Rowan Williams Davies & Irwin, Inc. *wind analysis* Management Alternatives *occupancy planning* Clark Construction Group, Inc. *construction*

PROJECT PROFILE

The Dale and Betty Bumpers Vaccine Research Center, Building 40, is an 82,500-square-foot research and conference / education building that is being constructed to fulfill President Clinton's challenge to NIH and the scientific community to develop an AIDS vaccine within the next ten years. President Clinton's announcement stated that "with the strides of recent years, it is no longer a question of whether we can develop an AIDS vaccine; it is simply a question of when." In accepting the challenge, Dr. Harold Varmus, Director of the National Institutes of Health, said, "The President has set a difficult goal for the research community, but NIH is ready to bring its scientific expertise and resources into play. Creating a vaccine that will block the AIDS virus is a formidable scientific task. There is no guarantee that we can produce a vaccine within ten years, but recent advances in immunology and virology have increased optimism that it can be done. NIH's new [Dale and Betty Bumpers] Vaccine Research Center will be a vital part of that effort." (Spaulding & Slye Press Release, January 29, 1999)

The Dale and Betty Bumpers Vaccine Research Center (VRC) will be a joint venture of the National Cancer Institute and the National Institute of Allergy and Infectious Diseases and will incorporate a core of NIH scientists with expertise in immunology, virology and HIV research.

The design of the Dale and Betty Bumpers Vaccine Research Center responds to the NIH Master Plan guidelines that specify that buildings are located in order to relate to each other through commonly defined open spaces and clearly articulated "front doors." Each quadrangle open space clearly identifies a building group. Its location and massing reinforce and complete the architectural enclosure of the West Lab Quadrangle, and the development of the "front doors" adjacent to the automobile courtyard establishes the identity for this building group on the NIH campus. Furthermore, with an overall building height of 112 feet, the VRC is approximately the same height as its surrounding neighbors and within the Master Plan guidelines. In order to complement the concrete and glass buildings of Buildings 36 and 37, a palette of light colored precast concrete and tinted glass curtainwall is employed. Additionally, the articulation of the new façade is in scale and character with the proposed Building 37 expansion. The result will be a cohesive and pleasing architectural expression that unites and augments the visual character of this building group in the West Lab Quadrangle to the NIH campus.

The Dale and Betty Bumpers Vaccine Research Center consists of five above grade floors plus a mechanical penthouse and one below grade level basement. Between each floor level is a partial interstitial service floor for the distribution of utilities and for the separation of science and maintenance.

A basement level, housing HVAC and electrical equipment, is located under the northern end of the first floor. Vertical shafts allow distribution of mechanical and electrical services, outside and exhaust air to the interstitial levels, the penthouse, and the exterior.

The VRC is organized with the Education and Conference Center and loading dock at the First Floor level. An entrance rotunda is located along the southern façade to announce the main entrance to the new facility and, additionally, to function as a ceremonial pre-function area for the Conference Center. A circulation space links the Conference Center with the VRC functions, terminating in a secondary lobby that serves as the primary access to the research laboratories above. This secondary lobby entrance also serves as a means of access to the new facility from the north end of the NIH campus. The Director's office suite and administrative support areas are housed at the western end of the First Floor. These elements combine to create a plinth, which supports the laboratory tower levels above.

The upper floors house the laboratories, support spaces, and Principal Investigator's offices, along with administrative and support spaces. The laboratories are organized along the east and west sides of a double-loaded corridor running north-to-south. The PI offices and administrative support spaces are located at the north end of the laboratory floors, overlooking the park-like green space at the corner of Covenant and South Drives.

A mechanical penthouse occupies the top floor of the building and houses the major HVAC equipment and other services components. In addition to the penthouse area, mechanical and electrical distribution on each floor is provided by a partial interstitial space above the laboratory space.

