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AIDS Vaccine Using Nasal Spray Shows Promise

Inoculated Chimps Resist Infection a Year Later, but Costs May Stall Additional Testing

By Rick Weiss

Washington Post Staff Writer

Chimpanzees inoculated with an experimental AIDS vaccine have successfully fought off repeated exposures to the AIDS virus up to a year after they were vaccinated, a research team reported yesterday.

The novel vaccine, which consists of a series of nasal sprays followed weeks later by a booster shot in the arm, is the latest addition to a small but growing arsenal of experimental AIDS vaccines showing early signs of promise after many years of mostly disappointing results.

Scientists cautioned that other vaccines have looked similarly effective in chimpanzees, only to fail in human clinical trials. But researchers said they were encouraged by the strength of the immune response triggered by this vaccine, and especially impressed with its ability to confer protection so long after vaccination.

In previous tests of AIDS vaccines, chimps or monkeys have been exposed to the AIDS virus, HIV, soon after they were vaccinated—an unrealistic scenario. The new vaccine worked even when chimps were challenged with a big HIV dose 50 weeks after they were vaccinated—longer than has worked in any other study.

Unfortunately, several researchers said, the company that helped develop the vaccine—Wyeth-Ayerst Research of Radnor, Penn.—has, like other

vaccine developers, been questioning the cost-effectiveness of ushering its vaccine through the expensive and time-consuming labyrinth of clinical trials and regulatory approval. Key Wyeth scientists who spearheaded the work have been removed from the project, leaving its future uncertain.

Given the latest chimpanzee results and President Clinton's recent call for a renewed national commitment to developing an AIDS vaccine within the next decade, however, scientists said they hoped the company would reconsider financing the necessary work that could lead to early safety tests in human volunteers.

"There is no doubt that a good percent of the pharmaceutical industry, for reasons that are in part understandable and obvious, have become in recent years less interested in financing development of an AIDS vaccine," said Robert C. Gallo of the Institute of Human Virology in Baltimore, who co-discovered HIV and was involved in the latest chimpanzee studies. "It's possible, and we hope it's true, that these and other recent promising findings will renew their interest."

Representatives for Wyeth-Ayerst did not return phone calls this week-end. But study leader Marjorie Robert-Guroff, of the National Cancer Institute, said the possibility of working toward a small safety trial in people was "under discussion."

The new vaccine was made from

an adenovirus—a kind of virus that can cause colds in people—that was genetically engineered to contain an extra gene called gp160, normally found only in HIV. When sprayed into the nasal passages of chimps, the modified virus settled into the animals' upper respiratory tracts and intestines.

During the next week or so, the viruses multiplied in the chimps' mucous membranes, and spewed out gp160 proteins. As predicted, the chimps' immune systems responded to the HIV proteins by making antibodies and white blood cells programmed to attack HIV.

The researchers boosted that protective immune response by giving the chimps a shot in the arm containing laboratory-made versions of a different HIV protein, gp120. More than 11 months later, they subjected the chimps to intravenous infusions of HIV.

Robert-Guroff and her colleagues reported in the June issue of *Nature Medicine*, released yesterday, that unvaccinated chimps became infected with the deadly virus within a month, but vaccinated chimps remained healthy and apparently uninfected until the study ended, almost a year later.

Adenovirus-based vaccines have a potential advantage over other kinds of AIDS vaccines because adenoviruses can stimulate a potent immune system response in mucous membranes, including the urinary tract, and vagi-

nal and rectal tissues. "We'd like to induce mucosal immunity," Robert-Guroff said, "because worldwide transmission of HIV is predominantly across mucosal barriers" through intercourse, rather than by intravenous infection.

The new report does not specifically reveal whether mucosal antibodies were generated in the chimps, but the U.S. military has given soldiers oral adenovirus vaccines for years to protect against upper respiratory tract infections, generating mucosal immunity and very few complications.

Nonetheless, researchers warned, any AIDS vaccine made from a live virus that is capable of causing disease in people, as adenoviruses can, will have to be tested carefully for safety. Several said they hoped that will happen soon.

"Eight thousand people a day and 3 million a year are being infected with HIV despite all the education and counseling, so most experts believe that to get control worldwide we are going to need a safe, affordable and effective vaccine," said Mark Mulligan, director of the HIV vaccine evaluation unit at the University of Alabama at Birmingham.

"This vaccine is an encouraging step in the pathway to getting there," Mulligan said. "My feeling is that adenovaccines should be given serious review for advancing into small, Phase 1 human trials where their safety and human immune response can be evaluated."

5/30/97

Washington
Post

Why an AIDS Vaccine?

The reviews are in on President Clinton's dramatic declaration pledging the United States to finding an AIDS vaccine, moonshot-like, within 10 years. Apart from AIDS activists who complain that the president did not commit serious moonshot money to the enterprise ("cheap talk"—Larry Kramer), the reaction was mostly favorable. Who, after all, can be against a vaccine against anything?

No one seems to want to raise the obvious, if indelicate, question: Why embark on a huge national venture to create a vaccine for a disease that is already extraordinarily preventable?

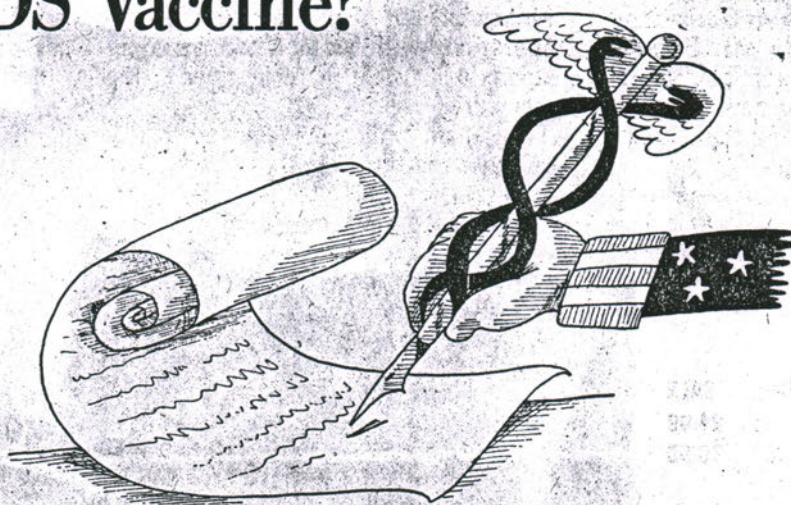
Unlike most communicable diseases, AIDS is not contracted casually. Unlike TB, it is not contracted by being coughed on in the subway. Unlike dysentery, it is not contracted by drinking the wrong water. To get AIDS you must, in all but the rarest cases, engage in very complicated consensual social behavior, namely unsafe sex or intravenous drug abuse.

It would be nice to live in a world where one could engage in such behaviors while enjoying vaccine-induced immunity. But is that really a top national priority? Would any president propose as a top national priority an anti-lung-cancer vaccine so that people who smoke—48 million Americans do—could do so with immunity?

Nor do presidents call for a 10-year campaign to produce a vaccine against cirrhosis of the liver. Why? Not because we want to stigmatize people who drink or smoke. But for a very practical reason: These behaviors being voluntary and preventable, it makes a lot more sense to spend the scarce intellectual, scientific and financial resources of the country trying to give people immunity from diseases that they cannot otherwise protect themselves against.

The classic case is polio. When FDR contracted it in 1921, we had not a clue how people got it. By the '50s, frightened parents kept their children away from swimming pools and movie theaters and even crowds. They lived in terror not knowing what they might be doing that was contributing to their kids' chances of getting polio.

With no obvious behavioral cause, polio was the classic case of a disease crying out for a vaccine. Meningitis, cervical cancer and multiple sclerosis occupy a similar position today. But AIDS?



BY MARGARET SCOTT

We abandoned public-health measures against AIDS because of political pressure. Now Clinton seeks an expensive magic wand instead.

Moreover, Clinton is calling for a huge technological innovation (which many in the field doubt is a reasonable prospect anyway) to prevent the spread of AIDS. Yet at the same time, the traditional way of controlling the spread of communicable diseases has been largely abandoned in the case of AIDS. And uniquely in the case of AIDS.

We fight just about every epidemic—tuberculosis, syphilis, gonorrhea—by identifying carriers and warning their contacts. The usual epidemiological tracing has not been done for AIDS. Gay activists and civil libertarians have vociferously opposed it. And the politicians have caved.

The story of this travesty—"the effective suspension of traditional public health procedures for AIDS"—is laid out in damning detail by Chandler Burr in the current Atlantic Monthly ("The AIDS Exception: Privacy vs. Public Health").

"AIDS has been so thoroughly exempted from traditional public health approaches," writes Burr, "that civil libertarians have defeated in court attempts by health authorities to notify the spouses of people who have died of AIDS that their husbands or wives were HIV-infected."

In 1985, in fact, gay activists brought suit to prevent the use of the first test for HIV, unless assured the tests would not be used

for widespread screening of gays. Even today they oppose mandatory HIV screening for pregnant women, even though we know that early treatment of the mothers would reduce by 50 to 75 percent the number of kids who are born with HIV.

"Traditional public health is absolutely effective at controlling infectious disease," says Dr. Lee Reichman, who works with tuberculosis and AIDS patients. "It should have been applied to AIDS from the start, and it wasn't. Long before there was AIDS, there were other sexually transmitted diseases, and you had partner notification and testing and reporting. This was routine public health at its finest and this is the way STDs were controlled."

Marcia Angell, executive editor of the New England Journal of Medicine, is blunter than most: "I have no doubt . . . that if, for example, we screened all expectant mothers, we could prevent AIDS in many cases. And if we traced partners, we would prevent AIDS in many cases. And if we routinely tested in hospitals, we would prevent AIDS in many cases."

And if we had a president with guts, he would be demanding these elementary measures to save people from getting AIDS today—instead of waving a wand and telling scientists to produce for him a magic vaccine 10 years from now.

The Washington Blade
May 23, 1997 • Vol 28 / No. 21

AIDS vaccine: The hope and the hoopla



by Clint Steib

by Lisa Keen

There was much hoopla over President Clinton's announcement last weekend that he was stepping up his administration's commitment to developing a vaccine against HIV. He said he would add \$17 million to the government's research budget to develop a vaccine and challenged

President Clinton's announced a push for a vaccine against HIV.

science to come up

with one within the next 10 years.

It was 10 years ago this year that the first presidential AIDS commission — under President Ronald Reagan — recommended moving “rapidly” to develop an AIDS vaccine. The commission identified five key obstacles to developing the vaccine at that time, and all but one of those obstacles still exist today:

- scientists do not have suitable animal models

Continued on page 22

Discovering a vaccine: the hope and the hoopla

Continued from page 1

on which to test a human vaccine;

- researchers will not know if a vaccine works in humans unless people who volunteer to test it put themselves at risk for becoming infected;

- if a vaccine does work, it will cause people to test positive on HIV antibody tests, leaving them vulnerable to discrimination and personal stigma; and

- pharmaceutical companies are reluctant to invest enormous resources to develop a vaccine which could, if flawed at any stage in development or use, leave the companies vulnerable to liability lawsuits.