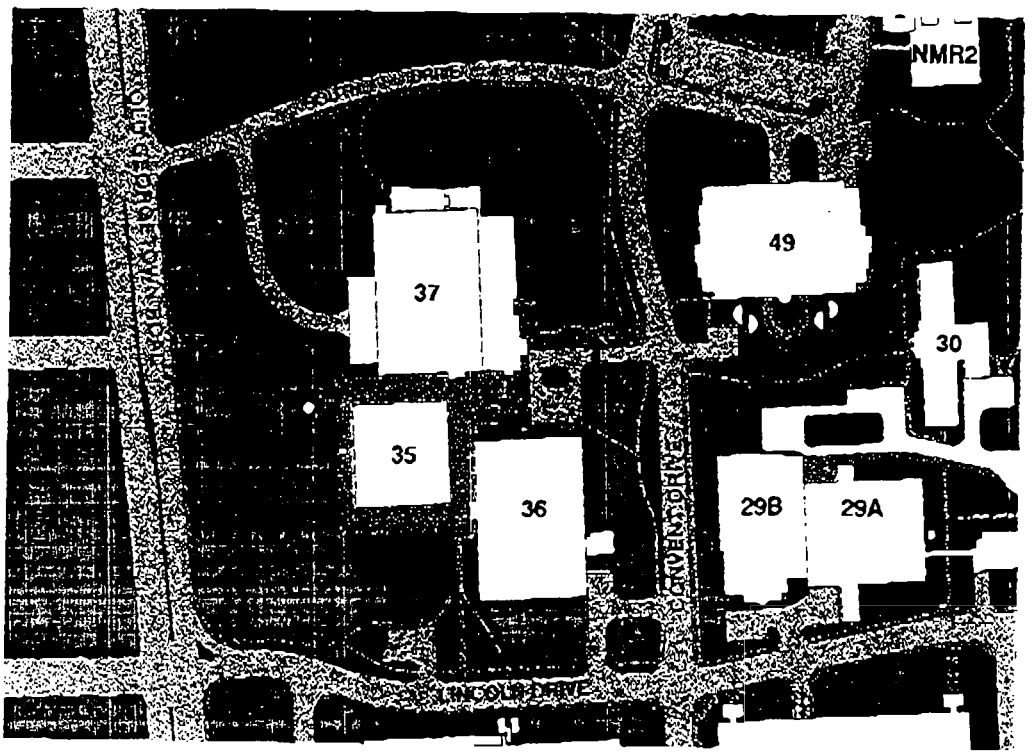
PROJECT PROFILE

NIH has proposed that a potential future expansion research wing could be constructed at the northern end of the project's site. The addition would be a mirror image of this initial project's laboratory floor, oriented so that future office space can by contiguous with the existing PI office suites. This approach allows potential future expansion to utilize the service core elements from the initial project's construction, increasing the overall building efficiency and providing flexibility in future interior space requirements. The total size and occupancy of both the initial project and potential future expansion will remain within the limits set for this site in the Master Plan.

NATIONAL INSTITUTES OF HEALTH

Dale and Betty Bumpers
Vaccine Research Center

Site Plan



The Dale and Betty Bumpers Vaccine Research Center is located in the southeast corner of the site, roughly parallel to Convent Drive. The southern façade of the new building encloses the Conference Center, with the research laboratories and support spaces organized in a linear fashion along Convent Drive. A public plaza is created at the corner of Convent Drive and establishes the new automobile courtyard to anchor the new building to its site and to contribute an outdoor pedestrian space along the campus' West Laboratory Quadrangle.