The one obstacle which experts have been able to mitigate since 1987 has been in filling in major gaps in the basic knowledge about how the virus infects cells and how the immune system might be stimulated to block that. Scientists today know much more about how HIV binds to and infects cells, and much of that knowledge has come just in the past two years. These recent advances, said White House liaison Richard Socarides, are what prompted President Clinton to make a push now — instead of four years ago.

But new obstacles and "uncertainties" have arisen since 1987 too, noted Patricia Fast of NIH's Division of AIDS at a conference on AIDS vaccines earlier this month at the National Institutes of Health. Scientists now know there are at least six major strains of HIV in existence, and those strains have sub-strains. One vaccine may not deliver immunity against all of them. Although Fast indicated that recent reports are beginning to suggest that scientists may not need to develop a different vaccine for each strain, it also appears that vaccines which work in one racial group might not work in another. (This is due to the intricate processes by which an immune

system is able to recognize foreign particles; some aspects of these processes are more common in people of some ethnic backgrounds than they are in others.)

Although there are currently more than 40 different vaccines under development throughout the world, most have not advanced beyond the earliest phases of testing and will "probably" have to be tested in "tens of thousands" of people, said Fast, before researchers can be sure they will be effective in even 10 percent of the population. And those tough odds have both medical and economic implications for vaccine development. Drug companies need to make a profit. And, in a sense, so do people who volunteer to test drugs. Tens of thousands of people with HIV have been and are eager to volunteer for clinical trials testing new antiviral drug therapies — the drugs could remedy or alleviate an infection they already suffer from. But testing a vaccine will require the benevolence of thousands of people, especially Gay men, who are *not* HIV-infected. The benefit, if a vaccine works, is less tangible and, arguably, achievable through other means.

And politically, there is chagrin among some AIDS activists that the sudden attention to developing a vaccine wasn't more of an urgency 10 years ago. And there is concern that the Clinton administration is committing an additional \$17 million to develop a vaccine in 10 years at the same time it is refusing to support an additional \$68 million to help ensure that people who cannot afford lifesaving AIDS therapies can get them right now.

"The most disconcerting thing about the president's speech and statement on the AIDS vaccine," said Gary Rose, treatment and research coordinator for the AIDS Action Council, "is that never

once did he refer to the challenge of people living with the virus now, and that is being borne out in budget decisions like the administration's refusal to ask" for \$68 million more dollars to help buy AIDS drugs for the sick. (See related story on Page 1.)

Socarides is emphatic: "Every time the president has talked about AIDS in a general context, he has stressed that a cure always has been and always will be our top priority." No other government program, said Socarides, has received the budget increases that AIDS-related programs have.

And there is some urgency, he said, to capitalize on the opportunity now to develop a vaccine: "In order not only to find a cure but to eradicate AIDS completely, we will have to find a vaccine."

Daniel Zingale, head of AIDS Action, agreed: "I think the president deserves credit for recognizing that AIDS is a global problem and that, if we are ever to defeat AIDS globally, a vaccine is going to have to be a part of that."

And, while most people think of vaccines as drugs used to *prevent* infection in people who are free of HIV, some "vaccines" can *treat* infection in those who are already saddled with the virus. For instance, early this month, researchers at the University of California-Davis reported to a conference of microbiologists that they have developed a vaccine which, in test-tube experiments, has stopped the AIDS virus from mutating. While test-tube successes are far from promises, if this can be developed further and used in humans, it could possibly give the body's immune system and antiviral drugs a much better chance of stopping the virus from replicating.

At the same microbiology conference, researchers from Harvard Medical School discussed a vaccine they hope to develop using an impotent form of the

deadly bacteria anthrax to deliver immunizing proteins to healthy cells that would protect them from the AIDS virus.

And even research on vaccines which are being developed for preventive purposes have the potential to yield important knowledge and breakthroughs that can be applied to treatment. The furthest along right now is the canary pox vaccine. At the NIH vaccine conference this month, researchers held out great hope for that vaccine — constructed from the virus which causes pox in canaries to provide immunity against HIV infection. Kent Weinhold of Duke University said the canary pox virus does not cause disease in humans and could be used to trigger the immune system to produce immune cells to fight out HIV.

Vaccine research can be beneficial to people with and without HIV infection, explained Sam Avrett, associate scientific director of the International AIDS Vaccine Initiative.

"I'm HIV negative and my lover is positive," said Avrett. "I don't want my lover to get sick and die, and he doesn't want me to become infected. We both want research to help end the epidemic. Everybody — whether they are negative or positive — cares about ending the epidemic."

Avrett said he heard it put best recently by D.C. congressional Del. Eleanor Holmes Norton during a speech at a function by the National Minority AIDS Council.

"She said we can't let people divide us into treatment versus vaccine, or research versus care or prevention," said Avrett. "I think people realize that — that we should advocate as a unified community on both research for vaccines and treatment and access to treatment and care, and prevention counseling and interventions. We need all of this together." ▼

A Deadline for an AIDS Vaccine

After months of quiet debate among officials and researchers, President Clinton last week called for a vaccine within a decade. But many scientists are reacting with caution rather than euphoria

Researchers regularly woo politicians for funding, but they get nervous when those same politicians respond too amorously. They worry that political and scientific goals don't always make a happy marriage. That is why many senior scientists in the past few months have pushed for additional funding for AIDS vaccine research while arguing that the president should not set a public deadline for a vaccine. Instead, they got President Bill Clinton's 18 May clarion call for a vaccine within a decade—and no specific commitment of increased funding.

At a commencement speech at Morgan State University in Baltimore, Clinton proclaimed the vaccine "a new national goal for

science in the age of biology," and compared it to President John Kennedy's challenge 36 years ago to land a man on the moon. Clinton pledged to create an AIDS vaccine research center at the National Institutes of Health (NIH) to spearhead the initiative, promised to enlist other countries in the endeavor, and challenged the U.S. pharmaceutical industry to make the vaccine "part of its basic mission." Leading AIDS vaccine researchers worry about the price that science might pay if it can't deliver. Yet, they also think the high profile Clinton has given their field—which has been struggling to come up with new approaches to the challenges facing it (see p. 1196)—may help them in future funding battles.

The vaccine push gathered strength at a 3 December meeting on AIDS research, in which Clinton, Vice President Al Gore, and then-Chief of Staff Leon Panetta gathered in the Oval Office with NIH director Harold Varmus; Anthony Fauci, head of the National Institute of Allergy and Infectious Diseases (NIAID); and Office of AIDS Research chief William Paul, among others. "One of the issues most strongly raised was the desperate need for a vaccine," Paul recalls. "There was a general recognition that this was really a goal worth pursuing."

During the spring, the Presidential Advisory Council on HIV/AIDS—a 33-member group made up of government, industry, aca-

Clinton Calls for 'Human Values' in Science

President Clinton's announcement of an AIDS vaccine initiative drew most of the attention in his commencement address last week at Morgan State University in Baltimore (see main text). But the speech as a whole presented a broad view of the promise of science and the dangers of misapplying it.

Speaking on 18 May, Clinton told graduates of the historically black university that "we must do nothing to stifle our basic quest for knowledge." But he added, "As we consider how to use the fruits of discovery, we must also never retreat from our basic human commitment to human values, the good of society, and our basic sense of right and wrong." Those issues, he said, are acute now because of the potential for abuse of new genetic technologies and cloning. Clinton's call for greater ethical sensitivity in applying research results irritated some scientists, however.

Administration officials say that the White House, motivated by the breakthroughs in biology, the new views of the universe coming from the Hubble Space Telescope, and the discovery of possible life on Mars, has long wanted to articulate a clear view of the pitfalls and promises of science. The president suggested the topic as one of the themes for his three commencement addresses, and Clinton's domestic-policy adviser Bruce Reed and John Podesta, deputy chief of staff, both strongly supported the idea, according to White House sources. The Office of Science and Technology Policy, led by Jack Gibbons, weighed in with a massive briefing book, and a large team of White House officials hashed out the details of the speech over the previous 2 weeks.

As examples of science gone wrong, Clinton cited the infamous Tuskegee syphilis experiments, in which African Ameri-

cans with the disease were left untreated for decades, and Cold War research in the same era that subjected individuals to doses of radiation. "We must never go back to those awful days in modern disguise," said Clinton.

The leaps in biomedicine pose new risks, he said, calling for bipartisan legislation that would prevent insurance companies from using genetic data to deny coverage or set premium rates for some individuals. He also said, "We should resist the temptation to clone ourselves," although he stopped short of proposing legislation banning human cloning. "This is a decision no president should make alone. No president is qualified to understand all of the implications," Clinton added. A panel of bioethicists will offer their recommendations on cloning to the president in a few weeks (see p. 1185).

The gap between the research community and the public also was on the president's mind. "Science can serve the values and interests of all Americans, but only if all Americans are given a chance to participate." He cited past discrimination in academia, and called for the "voices and talents of everyone in this stadium—especially those of you who are going on to pursue a career in science and technology." And he cautioned against the hubris that can accompany the search for knowledge. "Science is not God," the president said, adding, "our deepest truths remain outside the realm of science."

Some of these admonitions irked Carl Feldbaum, president of the Biotechnology Industry Organization. He said the president "has gone too far if he means to imply that scientists ... aren't deeply concerned or actively involved in addressing the ethical and moral issues associated with their work."

—A.L.



Sensitive to science. Clinton at Morgan State commencement.

WILFREDO LEE/AP

demic, and advocacy representatives—pondered possible next steps in HIV vaccine development as part of a broader examination of AIDS research. The council's nine-member research committee solicited opinion about AIDS vaccine R&D from a wide variety of researchers at an April panel discussion. While the researchers heartily agreed on the need for more financial support, they had little collective enthusiasm for some of the specific recommendations the council had floated.

A draft that was widely circulated prior to the meeting raised many eyebrows by recommending that the U.S. government spend \$400 million on AIDS vaccine research and development each year—roughly three times the total now spent on the effort. It also called for steps that would force NIH to share more of the responsibility for AIDS vaccine R&D with the Centers for Disease Control and Prevention and other federal agencies.

But it was the draft's recommendation that Clinton set a national goal of developing an AIDS vaccine by a certain date that drew the most fire. "It's folly to give a date," Fauci told the council at the April meeting. Added Paul: "Promising a vaccine within a specific period of time, within a decade, is not a wise thing. ... It could lead to disappointment." But Yichen Lu of the Virus Research Institute in Cambridge, Massachusetts, disagreed. "We need a date ... to generate a sense of urgency," said Lu.