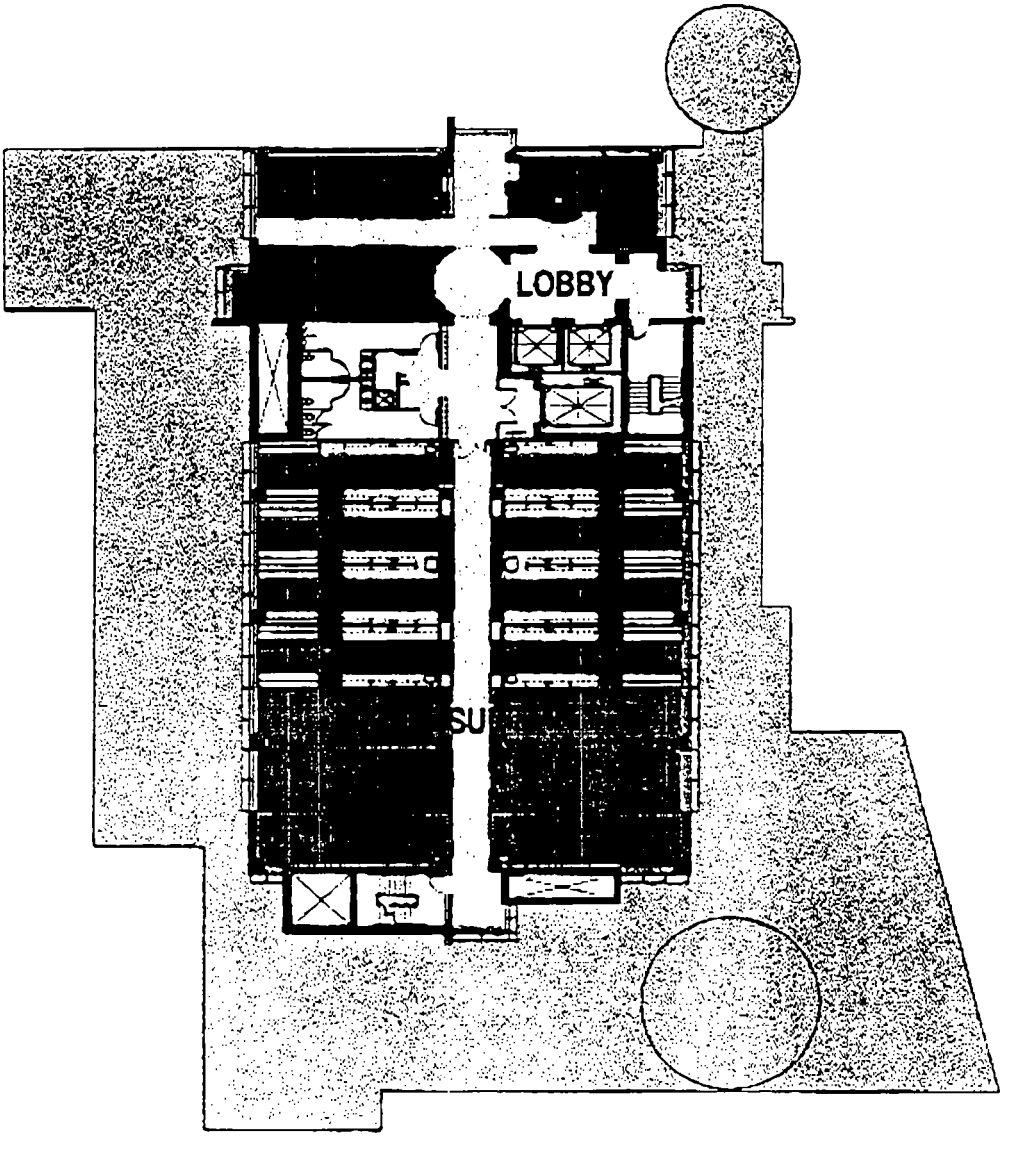
An automobile courtyard that serves as the primary drop-off point for Building 36, Building 37, and the day care facility in Building 35 defines the southern border of the site. This roadway creates an exterior courtyard that has been identified in the Master Plan as part of a potential east-west laboratory quadrangle that will serve as an organizing device for future development of the NIH campus.

Access to the loading docks and service area is provided from South Drive at the north end of the site, in accordance with the Master Plan. On the west side of the facility, an outdoor landscaped area is provided adjacent to the Director's office suite. With the exception of the new service and utility tunnel, trees and natural topography at the north end of the site will be left undisturbed.

NATIONAL INSTITUTES OF HEALTH

Dale and Betty Bumpers
Vaccine Research Center

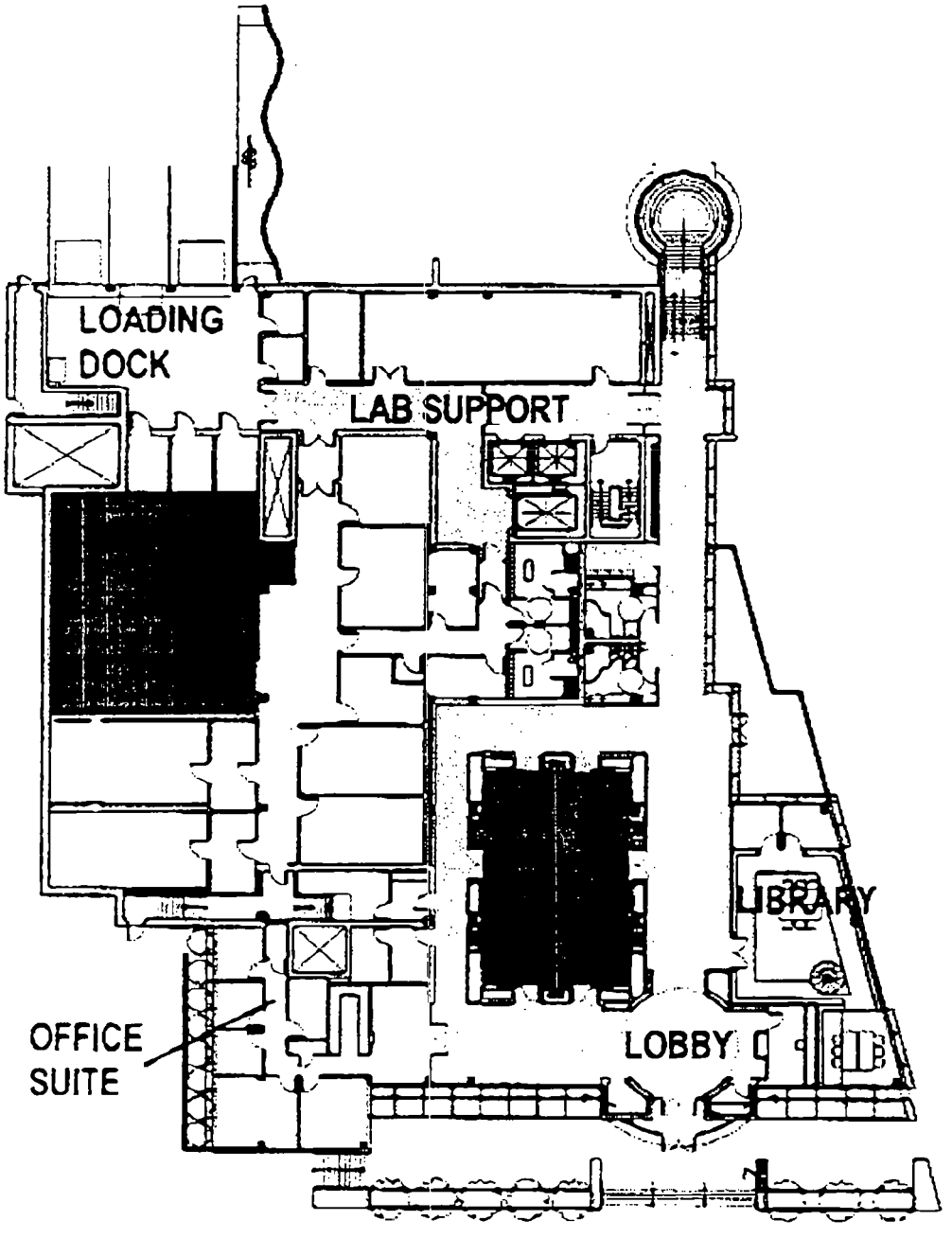
Typical Floor Plan



NATIONAL INSTITUTES OF HEALTH

Dale and Betty Bumpers
Vaccine Research Center

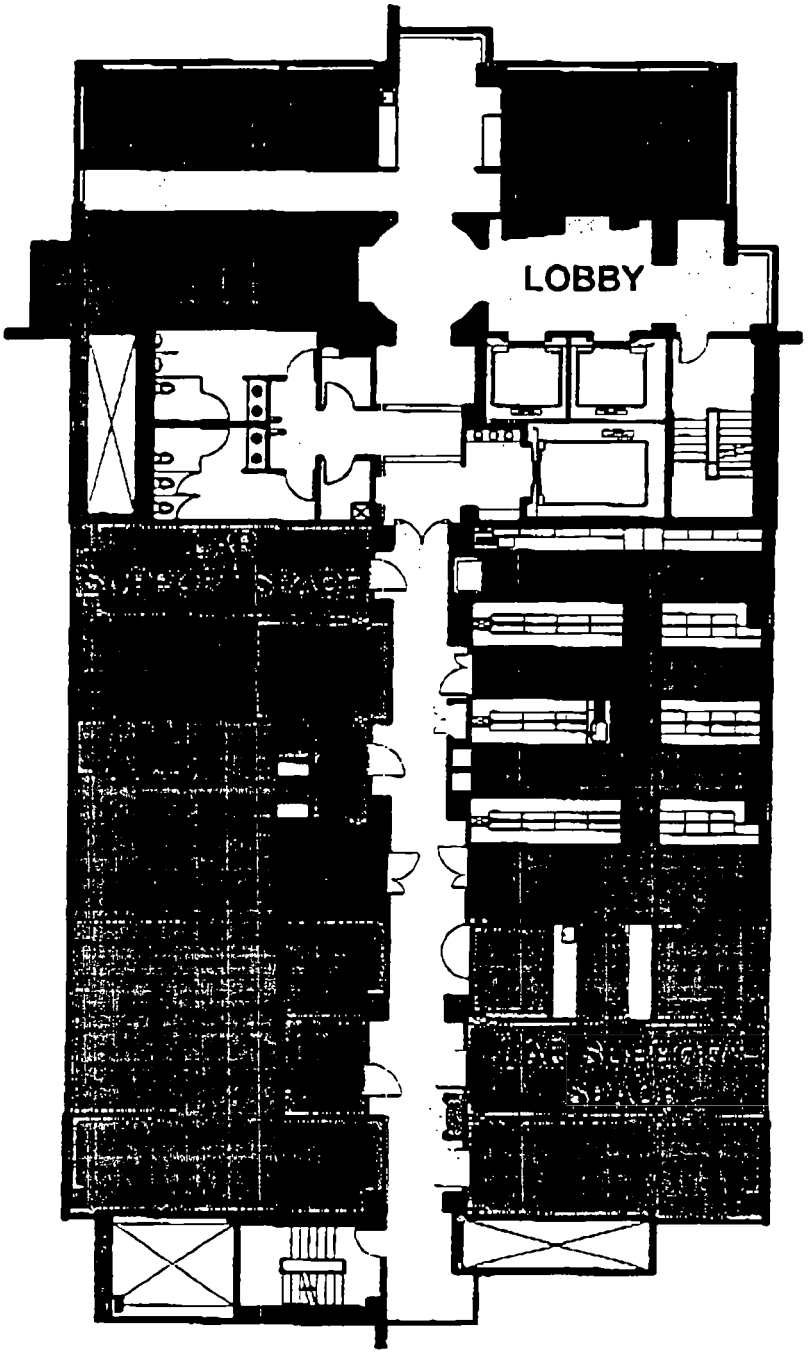
First Floor Plan



NATIONAL INSTITUTES OF HEALTH

Dale and Betty Bumpers
Vaccine Research Center

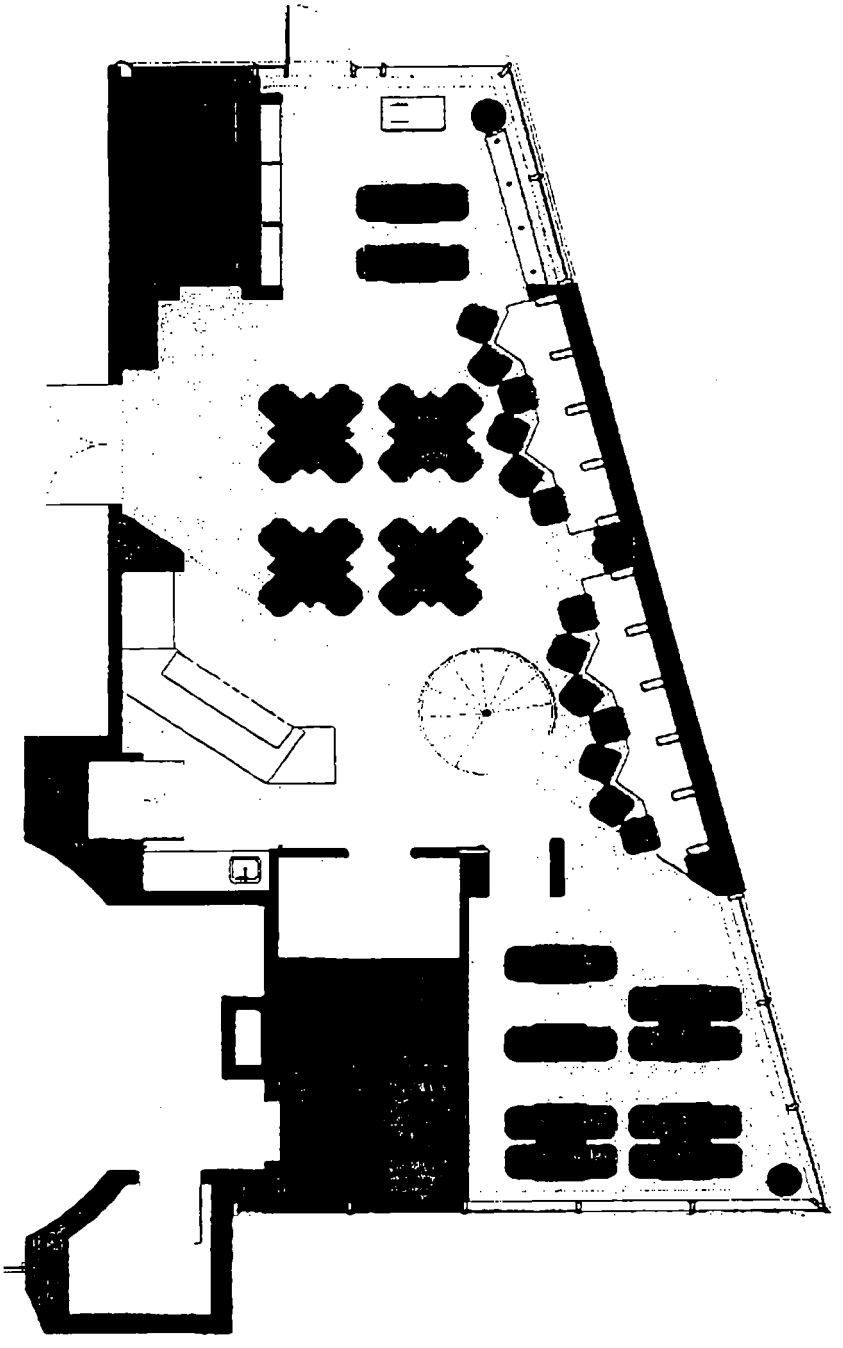
Fifth Floor Plan



NATIONAL INSTITUTES OF HEALTH

Dale and Betty Bumpers
Vaccine Research Center

Cyber-cafe Floor Plan



INSTITUTE PROFILES

NATIONAL CANCER INSTITUTE

The National Cancer Institute (NCI) is the largest of the seventeen biomedical research institutes and centers at the National Institutes of Health in Bethesda, Maryland. Established under the National Cancer Act of 1937, the NCI is the federal government's principal agency for cancer research and training. The National Cancer Act of 1971 broadened the scope and responsibilities of the NCI and created the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

In addition to conducting research in its own laboratories and clinics, the Institute supports and coordinates research projects conducted by universities, hospitals, research foundations and businesses both nationally and internationally. Also, NCI supports education and training in fundamental sciences and clinical