Lu's point of view won out in the council, which in April called for Clinton to "declare an urgent goal of developing a vaccine to prevent HIV/AIDS within a decade." The goal "is clearly feasible and should be considered of the highest priority for our government," the group stated. But the council rejected the proposal to triple vaccine funding, urging only "a significant and sustained increase in funds." And specific proposals for greater coordination among agencies and additional White House oversight were watered down.

The president accepted the council's advice, but he tempered his vaccine pledge by saying that "there are no guarantees. It will take energy and focus and demand great effort from our greatest minds." He added, however, 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. And it cannot come a day too soon."

After Clinton's announcement, Fauci said that "most of us were uncomfortable with saying we'll have a vaccine by this date," but he added, "I don't have an inherent fundamental problem with a goal ... as long as it's made clear that this is not a guarantee." Paul echoes that: "I would have had trouble [if Clinton had said] 'We will have a vaccine in a decade.'"

The most immediate outcome of the announcement will be an AIDS vaccine cen-

ter, which NIH will establish at Clinton's direction. The details of such a center are being hashed out now by the NIH AIDS Vaccine Research Committee led by Nobel Prize-winning virologist David Baltimore, which met on 9 May to discuss the project. It will start off as a "virtual center" jointly administered by NIAID and the National Cancer Institute (NCI), says Paul, before finding a physical home. Its major thrust, he says, will be to bring more immunology to the AIDS vaccine field, which has been dominated by virologists. The center also aims to attract vaccine developers from other fields. Paul adds that the center—formally called the NIAID/NCI AIDS Vaccine Center—may manufacture pilot lots of vaccines, a task now left to industry. That should help researchers test their ideas more quickly.

"The size is not fixed," he says. "In the early phase, it will be relatively small ... and obviously we will need to recruit senior people

from outside." NIH officials will soon set up a search committee to select a director and other senior staff. Meanwhile, the Administration has requested up to \$10 million for such a center in the 1998 budget, although it's not clear what its total cost would be. Money for the center, says Paul, will not come at the expense of extramural research funds.

There is little question that Clinton's initiative will create a more favorable environment in Congress and within the Administration for AIDS vaccine funding. "Think of what [the announcement] might mean next year when we're asking for money," says Fauci. "When the president of the United States starts putting that out, it can't hurt." So, while Clinton's embrace may be too close for comfort, researchers likely will cling to their newfound admirer.

—Andrew Lawler with Jon Cohen

Additional reporting by Eliot Marshall.

BIOETHICS

Panel Weighs a Law Against Cloning

When a Scottish research team startled the world by revealing 3 months ago that it had cloned an adult sheep, President Clinton moved swiftly. Declaring that he was opposed to using this exotic animal husbandry technique to clone humans, he ordered that federal funds not be used for such an experiment—although no one had proposed to do so—and asked an independent panel of experts chaired by Princeton President Harold Shapiro to report back to the White House in 90 days with recommendations for a national policy on human cloning. That group—the National Bioethics Advisory Commission (NBAC)—has been working feverishly to put its wisdom on paper, and at a meeting on 17 May, members endorsed a near-final draft of their recommendations.

NBAC will ask that Clinton's 90-day ban on federal funds for human cloning be extended indefinitely, and possibly that it be made law. But NBAC members are planning to word the recommendation narrowly to avoid new restrictions on research that involves the cloning of human DNA or cells—routine in molecular biology. The panel has not yet reached agreement on a crucial question, however: whether to recommend legislation that would make it a crime for private funding to be used for human cloning.

In a draft preface to the recommendations, discussed at the 17 May meeting,

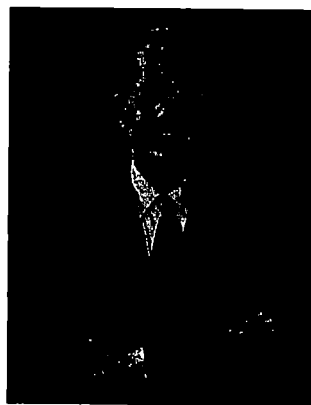
Shapiro suggested that the panel had found a broad consensus that it would be "morally unacceptable to attempt to create a human child by adult nuclear cloning." Shapiro explained during the meeting that the moral qualms stem mainly from fears about the risk to the health of the child. The panel then informally accepted several general conclusions, although some details have not been settled.

NBAC plans to call for a continued moratorium on federal government funding for any attempt to clone somatic cell nuclei to create a child. Because current federal law already forbids the use of federal funds to create embryos for research or to knowingly endanger an embryo's life, NBAC will remain silent on embryo research.

NBAC members also indicated that they will appeal to privately funded researchers and clinics to refrain from trying to clone humans by somatic cell nuclear transfer.

But they were divided on whether to go further by calling for a federal law that would impose a complete ban on human cloning. Shapiro and most members favored an appeal for such legislation, but in a phone interview, he said this issue was still "up in the air."

Many NBAC members wanted to recommend that no regulations be adopted that would interfere with the cloning of animals, cells, or DNA. Others preferred a more muted approach, on



Moral stand. Commission chair Harold Shapiro.

PHOTOGRAPH BY DENISE APPLEWHITE/PRINCETON UNIVERSITY

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FACSIMILE COVER SHEET

TO: Chris Jennings

FAX NUMBER: 456-5557

FROM: Sandy Thurman

DATE: May 23, 1997

PAGES INCLUDING COVER SHEET: 11

COMMENTS:

MEMORANDUM TO CHRIS JENNINGS

FROM:  Sandra Thurman, National AIDS Policy Coordinator

SUBJECT: Draft Memo to the President on AIDS Vaccine Initiative

As we discussed, I've drafted a follow-up memo to the President on the AIDS vaccine initiative, reviewing the community response and next steps to sustain and protect the initiative. I'd appreciate your feedback and suggested edits to make this a useful piece for the President. The last bullet on a White House meeting with industry is somewhat weak and your suggestions here would be most helpful.

Thanks!

Attachment

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MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Chris Jennings, Deputy Assistant to the President for Health Policy
Sandra Thurman, National AIDS Policy Coordinator

SUBJECT: AIDS Vaccine Initiative - Next Steps

This memorandum will summarize the broad response to the announcement of your commitment to developing an AIDS vaccine, and lay out a strategy to sustain momentum and solidify support for this initiative.

Response to Announcement

There has been broad-based and enthusiastic appreciation for your commitment to developing an AIDS vaccine. The Morgan State speech positively showcased your leadership and willingness to take on a critical research task with vital domestic and international implications. Prior to the announcement, we contacted major constituency groups and several industry leaders to ensure their support for this initiative. Attached are several comments that have been received.

AIDS Groups You have received a great response from the vast majority of national AIDS organizations. The AIDS Action Council, based in Washington and representing 1,400 community-based organizations (CBOs) across the country, and the National Association of People with AIDS have both written strong letters of support. The San Francisco AIDS Foundation, one of the largest CBOs in the country, and the Center for AIDS Prevention Studies, the leader in the prevention arena, continue to provide good comments for the media. The CAEAR Coalition, representing the 49 major cities receiving Ryan White CARE Act funding, are praising this initiative. Additional verbal and written responses are equally positive.

Some community groups and activists are expressing their concern around resource issues: a) will real resources be committed to this effort, and b) will funding or personnel be redirected from current treatment and prevention activities? Unfortunately, the timing of the Morgan State speech coincided with the Administration not requesting additional funds for AIDS drug assistance programs, and not placing AIDS funds in the "protected" category during the Budget discussions.

Consequently, the AIDS community feels that it is getting a mixed message. In their view, the Administration is focusing its efforts and dollars on a new initiative for vaccine development while at the same time de-prioritizing AIDS funding and underfunding treatment.

Foundations and Industry The Rockefeller Foundation has taken the lead in coordinating an international project known as the International AIDS Vaccine Initiative (IAVI). They strongly support Presidential leadership in this arena, and are anxious to participate in an international effort. UNAIDS, based in the World Health Organization in Geneva, has pledged to work with you to make this effort a success, and are delighted with your leadership. They are writing an op-ed piece to place in the Washington Post or NY Times.

The American Foundation for AIDS Research (AmFAR) in New York has put its support behind the initiative, as has the Albert Sabin Vaccine Foundation. Industry leaders, including those from Merck Pharmaceuticals, have been positive in their comments, but are waiting to see how this dialogue will evolve in the proposed White House meeting.

Next Steps

National Institutes of Health (NIH) Proposal The NIH has put forward more specifics around their proposed role in vaccine development. NIH has begun development of a Vaccine Research Center (VRC) as a joint venture of the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID). The VRC will begin incorporating a core group of NIH scientists with expertise in immunology, virology and vaccine research already on-site at NIH. The primary focus of VRC will be to stimulate multidisciplinary research from basic science through to vaccine design and production.

Initially the VRC will be a "laboratory without walls," while laboratory space is sought in the vicinity of the NIH campus to bring the scientists together. Later, as scientists are recruited from outside the NIH ranks, NIH will consider constructing new space on campus to house the VRC. The funding and support for the VRC will be jointly provided by NCI and NIAID. As you know, funds for AIDS research are allocated according to the plans developed by the Office of AIDS Research (OAR) with the NIH Institutes. The OAR has proposed \$17 million in FY 1998 for the VRC, bringing the overall NIH support to AIDS vaccines to \$150 million. A search committee will be named before the end of May to conduct a nationwide search for a scientist with specific expertise in vaccine development to serve as Director for the new VRC.

Plans to Address Community Concerns To demonstrate that this is a serious proposal, we have set up several meetings to provide information to the community and walk through their concerns. On Wednesday, Sandy Thurman will have a news briefing in her office with Dr. Harold Varmus, Director of the NIH, Dr. Bill Paul of the Office of AIDS Research, and Dr. Tony Fauci of NIAID to provide more details about NIH's plan for a vaccine research center. A follow-up meeting with the community will take place after the news briefing. Sandy has already met with most of the national AIDS organizations individually this week. We are also setting up a meeting next week for the community with OMB to explain FY'97 and FY'98

Page 3 - The President

budgetary issues and reaffirm the Administration's full and equal commitment to all of the AIDS programs -- prevention, research and care.

To continue in a consistent and positive direction, we will identify opportunities to reaffirm the breadth of the Administration's commitment to HIV/AIDS. By early June, the expert panel sponsored by HHS and Kaiser Family Foundation to develop model clinical practices for care of adult HIV infection will be ready to publish their recommendations in the Federal Register for public comment. This has been an anxiously awaited document, given the increasing complexity of HIV care with many new drug combinations and laboratory tests to monitor HIV disease. This is a clear demonstration of the Administration's commitment to translating research gains into improved care for all persons living with HIV. A White House roll-out could be orchestrated with both health care providers and community groups.