disciplines for participation in research and treatment programs relating to cancer. Finally, the NCI continues to be a major source of information about cancer, and one of its primary responsibilities is to collect and distribute information about cancer. Through the Cancer Information Service, established in 1906, the NCI provides the latest available information to people around the county by answering calls made to its toll-free hotline and by providing outreach to communities nationwide. Additionally, the Physician's Data Query database, which may be accessed on the World Wide Web, provides current information on clinical trials, cancer screening, prevention, treatment, physicians, organizations, and facilities active in cancer medicine.

The commitment to basic research at the National Cancer Institute has led to critical discoveries in the identification and treatment of diseases other than cancer, including cystic fibrosis, rheumatoid arthritis, and hepatitis. NCI researchers in immunology, virology and cell and molecular biology have also done landmark work in AIDS research. Dr. Robert C. Gallo, the NCI researcher who first discovered the human RNA virus, became the co-discoverer of HIV, which causes AIDS. The National Cancer Institute remains active in AIDS research, especially on AIDS-related cancers.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports research aimed at preventing, diagnosing, and treating illnesses such as AIDS and other sexually transmitted diseases, tuberculosis, asthma and allergies. In 1986, NIAID formed the Division of the Acquired Immunodeficiency Syndrome to address the national research needs created by the advent and spread of HIV/AIDS pandemic by ensuring that federally-sponsored scientific investigation of HIV infections is focused and appropriately balanced on the most critical biomedical research issues. Its purpose is to increase basic knowledge about HIV/AIDS and promote progress in its detection, treatment and prevention through basic and clinical research, discovery and development of therapies for HIV infection and its complications, development of vaccine and training of researchers in these three activities.

In discussing the need for an AIDS vaccine, NIAID Director Dr. Anthony S. Facui says, "Developing a safe and effective vaccine against HIV is critical to our efforts to control the devastating pandemic of HIV and AIDS. Over the past year, in an effort led by Dr. Jack Killen, director of NIAID Division of AIDS, and his staff, the Institute has formulated a flexible strategic plan, with an integrated program of fundamental and empiric research, to facilitate the most efficient development of HIV research."