Many of the leading national AIDS organizations come together in Washington, DC on June 23, 1997 to kick off the HIV Testing Project -- an initiative to encourage people to voluntarily learn their HIV status so they can benefit from effective new treatments. This would be another opportunity to announce the expert panel recommendations to visibly cement your support for the spectrum of AIDS prevention and care issues in addition to active research and vaccine development components.

Sustaining Momentum on Vaccine Initiative The U.S. has proposed that the leaders of the eight major industrialized nations meeting at the Denver Summit in June agree to support a worldwide AIDS vaccine research initiative. The UNAIDS program and the International AIDS Vaccine Initiative (IAVI) are working with us to fashion a proposal acceptable to participating countries. Four countries have already contacted UNAIDS around what specifics could be developed. A few satellite meetings with the scientific and research communities could be put together in Denver to highlight this initiative. We are coordinating with Dan Tarullo of the NEC around the possibility of coordinating an announcement at the Summit.

In the next few months, a White House meeting to bring together vaccine development experts, government scientists, community leaders, and representatives of biotech and vaccine manufacturing companies can be put together. This would create an opportunity for you to deliver brief remarks, and for the Vice President to engage biotechnology and pharmaceutical industry partners in AIDS drug and vaccines development efforts.

We are working on a follow-up memo that will provide additional information, including plans relative to the June G8 Summit in Denver.



May 20, 1997

The Honorable Bill Clinton
President of the United States
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20515

Dear Mr. President:

On behalf of the 1,400 community-based organizations AIDS Action Council represents, I would like to take this opportunity to applaud your call this past Sunday, May 18, to make the development of an AIDS vaccine a "new national goal for science." By likening your challenge to find an AIDS vaccine within the next decade to President John F. Kennedy's call to put an American on the moon, you have reminded the country, indeed, the world, that much remains to be done before this terrible epidemic is truly over.

Mr. President, AIDS Action Council recognizes your leadership in the fight against this dread disease. Sixteen years into the AIDS epidemic, the AIDS community is enjoying the new hope that promising AIDS drug therapies represent. Thousands of people living with HIV and AIDS are benefiting from state-of-the-art care, which has contributed to an historic decline in AIDS deaths in the United States. History will record these two advancements, as well as your AIDS vaccine announcement last Sunday, as a part of your legacy on AIDS.

AIDS Action Council urges you to expand that legacy by continuing to make funding for AIDS research, care, prevention, and housing a budgetary priority in fiscal year 1998 and beyond. Research to find more effective treatments, a vaccine, and a cure must continue to be a priority. All Americans living with HIV and AIDS must have access to the health care and the social services they need to stay alive and healthy. Every weapon at our disposal, including needle exchange programs, must be put to good use to curb the further spread of HIV. And no individual living with HIV disease should want for adequate, stable housing. AIDS Action Council is anxious to work with you to ensure that this era of hope – raised to a new level by your call to re-energize our nation's search for an AIDS vaccine – touches the life of every American living with, and affected by, HIV and AIDS.

Best Regards,

A handwritten signature in black ink that reads "Daniel Zingale". The signature is fluid and cursive, with a large, sweeping "D" and a long, trailing "Z".

Daniel Zingale
Executive Director

cc The Honorable Donna Shalala
Sandra Thurman, Director, Office of National AIDS Policy

1875

Connecticut Ave NW

Suite 700

Washington DC

20009

Fax 202 986 1345

Tel 202 986 1300

**NAPWA****NATIONAL
ASSOCIATION
OF PEOPLE
WITH AIDS**

May 21, 1997

The President
The White House
Washington, DC 20500

Dear Mr. President:

I am writing on behalf of the National Association of People with AIDS (NAPWA), to commend you on the announcement of a national initiative to develop a protective vaccine against the Human Immunodeficiency Virus (HIV) in the next ten years. NAPWA salutes your commitment to making this a serious national priority.

As the national voice of people living with HIV, NAPWA represents the needs of countless thousands of Americans who face the day-to-day challenges of living with HIV disease. We remain committed to working for a cure for AIDS. We have never strayed from our responsibility, however, to promote and support effective HIV prevention and education. For millions of people at-risk for HIV infection across the globe, the simple knowledge that the greatest nation on earth will lead the effort to develop a preventive vaccine is very powerful.

We applaud your leadership and the leadership of Vice President Gore. In announcing this initiative, NAPWA strongly urges you to renew your commitment to maintaining and expanding HIV/AIDS Housing, Prevention, Research, Medicaid and Medicare and CARE Act services.

Sincerely,

A. Cornelius Baker
Executive Director



UNAIDS
UNICEF • UNDP • UNFPA
UNESCO • WHO • WORLD BANK

The Executive Director

Joint United Nations Programme on HIV/AIDS

Reference: exr

President William J. Clinton
The White House
Washington, D.C.

20 May 1997

Mr President,

Your extraordinary leadership in setting the goal for the development of an AIDS vaccine in the next ten years merits sincere praise. For too long, the research agenda has been turned on its head, with ninety percent of research funds in AIDS going towards cures and only ten percent to vaccines. Important as the new developments in therapy are in reducing the suffering and prolonging lives of people living with HIV/AIDS in the few countries where treatment is possible and affordable, they are doing nothing to halt the relentless march of this disease in Africa, Asia, Latin America and Eastern Europe.

For a vaccine to be brought to the parts of the world where the disease is having its greatest impact, the countries of the industrialized world and the developing world will need to work closely together. The Joint United Nations Programme on HIV/AIDS (UNAIDS) has a Vaccine Advisory Committee, which is chaired by Dr Barry Bloom of the Albert Einstein College of Medicine in New York, and includes representatives from several industrialized and developing countries. UNAIDS and its Committee have as their mission to promote and facilitate the scientific, ethical, legal, and practical involvement of developing countries in vaccine research and testing.

Mr President, we pledge UNAIDS to work with you, Secretary Shalala, the National Institutes of Health and other U.S. institutions in the forefront of this crusade against AIDS. A vaccine which effectively addresses a virus which is devastating the world, must be tested and proven in the most affected countries in accordance with the highest standards of science and ethics.

Again, Mr President, I should like to congratulate you for your bold step forward. By directing the scientific community to leap beyond the tested borders of biology in the 21st century, you do much to ensure your own place in the history of our planet.

Please accept, Mr President, the assurance of my highest consideration.

Peter Piot



May 19, 1997

The Honorable William Jefferson Clinton
President
The White House
Washington, DC 20510

Dear Mr. President:

The Cities Advocating Emergency AIDS Relief (CAEAR) Coalition commends you on the announcement of a ten year federal initiative to develop a vaccine for the Human Immunodeficiency Virus (HIV). We salute your use of the Presidency to keep issues related to the worldwide AIDS pandemic at the forefront.

The CAEAR Coalition represents the federal policy and appropriations interests of the 49 U.S. epicenters of the AIDS epidemic that receive funding through Title I of the Ryan White CARE Act. We are people living with HIV and AIDS, medical providers, support service providers, and health planners who are on the front lines of the U.S. AIDS epidemic. We acknowledge the importance of a targeted initiative for vaccine development and recognize that a vaccine is critical to preventing new infections in youth and adults at risk for infection. We trust that the leadership of the United States in this initiative will have a ripple effect in governments and communities around the world--encouraging them to increase their efforts to end this devastating pandemic.

As consumers and providers of CARE services for people living with HIV, we ask that you continue to use the Presidency as a bully pulpit to keep the issues of people living with HIV in the hearts and minds of the American people. CARE programs will continue to need significant increases in support from the federal government as more people live longer with HIV disease. Medical care, housing, substance use treatment, mental health treatment, transportation, nutrition, and of course new antiretroviral drug therapies continue to be critical to the quality of life and survival of people living with HIV. Your ongoing support for increased funding for CARE programs is paramount to our success in filling these needs.

Thank you for your leadership and the leadership of Vice President Gore. We encourage you to continue to clearly articulate your commitment to ending this epidemic while caring for those living with HIV. The CAEAR Coalition looks forward to working with you to realize the goal of this laudable initiative.

The CAEAR Coalition

1413 K Street N.W., Suite 700
Washington, D.C. 20005

202 789 3565
202 789 4277 fax

Executive Committee

Ernest Hopkins, *Chair*
Suzi Rodriguez, *Vice Chair*
Robert Rybicki, *Treasurer*
Jacqueline Muther, *Southern*
Marc Halpert, *Southwestern*
Rex Sandborg, *Midwestern*
A. Gene Copello, *Northwestern*
Matthew McClain, *Mid-Atlantic*
Paul DiDonato, *At-Large*
Shawn Griffin, *At-Large*
Kathy Cerra, *At-Large*
Luanna Clark, *At-Large*

**Administrator of
Federal Affairs**

H. Alexander Robinson

**Governmental Relations
Representative**

The Sheridan Group

Sincerely,

~~Judy Moore-Nichols~~
Jerry Walker
Andre Lamm

~~Don~~
~~Shirley W~~
Suzi Rodriguez
Anna Heath

~~Barclay Miller~~
Vanelle Deacon

Lawrence W. Jew
William E. Wiles

Mark W. Pickering, M.S.W.

Guy L. Frazier
Carlton R. Smith
BALTIMORE EMA

K. C., EMA
Portland, OR EMA
Santa Rosa, California

Los Angeles, CA
N. Hollywood (A. Gaither) EAC
Vice Chair CAEAR Coalition
Los Angeles, CA
San Francisco CA

San Francisco, CA
San Francisco, CA

St Louis, MO
St Louis, MO

St. Louis, MO

Fat, Vanderdale, FL
Baltimore Md EMA

Brian Longue

Nancy M. Elyan

Chris Wade

Logan A. Gooden

Joseph Wynn

M. O'Neil

Patricia Gans

Wm. Kim

James J. Funder

William Thomas

~~Edward H. Hapless~~

Jo Ann Schop

Andrew Deppe

Ladonna Love-Kretschmer

Glenn P. Hagan

Mary Clark

St. Louis EMA

Los Angeles Calif. HIV-DATF

Los Angeles TARZANA Treatment Cent

HIV+
Kansas City, MO R.W. Co-Chair

Miami, FL EMA

Chicago, Ill EMA

Phila. Pa EMA

Denver EMA

Denver EMA

Chicago EMA

Chairman CAHR Coalition
Wash. D.C.

New York City EMA

Chicago Dept. of Health

Chair Austin HIV Planning Council

Palm Beach County EMA

Boston EMA

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

808 17th Street, N.W., 8th Floor
Washington, D.C. 20006

Phone: 202-632-1090

Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: Bruce Reed

FAX NUMBER: 456-2878

FROM: Sandy Thurman

DATE: May 23, 1997

PAGES INCLUDING COVER SHEET: 9

COMMENTS:

MEMORANDUM TO BRUCE REED

FROM:  Sandra Thurman, National AIDS Policy Coordinator

SUBJECT: Draft Memo to the President on AIDS Vaccine Initiative

As discussed, I have drafted a follow-up memo to the President on the AIDS vaccine initiative, covering the community response and next steps to sustain and protect this initiative. Let me know if you think this is on target for what is useful to the President, and any edits you'd like to see.

Thanks!

Attachment

DRAFT -- DRAFT -- DRAFT -- DRAFT -- DRAFT -- DRAFT -- DRAFT

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Chris Jennings, Deputy Assistant to the President for Health Policy
Sandra Thurman, National AIDS Policy Coordinator

SUBJECT: AIDS Vaccine Initiative - Next Steps

This memorandum will summarize the broad response to the announcement of your commitment to developing an AIDS vaccine, and lay out a strategy to sustain momentum and solidify support for this initiative.

Response to Announcement

There has been broad-based and enthusiastic appreciation for your commitment to developing an AIDS vaccine. The Morgan State speech positively showcased your leadership and willingness to take on a critical research task with vital domestic and international implications. Prior to the announcement, we contacted major constituency groups and several industry leaders to ensure their support for this initiative. Attached are several comments that have been received.

AIDS Groups You have received a great response from the vast majority of national AIDS organizations. The AIDS Action Council, based in Washington and representing 1,400 community-based organizations (CBOs) across the country, and the National Association of People with AIDS have both written strong letters of support. The San Francisco AIDS Foundation, one of the largest CBOs in the country, and the Center for AIDS Prevention Studies, the leader in the prevention arena, continue to provide good comments for the media. The CAEAR Coalition, representing the 49 major cities receiving Ryan White CARE Act funding, are praising this initiative. Additional verbal and written responses are equally positive.

Some community groups and activists are expressing their concern around resource issues: a) will real resources be committed to this effort, and b) will funding or personnel be redirected from current treatment and prevention activities? Unfortunately, the timing of the Morgan State speech coincided with the Administration not requesting additional funds for AIDS drug assistance programs, and not placing AIDS funds in the "protected" category during the Budget discussions.

Consequently, the AIDS community feels that it is getting a mixed message. In their view, the Administration is focusing its efforts and dollars on a new initiative for vaccine development while at the same time de-prioritizing AIDS funding and underfunding treatment.

Foundations and Industry The Rockefeller Foundation has taken the lead in coordinating an international project known as the International AIDS Vaccine Initiative (IAVI). They strongly support Presidential leadership in this arena, and are anxious to participate in an international effort. UNAIDS, based in the World Health Organization in Geneva, has pledged to work with you to make this effort a success, and are delighted with your leadership. They are writing an op-ed piece to place in the Washington Post or NY Times.

The American Foundation for AIDS Research (AmFAR) in New York has put its support behind the initiative, as has the Albert Sabin Vaccine Foundation. Industry leaders, including those from Merck Pharmaceuticals, have been positive in their comments, but are waiting to see how this dialogue will evolve in the proposed White House meeting.

Next Steps

National Institutes of Health (NIH) Proposal The NIH has put forward more specifics around their proposed role in vaccine development. NIH has begun development of a Vaccine Research Center (VRC) as a joint venture of the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID). The VRC will begin incorporating a core group of NIH scientists with expertise in immunology, virology and vaccine research already on-site at NIH. The primary focus of VRC will be to stimulate multidisciplinary research from basic science through to vaccine design and production.

Initially the VRC will be a "laboratory without walls," while laboratory space is sought in the vicinity of the NIH campus to bring the scientists together. Later, as scientists are recruited from outside the NIH ranks, NIH will consider constructing new space on campus to house the VRC. The funding and support for the VRC will be jointly provided by NCI and NIAID. As you know, funds for AIDS research are allocated according to the plans developed by the Office of AIDS Research (OAR) with the NIH Institutes. The OAR has proposed \$17 million in FY 1998 for the VRC, bringing the overall NIH support to AIDS vaccines to \$150 million. A search committee will be named before the end of May to conduct a nationwide search for a scientist with specific expertise in vaccine development to serve as Director for the new VRC.

Plans to Address Community Concerns To demonstrate that this is a serious proposal, we have set up several meetings to provide information to the community and walk through their concerns. On Wednesday, Sandy Thurman will have a news briefing in her office with Dr. Harold Varmus, Director of the NIH, Dr. Bill Paul of the Office of AIDS Research, and Dr. Tony Fauci of NIAID to provide more details about NIH's plan for a vaccine research center. A follow-up meeting with the community will take place after the news briefing. Sandy has already met with most of the national AIDS organizations individually this week. We are also setting up a meeting next week for the community with OMB to explain FY'97 and FY'98

Page 3 - The President

budgetary issues and reaffirm the Administration's full and equal commitment to all of the AIDS programs -- prevention, research and care.

To continue in a consistent and positive direction, we will identify opportunities to reaffirm the breadth of the Administration's commitment to HIV/AIDS. By early June, the expert panel sponsored by HHS and Kaiser Family Foundation to develop model clinical practices for care of adult HIV infection will be ready to publish their recommendations in the Federal Register for public comment. This has been an anxiously awaited document, given the increasing complexity of HIV care with many new drug combinations and laboratory tests to monitor HIV disease. This is a clear demonstration of the Administration's commitment to translating research gains into improved care for all persons living with HIV. A White House roll-out could be orchestrated with both health care providers and community groups.

Many of the leading national AIDS organizations come together in Washington, DC on June 23, 1997 to kick off the HIV Testing Project -- an initiative to encourage people to voluntarily learn their HIV status so they can benefit from effective new treatments. This would be another opportunity to announce the expert panel recommendations to visibly cement your support for the spectrum of AIDS prevention and care issues in addition to active research and vaccine development components.

Sustaining Momentum on Vaccine Initiative The U.S. has proposed that the leaders of the eight major industrialized nations meeting at the Denver Summit in June agree to support a worldwide AIDS vaccine research initiative. The UNAIDS program and the International AIDS Vaccine Initiative (IAVI) are working with us to fashion a proposal acceptable to participating countries. Four countries have already contacted UNAIDS around what specifics could be developed. A few satellite meetings with the scientific and research communities could be put together in Denver to highlight this initiative. We are coordinating with Dan Tarullo of the NEC around the possibility of coordinating an announcement at the Summit.

In the next few months, a White House meeting to bring together vaccine development experts, government scientists, community leaders, and representatives of biotech and vaccine manufacturing companies can be put together. This would create an opportunity for you to deliver brief remarks, and for the Vice President to engage biotechnology and pharmaceutical industry partners in AIDS drug and vaccines development efforts.

We are working on a follow-up memo that will provide additional information, including plans relative to the June G8 Summit in Denver.

MEMORANDUM TO BRUCE REED

FROM: Sandra Thurman, National AIDS Policy Coordinator

SUBJECT: Draft Memo to the President on AIDS Vaccine Initiative

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Thank you.

Attachment

MEMORANDUM TO CHRIS JENNINGS

FROM: Sandra Thurman, National AIDS Policy Coordinator

SUBJECT: Draft Memo to the President on AIDS Vaccine Initiative

As we discussed, I've drafted a follow-up memo to the President on the AIDS vaccine initiative, reviewing the community response and next steps to sustain and protect the initiative. I'd appreciate your feedback and suggested edits to make this a useful piece for the President. The last bullet on a White House meeting with industry is somewhat weak and your suggestions here would be most helpful.

Thank you.

Attachment



May 20, 1997

The Honorable Bill Clinton
President of the United States
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20515

Dear Mr. President:

On behalf of the 1,400 community-based organizations AIDS Action Council represents, I would like to take this opportunity to applaud your call this past Sunday, May 18, to make the development of an AIDS vaccine a "new national goal for science." By likening your challenge to find an AIDS vaccine within the next decade to President John F. Kennedy's call to put an American on the moon, you have reminded the country, indeed, the world, that much remains to be done before this terrible epidemic is truly over.

Mr. President, AIDS Action Council recognizes your leadership in the fight against this dread disease. Sixteen years into the AIDS epidemic, the AIDS community is enjoying the new hope that promising AIDS drug therapies represent. Thousands of people living with HIV and AIDS are benefiting from state-of-the-art care, which has contributed to an historic decline in AIDS deaths in the United States. History will record these two advancements, as well as your AIDS vaccine announcement last Sunday, as a part of your legacy on AIDS.

AIDS Action Council urges you to expand that legacy by continuing to make funding for AIDS research, care, prevention, and housing a budgetary priority in fiscal year 1998 and beyond. Research to find more effective treatments, a vaccine, and a cure must continue to be a priority. All Americans living with HIV and AIDS must have access to the health care and the social services they need to stay alive and healthy. Every weapon at our disposal, including needle exchange programs, must be put to good use to curb the further spread of HIV. And no individual living with HIV disease should want for adequate, stable housing. AIDS Action Council is anxious to work with you to ensure that this era of hope – raised to a new level by your call to re-energize our nation's search for an AIDS vaccine – touches the life of every American living with, and affected by, HIV and AIDS.

Best Regards,

A handwritten signature in black ink that reads "Daniel Zingale". The signature is fluid and cursive.

Daniel Zingale
Executive Director

cc The Honorable Donna Shalala
Sandra Thurman, Director, Office of National AIDS Policy

1875
Connecticut Ave NW
Suite 700
Washington DC
20009
Fax 202 986 1345
Tel 202 986 1300

THE PRESIDENT INTRODUCES INITIATIVES TO FULFILL HIS COMMITMENT TO DEVELOP AN AIDS VACCINE

Today President Clinton challenged the nation to commit itself to the goal of developing an AIDS vaccine within the next ten years. The President also announced a number of important initiatives to help fulfill this commitment, including high-level international collaboration, a dedicated research center for AIDS vaccine research at the National Institutes of Health (NIH), and outreach to scientists, pharmaceutical companies, and patient advocates to maximize the involvement of both the private and public sectors in the development of an AIDS vaccine. The President has already taken steps to enhance the possibility of developing an AIDS vaccine by increasing funding for NIH vaccine research and development over 33 percent in the last two years. The initiatives the President announced today, which build on an exceptional commitment to develop better ways to prevent, diagnose, treat, and eventually cure AIDS, include:

- **A New NIH AIDS Vaccine Center.** A dedicated intramural HIV vaccine research and development center is being established at the National Institutes of Health. This vaccine center, which will be fully operational within the next several months, is uniting outstanding scientists in immunology, virology, and vaccinology to join in a highly-collaborative effort to develop an AIDS vaccine. Bringing together a broad array of researchers in an intensely-focused environment has been a successful way of developing vaccines in the past.
- **A Global AIDS Vaccine Research Initiative.** The United States is proposing that the leaders of the eight major industrialized nations meeting at the Denver Summit in June agree to support a worldwide AIDS vaccine research initiative. The proposal calls for each nation to make a commitment to provide the necessary investments in their country to accelerate research toward the development of an HIV/AIDS vaccine as a scientific and public health priority. Joint meetings of key scientists from participating nations will address research progress, identify scientific gaps and opportunities, and design collaborative programs.
- **A Challenge to Pharmaceutical Manufacture Industry to Invest in Innovative Research to Develop an AIDS Vaccine.** We can only be successful in developing an AIDS vaccine if private and public sectors make this goal a priority. The President is challenging the pharmaceutical industry to join the government in a partnership to realize this important goal.