"This plan provides a framework for the decision-making process in the development of any candidate vaccine, from basic research through preparation for large-scale efficacy trials." (NIAID Press Release, February 12, 1996)

In addition to being Director of the National Institute of Allergy and Infectious Diseases, Dr. Fauci is the Chief of the Laboratory of Immunoregulation and has made seminal contributions to the understanding of how the AIDS virus destroys the body's defenses leading to its susceptibility to deadly infections. He has also been instrumental in developing strategies for the therapy and immune reconstitution of patients with this serious disease, as well as for a vaccine to prevent HIV infection. He continues to devote much of his research time to AIDS research and vaccine development.

FIRM PROFILES

Spaulding & Slye

Spaulding & Slye Colliers, as the Development Manager, is the team leader responsible for coordinating all of the design and construction consultants working on the Dale and Betty Bumpers Vaccine Research Center. Spaulding & Slye Colliers is an integrated real estate services company with offices in Boston and Washington, DC. Established in 1966, the firm specializes in office, research and development, industrial, and retail space. The service groups include brokerage, capital markets, construction, advisory services, property, facility, and development management. In addition, Spaulding & Slye Colliers is an owner/member of Colliers International, a corporate partnership of 50 real estate services companies with approximately 4,400 professionals in over 255 offices worldwide. Spaulding & Slye Colliers has serviced several billion dollars in commercial real estate properties and has assisted numerous local, national and international companies with planning and implementing successful real estate strategies. The firm's web site is at www.SpauldSlye.com.

HLM Design

HLM Design is the Architect responsible for the design of the Dale and Betty Bumpers Vaccine Research Center and is also providing planning, interior design, and structural engineering services. HLM is one of the nation's largest architectural and engineering firms with over 300 professionals in eleven offices across the country and one office abroad. HLM is consistently ranked among the top medical architects in the U.S. by *Modern Healthcare Magazine*. Over the years, HLM Design has designed over one billion square feet of constructed facilities. The firm's clients include many of America's leading healthcare providers, academic medical centers, universities, government agencies, and corporations. HLM's suburban Washington, DC office was established in 1988. Since then, that office has been responsible for more than $250 million of construction, including architecture and structural engineering for the Dale and Betty Bumpers Vaccine Research Center, the Louis B. Stokes Laboratories / Building 50 and the addition to Building 11, all at the National Institutes of Health in Bethesda, Maryland.

RMF Engineering

RMF is a 120-person consulting engineering firm located in Baltimore, Maryland and Durham, North Carolina. The firm consists of twenty-two professionally registered engineers, a registered architect and over sixty engineering college graduates. RMF is designing all of the mechanical, electrical, and plumbing systems for the Dale and Betty Bumpers Vaccine Research Center. RMF has been working on the NIH Bethesda campus for the past nine years on the Infrastructure Modernization and Improvement Program. The projects have included expansion and modernization of the central plant and underground utility distribution throughout the campus.

sst planners

sst planners, a Virginia-based small business, is a specialty laboratory planning and design firm with expertise in biomedical research facilities. From its inception, the firm has planned and programmed approximately 2 million-square-feet of research space annually. The essence of our firm is in the approach to our practice and the expertise of our employees. Our approach is one that values and insists that firm principals be involved from project inception until the building is delivered to the client. Our employees are all registered professionals who selected this technically complex project type on which to focus their considerable talents.

A. Morton Thomas & Associates, Inc.

AMT has been providing civil engineering, planning, surveying and landscape architecture services to a wide variety of clients since it was founded in 1955. For 42 years, the firm's practice has focused on a knowledge of principals applied to public works, land use and environmental concerns. The firm employs approximately 70 professional, technical and

FIRM PROFILES

support personnel. AMT provides services from initial evaluation and planning through surveying, design, permitting and construction on a wide range of engineering projects.

Schnabel Engineering Associates, Inc.

Schnabel Engineering Associates, Inc., a 160-person firm with offices in Maryland, Virginia, Pennsylvania, Georgia, Colorado, South Carolina, and New Jersey, is providing geotechnical engineering and testing services for the Dale and Betty Bumpers Vaccine Research Center through its local office in Bethesda, Maryland. Geotechnical engineering services form the base of Schnabel Engineering Associates, Inc. In-house research and an extensive working knowledge of local geologic settings and ground water regimes enable them to minimize technical and financial risks for clients. Schnabel professionals excel at developing a detailed array of practical geotechnical solutions specifically suited to each project.