Background on HIV/AIDS. HIV/AIDS remains a global public health threat. More than 29 million men, women and children around the world have been infected with HIV -- more than 3 million infections occurring within the last year. Without an effective vaccine, AIDS will soon overtake tuberculosis and malaria as the leading cause of death among persons between 25-44 years of age. Between 650,000-900,000 Americans are estimated to be living with HIV disease, and over 300,000 Americans have already died from AIDS.

Clinton Administration Accomplishments on HIV/AIDS. The Clinton Administration has made a sustained commitment to addressing the HIV epidemic through investments in prevention, research and treatment.

- **Increased funding for the NIH vaccine by 33 percent.** Funding for NIH vaccine research and development has increased over 33 percent in the last two years -- from \$111.1 million in FY 1996 to \$148 million proposed in the President's FY 1998 budget.
- **Funding for AIDS research, prevention and care increased by more than 50 percent in the first four years of the Clinton Administration.** Funding for AIDS Drug Assistance Programs (ADAP), which help low-income people purchase needed therapies, has tripled, while funding for the Ryan White CARE Act increased 158 percent. The approval of new AIDS drugs has greatly accelerated, with 16 new AIDS drugs and two diagnostic tests.



May 19, 1997

President Bill Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Mr. President:

The International AIDS Vaccine Initiative strongly supports your call for an urgent increased and time-bound effort to develop safe and effective HIV vaccines. We agree that an HIV vaccine is possible and with nearly 10,000 new infections occurring a day worldwide, time is of the essence.

We also applaud your plans to call for the leaders of the G-7 countries and Russia to join the U.S. in a global effort to create a vaccine. HIV is the first large global epidemic of an emerging infectious disease in this era of global interconnectedness. How we deal with this epidemic portends how we will contend with future, yet undiscovered infectious diseases. Your leadership on this issue internationally will intensify recognition of the impact of HIV/AIDS on international health and development, and bring together the strengths and commitment of national and international agencies and organizations to address and solve the impact of HIV/AIDS on worldwide human and economic development.

We concur that the U.S. government must continue to support or even enhance the excellent basic scientific research that serves as the essential underpinning of vaccine development. In addition, we need to enhance applied vaccine development efforts. Without good animal models and without clear correlates of protection, there is no substitution for clinical testing of promising safe candidates in humans at an early stage. Results (whether positive or negative) from clinical testing will drive the basic science agenda as much as findings in basic science will inform the product development process.

We support the creation of a new vaccines effort at the NIH which will facilitate the important linkage between basic and clinical research. As you have acknowledged, however, industry is the best source of applied work. Unfortunately, as you are aware, there currently are not the market incentives for industry to invest substantial resources in HIV vaccine development. A new initiative needs to be considered. This initiative should be a directed research effort which

IAVI

Interim Secretariat • c/o The Rockefeller Foundation • 420 Fifth Avenue • New York, NY 10018-2702 • USA
phone (212) 852-8349 • fax (212) 852-8279

President Bill Clinton
May 19, 1997

Page 2

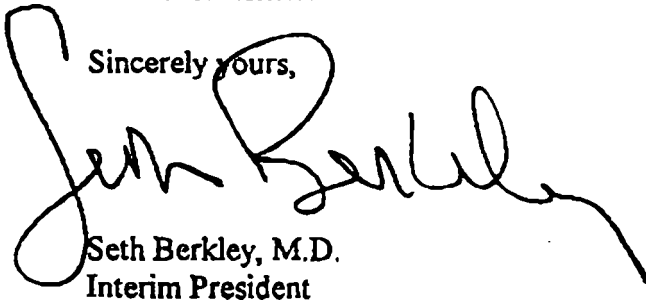
is goal oriented with clear benchmarks using the world's most experienced HIV/AIDS researchers and vaccinologists. Vaccines cannot be developed by researcher oriented mechanisms. Vaccines need to be developed by an experienced team of vaccinologists and other scientists that will, step by step, solve the problems encountered during the development process.

In addition, vaccines need to be designed for testing and use in international settings where the epidemic is spreading most rapidly and where testing can be efficiently accomplished. Use in international settings may require special characteristics such as simplicity, stability and cost that may require different vaccine designs than are being evaluated for the U.S. market.

The International AIDS Vaccine Initiative was established with just this purpose in mind -- to ensure the development of safe, effective, preventive HIV vaccines for use throughout the world. IAVI has established a partnership of international agencies (UNAIDS and the World Bank) to work directly with those in the private sector without the constraints of government funding mechanisms to accelerate vaccine development. We would welcome the opportunity to work with your staff to assure the completion of your noble and just target of a safe and effective HIV vaccine by the end of the decade.

With best wishes.

Sincerely yours,

A large, stylized handwritten signature in black ink, appearing to read 'Seth Berkley'.

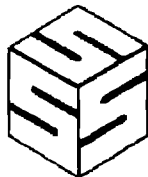
Seth Berkley, M.D.
Interim President

cc: Sandra Thurman

SFB/pb

IAVI

Interim Secretariat • c/o The Rockefeller Foundation • 420 Fifth Avenue • New York, NY 10018-2702 • USA
phone (212) 852-8349 • fax (212) 764-3468



Social & Scientific Systems
7101 Wisconsin Avenue, Suite 1300
Bethesda, MD 20814

(301) 986-4870 telephone
(301) 913-0351 facsimile

FACSIMILE MESSAGE

DATE: May 22, 1997

Pages: 2
(including cover)

TO: Sandra Thurman

FROM: Ann Borlo

MESSAGE:

A conference call will be held at 9 a.m. (eastern), Friday, May 23. The number to dial at 9 a.m. is (800) 432-2198; the host code is 502766 and the participant code is 681274.

Please contact me at (301) 986-4870 if you have any questions or concerns. Thanks.

cc: Daniel Montoya

*9:00 am
conference
call*

*Call Sandra Thurman
9-1-213-0351*

MEMORANDUM

TO: Sandra Thurman

CC: Daniel Montoya

FROM: Elliot Han

RE: AIDS Vaccine Initiative Conference Call

DATE: May 22, 1997

Individuals who were on the conference call:

- | | |
|------------------------|----------------------|
| 1. Eric Goosby | 8. Helen Miramontes |
| 2. Jerry Cade | 9. Sandra Thurman |
| 3. Phyllis Greenberger | 10. Daniel Montoya |
| 4. Bob Hattoy | 11. Bruce Weniger |
| 5. Scott Hitt | 12. Nicholas Bollman |
| 6. Ron Johnson | 13. Joseph Edelheit |
| 7. Alexander Robinson | 14. Robert Fogel |

-Ms. Thurman states that the objective of the conference call is to discuss what direction the Council must move toward and what should they do following the aftermath of the AIDS Vaccine Initiative.

-Concerns with the AIDS Vaccine Initiative:

Africa America

- Why was it disclosed at the Morgan State University Commencement?
 - Ms. Thurman replies that the reason is because Morgan State graduates the highest number of science/technology oriented students in the area.
- The participants of the call express concern and discontentment with the President's decision to reveal the initiative without any forewarning to the Council.
- Bob Hattoy believes that the Domestic Policy Council was fully aware of their action, and thus revealed their stance of unconcern for the Vaccine Initiative in light of the budget.
- Members asked: Why there was no additional money set aside and who will monitor the issue of the money being distributed for this initiative?
- Thus, the conference call participants believed that the way the budget was handled put AIDS funding at risk.

-Proposal to address the above questions:

- The participants of the call recommended that a letter should be written directly to the President that the committee is concerned that they did not receive any notice about the budget changes and its effect on AIDS funding.
- It was proposed that Scott Hitt should write the letter, but Bob Fogel argued that Ms. Thurman should write it instead, because she is “the director” of the AIDS Policy Office. However, no decision was made on who was to write the letter.
- Ms. Thurman says that we should not think that this incident means that AIDS is not a priority for the President and his Administration.
- Therefore, it is proposed, for reassurance, that someone senior at the White House issue a memorandum which states that AIDS Policy is a priority.
- They want this memo to address the following questions:
 1. What happened in the budget? Why was not any money set aside for AIDS?
 2. What is the Administration’s stance? Is AIDS a priority or not? And if it is a priority, will the President make a commitment to maintain it as such?

Other proposals:

- The participants of the call want to establish a small group within the Council whose function is to serve as a budget monitoring caucus.
 - The members realize the need, but have the question of how to implement it?
- Finally, they proposed a Research Committee Conference call for next week or the following week.

Memorandum

TO: Sandra Thurman
CC: Daniel Montoya
From: Michael Diz, Sarah Holewinski
Date: May 21, 1997
Re: Congressional Task Force on International HIV/AIDS: Briefing on HIV Vaccine Research and Development.

Congresswoman Morella's remarks were brief, centering on the goal of the Congressional Task Force on HIV/AIDS to include a 9% increase in funding for vaccine research as opposed to the President's suggested 2.6%.

Subsequent remarks were given by:

Dr. Anthony Fauci: National Institute for Allergy and Infectious Diseases, National Institute for Health;
Seth Berkley: Associate Director, Health Sciences, The Rockefeller Foundation, International AIDS Vaccine Initiative;
Margaret Johnston: Scientific Director, International AIDS Vaccine Initiative;
Dr. Gordon Douglas: President, Merck Vaccines, Merck & Co. Inc.

Dr. Fauci

Dr. Fauci gave his remarks before a crowded briefing room; unfortunately, representatives from the ONAP were not yet in that room.

Seth Berkley

Mr. Berkley began by listing various facts regarding an HIV Vaccine: first, such a vaccine is urgently needed; second, development is possible; third, presently allocated resources dedicated to vaccine research are inadequate; and finally, the current international environment does not meet the expansive needs for the development of vaccines that would serve all populations.

He then went on to assert that HIV is the largest killer in the world and that the cost of providing current drugs to all of those in need would be between \$300 and \$400 billion per year. Obviously, drug treatment is not the most cost-effective or feasible way to attack this epidemic. Therefore, the focus of funding and research should shift toward the development of a vaccine.

HIV/AIDS vaccine on an international scale. A great concern was expressed by all of those who spoke on overcoming a variety of obstacles to global HIV vaccination.

Among the most urgent of barriers was establishing a global supervising force to oversee a multitude of issues, including but not limited to: regulations in testing, distribution, financing and monopoly control. Dr. Douglas pointed out that the lack of an 'international government' creates debate over intellectual property rights, black market sales, inadequate data on the epidemiology of HIV infection, and, as previously mentioned, the lack of an established health care network. In terms of funding, Seth Berkley pointed out the enormous cost of not only the research but the subsequent distribution and administration of the vaccine.