Rolf Jensen & Associates, Inc.

Established in 1969, Rolf Jensen & Associates, Inc. is engaged exclusively in fire protection engineering and building code consulting and is currently recognized as one of the world's leading fire protection engineering firms. RJA has extensive experience in the evaluation of new and existing buildings for fire protection, life safety, and accessibility features, including survey and analysis of these structures. RJA employs over ninety professionals in its eleven regional offices, and of these employees, over forty have degrees in fire protection engineering. The remaining professionals have degrees in architecture or other engineering disciplines. These professionals have been involved in many of architecture's most distinguished achievements. Their function is to know, understand and work with building code authorities and interpret these codes for their clients. More importantly, RJA employees have developed and have received approval for many "equivalent solutions" to code compliance problems. They are skilled at helping architects, engineers and owners achieve distinctive, innovative designs while still complying with fire protection and life safety requirements.

Polysonics, Inc.

Polysonics, a professional registered engineering firm in Washington, DC, has been in business for forty years providing noise and vibration control in buildings, designing "state-of-the-art" audio/video systems and developing noise standards for land uses. Our reputation for providing clients with cost-effective and practical solutions for noise and vibration problems and audio/visual systems is firmly established. For determination of building vibration, Polysonics provides on-site vibration measurement and computer modeling using finite element analysis. Computer modeling techniques have been developed to predict the level of building floor vibrations on buildings still in the design phase. Modeled vibration sources on such buildings include transportation, mechanical equipment and human footfalls. This technique has been used in the structural design and development of medical and scientific research laboratory buildings that require extremely low levels of floor vibration but enjoy architectural benefits of long span construction techniques.

Lerch Bates & Associates, Inc.

Lerch, Bates & Associates (LBA) has over fifty years of experience in providing specialized consulting services in the field of vertical transportation systems. Lerch Bates Hospital Group (LBHG) was formed in 1984 to meet the complex materials management challenges of health care projects. LBHG is headquartered in Littleton, Colorado with regional offices in Timonium, Maryland and Petlauma, California. LBHG personnel have been responsible for the analysis of need, development of recommendations, specification of design of more than $1.5 billion worth of elevators, escalators, and other materials handling systems.

FIRM PROFILES

Rowan Williams Davies & Irwin, Inc.

Located in Guelph, Ontario, RWDI is an international consulting engineering firm specializing in environmental studies. One of the firm's areas of expertise is air quality studies, and over 1,000 air quality projects have been conducted by the firm's staff of more than 150, including a team of engineers and specialists, meteorologists, engineering technologists, and technicians. These resources allow RWDI to offer a wide variety of services, including consultations, scale model studies, numerical modeling, field monitoring and site inspections. For the Dale and Betty Bumpers Vaccine Research Center project, RWDI was retained to conduct a review of air quality issues using numerical modeling. The objectives were to assist in the design of the VRC's exhaust and placement of the fresh air intakes and to demonstrate compliance of the exhaust with air quality standards.

Management Alternatives

Management Alternatives is the oldest and largest relocation project planning and management firm in the Mid-Atlantic region. Headquartered in Washington, DC, Management Alternatives was founded in 1983 by Patricia A. Henriques. Over the last 16 years, Management Alternatives has expanded its expertise and scope of services to meet the demands of an ever-changing and more technically-diverse client base. From laboratories and research facilities to airports, public authorities, law offices and complex computer facilities, we have expanded our portfolio to become experts at managing high-risk, logistics intensive projects.

Clark Construction Group, Inc.

Founded in 1906, The Clark Construction Group is one of the nation's largest building contractors and the largest contractor in the Washington Metropolitan area. Headquartered in Bethesda, MD, Clark employs over 900 full-time personnel and 1,600 tradespersons in offices throughout the country. The company provides general contracting, construction management and design/build services to both public and private sector clients on a wide range of project types. Notable projects such as MCI Center, Jack Kent Cooke Stadium, Oriole Park at Camden Yards, The Warner Theatre, The Willard Hotel, Reston Town Center, National Archives II, and the Women in Military Service for America Memorial underscore Clark's reputation as one of the nation's leading providers of quality construction services.

CREDITS

The Consultant team is composed of:

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