The lack of global supervision creates sociological side effects resulting in the further polarization amongst those populations with access as opposed to those without. Mr. Berkley termed this phenomenon 'another apartheid' that would increase the separations between the industrialized countries and developing nations. By holding the conditions in the United States and other Western nations as a standard for research and distribution, problems arise involving environment (temperature control), ease of use, and cost of vaccination in developing countries. Hence, new barriers emerge, when thinking on a global scale, that serve to complicate the quest for a universal solution to the HIV/AIDS epidemic.

A question and answer period followed the prepared remarks and proceeded as follows:

Q: Assuming the sky was the limit, how much funding could the NIH responsibly handle?

A: (Dr. Fauci) An exact number is impossible to determine. It is clear that a larger percentage of the NIH Budget needs to be allocated to vaccine research.

Q: What do you say in response those who insist that the shifting of money from treatment research to vaccine development is decreasing the size of their already small pie?

A: (Dr. Fauci) The reality is that the pie to which you are referring is quite large, and has been growing tremendously in recent years. The real issue is figuring out how to protect the millions of people who are not already infected.

Q: Please comment on the status of the "envelope" vaccine in Thailand.

A: (Ms. Johnston) Testing will begin soon on an envelope vaccine for sub-type "E." We need to have development of various vaccines that will illicit different immune responses so that we may learn what will be most effective.

Q: Have there been efforts to bring together experts from the "Hots Spots" around the world?

A: (Mr. Berkley) Yes, but they have not focused on vaccine development. We are pushing for that now, but need the help of leaders in developing countries.

Q: Dr. Douglas, is there anything that the President has said recently that gives you incentive to do more.

A: (Dr. Douglas) It is nice to have the President share this goal with us.

Q: Can the government do anything to increase the world-wide effort?

A: (Dr. Douglas) Yes. A collaborative effort must begin immediately, with its goal to break down the barriers to vaccine development and distribution.

Q: Is a decade a realistic time frame for developing a vaccine?

A: (Dr. Douglas) It is impossible to say for sure, but yes, that is a reasonably good figure-- 5 years would have been too short, 20 too long.

Q: IN 1985, MARGARET HECKLER PREDICTED THAT WE WOULD HAVE AN AIDS VACCINE IN TWO YEARS. THAT WAS OVER TEN YEARS AGO. MOREOVER, AT A RECENT CONFERENCE, DR. ROBERT GALLO INDICATED THAT WE MAY NEVER SEE AN EFFECTIVE AIDS VACCINE. WHY SHOULD WE BELIEVE THAT THE PRESIDENT'S PROMISE THAT WE CAN DEVELOP AN AIDS VACCINE IN A DECADE?

A: We know much more about the AIDS virus today than we knew in 1985 or even in 1995. Recent scientific advances have taught a great deal about how the AIDS virus infiltrates the human and begins to destroy the human immune system. We have developed a whole new series of drugs that inhibit the reproduction of the AIDS virus.

There are many credible scientists and medical researchers who are believe that it is not a question of whether we will ever get an AIDS vaccine but when. The scientific leaders at the National Institutes of Health have said that are extremely encouraged by recent progress in the AIDS vaccine and believe that the development of a vaccine is feasible. In fact, there were numerous presentations at the conference that spoke about the tremendous progress we have made in the AIDS vaccine development and in vaccine development in general.

The President announced today that we should commit ourselves to developing an AIDS vaccine in the next ten years. He acknowledged that there are no guarantees. But he believes that we should commit our energy, our focus, and the efforts from our greatest minds to finding an AIDS vaccine.

Q: HOW ARE THE INITIATIVES THE PRESIDENT ANNOUNCED TODAY BEING PAID FOR? ARE THEY A PART OF THE BALANCED BUDGET AGREEMENT?

A: All of the costs for developing an AIDS vaccine are being paid for by NIH's existing budget. NIH has already increased funding for AIDS vaccine research by 33 percent in the last two years -- from \$111 million in FY 1996 to \$148 million proposed in the President's FY 1998 budget. *\$17,197 - \$131 million*

Q: THE BALANCED BUDGET AGREEMENT CALLS FOR CAPS ON DISCRETIONARY DOMESTIC SPENDING. WON'T ADDITIONAL FUNDING FOR AN AIDS VACCINE MEAN LESS FOR OTHER IMPORTANT PRIORITIES? WHY NOT EXPEND THIS KIND OF ENERGY AND RESOURCES ON A CURE FOR BREAST CANCER OR HEART DISEASE OR DIABETES?

A: This Administration has made a strong improving biomedical research an extremely important priority. We have increased investments in biomedical research at the National Institutes of Health by an impressive 16 percent since the President took office and the President's FY 1998 budget proposes a ~~\$12 million~~ increase.

These additional investments has been used to increase investments in biomedical research in a number of important areas. For example, funding for breast cancer research has increased by 76 percent since the President took office .

Developing an AIDS vaccine is one important priority in our investments in biomedical research. Without an effective vaccine, AIDS will soon take over as the leading cause of death for persons between the ages of 25 and 44. Between 650,00 and 900,000 Americans are estimated to be living with HIV and over 300,000 have died of AIDS.

While we have made enormous strides in the last year in treating AIDS, these treatments are not always effective and are often prohibitively expensive both for Americans and throughout the world. Also scientists at NIH believe that it is only a matter of time before we develop an AIDS vaccine. Increasing our commitment to developing a vaccine could make an enormous difference and save millions of lives both in this country and throughout the world.

AIDS VACCINE Q&AS

Q: DOESN'T THE PRESIDENT'S CHALLENGE RING HOLLOW SINCE YOU ARE NOT INVESTING ANY NEW RESOURCES DEVELOPING AN AIDS VACCINE?

A: The President has committed additional resources to developing an AIDS vaccine. In the last two years, he has increased funding for the AIDS vaccine by 33 percent and his FY 1998 budget increases spending for AIDS vaccine research by \$17 million.

Moreover, scientists have informed the President that it is not only money that we need to meet the challenge of finding an AIDS vaccine, but that we also need to promote collaboration between experts in this area. That is why the President has announced that there will be a new AIDS Vaccine Center at NIH which will unite scientists in immunology, virology, and vaccinology to join in a highly collaborative effort to develop an AIDS vaccine.

That is also why he is calling on the leaders of the eight major industrialized nations meeting at the Denver summit in June to support a worldwide AIDS vaccine research initiative. These important initiatives are what scientists believe we need to do to fully commit ourselves to the goal of developing an AIDS vaccine.

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Q: IF WE ARE INVESTING MORE TO DEVELOP AN AID VACCINE AREN'T WE TAKING AWAY FROM INVESTMENTS ON TREATING PEOPLE WHO ALREADY SUFFER FROM THIS DISEASE?

A: Since he took office, the President has made an extraordinary commitment to increasing our investments in AIDS. Funding for AIDS research, prevention and care increased by more than 50 percent in the first four years of the Clinton Administration. Funding for AIDS Drug Assistance Programs (ADAP), which help low-income people purchase needed therapies, has tripled, while funding for the Ryan White CARE Act increased 158 percent. The President believes that we need to continue to increase our investments in all of these areas and his FY 1998 budget reflects that commitment, with additional investments in AIDS research, prevention and care.

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Increasing our commitment to developing a vaccine could make an enormous difference and save millions of lives both in this country and throughout the world.

THE PRESIDENT INTRODUCES INITIATIVES TO FULFILL HIS COMMITMENT TO DEVELOP AN AIDS VACCINE

Today President Clinton challenged the nation to commit itself to the goal of developing an AIDS vaccine within the next ten years. The President also announced a number of important initiatives to help fulfill this commitment, including high-level international collaboration, a dedicated research center for AIDS vaccine research at the National Institutes of Health (NIH), and outreach to scientists, pharmaceutical companies, and patient advocates to maximize the involvement of both the private and public sectors in the development of an AIDS vaccine. The President has already taken steps to enhance the possibility of developing an AIDS vaccine by increasing funding for NIH vaccine research and development over 33 percent in the last two years. The initiatives the President announced today, which build on an exceptional commitment to develop better ways to prevent, diagnose, treat, and eventually cure AIDS, include:

- **A New NIH AIDS Vaccine Center.** A dedicated intramural HIV vaccine research and development center is being established at the National Institutes of Health. This vaccine center, which will be fully operational within the next several months, is uniting outstanding scientists in immunology, virology, and vaccinology to join in a highly-collaborative effort to develop an AIDS vaccine. Bringing together a broad array of researchers in an intensely-focused environment has been a successful way of developing vaccines in the past.
- **A Global AIDS Vaccine Research Initiative.** The United States is proposing that the leaders of the eight major industrialized nations meeting at the Denver Summit in June agree to support a worldwide AIDS vaccine research initiative. The proposal calls for each nation to make a commitment to provide the necessary investments in their country to accelerate research toward the development of an HIV/AIDS vaccine as a scientific and public health priority. Joint meetings of key scientists from participating nations will address research progress, identify scientific gaps and opportunities, and design collaborative programs.
- **A Challenge to Pharmaceutical Manufacture Industry to Invest in Innovative Research to Develop an AIDS Vaccine.** We can only be successful in developing an AIDS vaccine if private and public sectors make this goal a priority. The President is challenging the pharmaceutical industry to join the government in a partnership to realize this important goal.

Background on HIV/AIDS. HIV/AIDS remains a global public health threat. More than 29 million men, women and children around the world have been infected with HIV -- more than 3 million infections occurring within the last year. Without an

effective vaccine, AIDS will soon overtake tuberculosis and malaria as the leading cause of death among persons between 25-44 years of age. Between 650,000-900,000 Americans are estimated to be living with HIV disease, and over 300,000 Americans have already died from AIDS.

Clinton Administration Accomplishments on HIV/AIDS. The Clinton Administration has made a sustained commitment to addressing the HIV epidemic through investments in prevention, research and treatment.

- **Increased funding for the NIH vaccine by 33 percent.** Funding for NIH vaccine research and development has increased over 33 percent in the last two years -- from \$111.1 million in FY 1996 to \$148 million proposed in the President's FY 1998 budget.
- **Funding for AIDS research, prevention and care increased by more than 50 percent in the first four years of the Clinton Administration.** Funding for AIDS Drug Assistance Programs (ADAP), which help low-income people purchase needed therapies, has tripled, while funding for the Ryan White CARE Act increased 158 percent. The approval of new AIDS drugs has greatly accelerated, with 16 new AIDS drugs and two diagnostic tests.

THE WHITE HOUSE

WASHINGTON

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Major Clinton Administration Accomplishments in HIV/AIDS

- Increased funding for AIDS research, prevention, and care by more than 50% in first four years.
- Increased funding for the Ryan White CARE Act by 158 percent and increased number of cities eligible for CARE Act funds from 34 to 49.
- Tripled funding for the AIDS Drug Assistance Programs, which helps low-income uninsured people with AIDS purchase needed therapies.
- Created the Office of National AIDS Policy at the White House to direct Federal AIDS policy.
- Signed the NIH Revitalization Act of 1993, creating a strengthened Office of AIDS Research at NIH and vesting it with authority to plan and carry out the AIDS research agenda.
- Accelerated AIDS drug approval to record times. Since 1993, the Food and Drug Administration has approved 16 new AIDS drugs and two new diagnostic tests.
- Facilitated creation of the Forum for Collaborative HIV Research to identify research opportunities to improve care for people with HIV.
- Preserved the Medicaid guarantee of coverage for people living with AIDS. Nearly 50 percent of people with AIDS and 92 percent of children with AIDS rely on Medicaid for health coverage.
- Launched the community planning partnership, which empowers local communities to make decisions about the distribution of AIDS prevention funding.
- Vigorously enforced the Americans with Disabilities Act, which prohibits discrimination against people with HIV/AIDS.

Genetic trick may seriously hamper HIV

A team of scientists at UCLA and the University of Rochester report in today's *Journal of Biological Chemistry* that they have found a way to "trick" the AIDS virus into screwing up its own replication process.

The trick, say the scientists, is to genetically engineer a mutation in a "primer" molecule that HIV uses to attach itself in a specific way to a cell's genetic RNA. Mutating the primer (called transfer RNA) causes the virus to attach to the RNA in an askew fashion — akin to a typist's fingers starting in the wrong position on a keyboard. Sitting in the wrong spot, HIV suffers "major inhibition" of its replication process because it cannot properly transcribe the genetic code.

The trick now will be to translate this into some clinical therapy.

In brief ...

- **NEW WEB SITE:** It seems like every week there's a new AIDS-related Web site to report. This week's is put together by researchers at the University of California-San Francisco, where many ground-breaking studies have taken place. The site, hivsite.ucsf.edu, promises "up-to-the-minute updates" on AIDS treatments and research.

- **USING PROTEASES:** A survey of more than 1,000 clients of an AIDS service group in Los Angeles this year found that three-fourths of white clients are taking protease inhibitors while only about half of people of color are. The survey data was presented at a June 2 Capitol Hill briefing on how AIDS is having an impact on people in racial minorities.

- **USING CONDOMS:** Surveys of more than 2,000 young adults in Switzerland in 1987 and 1994 found that safer sex campaigns led to increased use of condoms but did not result in people having more sex partners or more "casual" sex. The study was published in last month's *American Journal of Public Health*.

- **TESTING FOR HTLV:** HTLV is a virus similar to HIV and is prevalent in the same risk groups as HIV. But HTLV causes leukemia. A report in the June 10 *Proceedings of the National Academy of Sciences* says that the standard test used by most blood banks to screen for HTLV may be missing some cases.

- **VACCINE SUCCESS:** The June issue of *Nature Medicine* reports that a "combination" vaccine using both a nasal spray and an injection protected three chimpanzees against a "high-dose" challenge by HIV even a year after the immunization. It's the longest any experimental AIDS immunization has lasted.

— Lisa Keen

AIDS DIGEST

Protease inhibitors may trigger CMV

A team of AIDS physicians in the U.S. reported last month that patients who have very low CD4 counts when they start triple-drug therapies may still develop CMV retinitis when their CD4 counts go back above 50.

Typically, noted the U.S. researchers, patients with HIV develop CMV retinitis — a debilitating infection of the eyes — only when their CD4 cell counts have gone below 50. Triple-drug therapies which include a protease inhibitor have been very effective in increasing patients' CD4 counts "dramatically." But doctors have wondered, for some time, whether the increase in CD4 counts translates into an improved ability by the immune system to ward off certain opportunistic infections which often attack when the CD4 count is low. They know that the immune system pegs each CD4 cell to fight off a particular disease. As HIV destroys CD4 cells, those pegged against some diseases can be completely depleted. When a drug therapy helps the body restore the number of CD4 cells, it can duplicate only those cells still remaining. However, researchers have speculated that the immune system might be able to adapt and still ward off opportunistic infections. If it does, patients could conceivably stop taking some of their medications — those taken to prevent opportunistic infections.

But the report in the May 17 *Lancet* seems to suggest patients won't be able to stop taking such preventive medicines, at least not for CMV retinitis.

The doctors reported five patients who developed CMV retinitis even though their CD4 counts had gone from 82 or less back up to 197 or higher after starting triple-drug therapy.

The doctors, from UCLA and other universities around the country, said the findings suggest that physicians treating patients on triple-drug protease therapies should now anticipate that CMV retinitis can develop at CD4 counts above 100, particularly in patients who start triple-drug therapy when their CD4 counts are already very low.

In an interview this month with *AIDS Treatment News*, Clifford Lane, an expert on this issue with the National Institute of Allergy and Infectious Diseases, said he would continue preventive medications for pneumonia, too.

The National Institutes of Health is expected to publish a draft of its recommendations for therapy in the *Federal Register* soon.

Sale of HIV test kits to benefit media watchdog

HOFFMAN ESTATES, Ill. — Home Access Health Corporation, maker of an at-home HIV antibody test kit, announced May 29 that it will donate \$5 to the Gay and Lesbian Alliance Against Defamation for every kit sold during the month of June to customers who say "I'm GLAAD that Home Access advertised on *Ellen* and supports our community."

The Illinois-based company advertised its Home Access Express kit during

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Washington Blade ⑤

Continued from page 16 ①
the *Ellen* show's now-famous April 30 episode, in which actor Ellen DeGeneres's lead character came out as a lesbian. The company since then has received thousands of favorable responses from Gays and others who have praised the company's support of the Gay episode, said Kevin Johnson, spokesperson.

The HIV Home Access Express kit is available in most major drug stores, although only those "Express" kits ordered over the company's 1-800-HIV-TEST phone number — along with the aforementioned quote — will benefit the media watchdog group GLAAD.

The "Express" kits cost \$49.95 and results are guaranteed within three business days, said Johnson.

AIDS drugs, doctors say

Food affects how protease inhibitors work

by Viet Dinh

People with HIV infection taking the protease inhibitors ritonavir and saquinavir should have them "with a McDonald's Happy Meal," said Dr. Norrha Muurahainen of the Graduate Hospital in Philadelphia.

Muurahainen was speaking on a panel at a May 22 community forum in D.C. sponsored by the Carl Vogel Center. At the forum, "Nutrition Issues in the Era of Protease Inhibitors," she noted that those two protease inhibitors should be taken with foods that have a high fat content.

"Some drugs are difficult for the body to absorb," she said. "And since some drugs are absorbed better with fat, it's wise to have fat content in the stomach when taking those drugs."

"A drug's efficiency is relative to how well it's absorbed by each person," said Muurahainen.

The panel gave these general dietary recommendations for people with AIDS who are taking some of the common protease inhibitors:

- ritonavir (brand name Norvir) and saquinavir (brand name Invirase) should be taken with foods with *high* fat content.
- indinavir (brand name Crixivan) should be taken with foods with *no* fat content.
- nelfinavir (brand name Viracept)

should be taken with foods with *some* fat content ("A muffin or pastry made with butter will suffice," said Muurahainen.)

In addition to Muurahainen, the panel consisted of Dr. Richard Elion, a D.C. physician, and Cade Fields-Gardner, the director of services for a health care firm in Chicago, who urged people taking protease inhibitors to consult a dietitian to address each individual's needs.

Elion noted that there are studies which indicate how certain vitamin and nutrient supplements may contribute to increased health. In particular, he said, in proper doses, antioxidants — minerals such as selenium that prevent intracellular oxidation — may play a role in reducing inflammation of tissues.

The amount and frequency of any nutritional and vitamin supplements, however, should be monitored by a dietitian to avoid under- or over-supplementing, said the panel members. Panel members also cautioned against taking Geritol or other supplements with iron content.

"There's data showing that eating a diet too high in iron is not good," said Elion. "High iron can get stuck in your liver. There's no good reason to take iron unless you're deficient. And, at the very least, your vitamin supplements should be iron-free." ▼

ACTING UP: The Screen Actors Guild last month began providing free AIDS-fighting drugs to its uninsured members, making it the first union or corporation to do so, according to United Press International. The drug therapies can cost up to \$16,000 annually.

6/13 Washington Blade

by Lou Chibbaro Jr.

Six AIDS service groups in Florida decided two weeks ago to sever ties with the Los Angeles entrepreneur who promotes the nation's AIDS Rides, triggering a flurry of press reports about the overhead costs associated with the fundraisers.

The spate of negative publicity has prompted officials with D.C.'s Whitman-Walker Clinic and Food and Friends to defend the promoter and the AIDS Rides, which function as large-scale bike-a-thons. The two D.C. groups noted that last year's Philadelphia-D.C. AIDS Ride pulled in more than \$1.5 million in profits for them. Food and Friends head Craig Schniderman said this year's D.C. AIDS Ride, set to begin next week in Raleigh, N.C., is expected to yield at least that amount.

The Florida groups, led by CenterOne, a nonprofit AIDS service group in Fort Lauderdale, announced in late May that they no longer want promoter Dan Pallotta and his for-profit company, Pallotta TeamWorks

Inc., to organize the annual Orlando to Miami AIDS Ride.

CenterOne official John Weatherhead said the groups are upset because for two years in a row — 1996 and 1997 — only 18 cents of every dollar raised in the Florida AIDS Ride went to programs that help people with AIDS. The remaining 82 cents on the dollar went to overhead costs, including a \$160,000 fee to Pallotta TeamWorks, Weatherhead said.

He said the Florida groups are considering organizing their own bike benefit ride next year, even though the Pallotta firm has copyrighted the term "AIDS Ride."

The Pallotta firm founded the AIDS Ride concept in 1994. Since that time, the firm has served as promoter and chief organizer of the rides in cities across the country, including D.C.

Pallotta TeamWorks officials say that the high overhead costs associated with the Florida AIDS

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Florida AIDS groups drop promoter of bike-a-thon

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Continued from page 16

Ride, as well as with last year's Philadelphia ride, are exceptions to the norm and were due to problems that occurred with those two rides. According to the Pallotta firm, no more than 43 cents to the dollar has gone to overhead costs in all of the other rides and overhead costs for some of them were below 40 cents to the dollar. The firm has argued that in spite of what some consider high overhead costs, the AIDS Rides in various cities across the country have yielded \$22 million in profits for AIDS groups between 1994 and 1996.

Nevertheless, reports about the overhead costs associated with the rides have surfaced recently in the *Washington Post*, *U.S. News and World Report*, and the *Fort Lauderdale Sun Sentinel*. Gay community newspapers in a number of cities, including San Francisco, have also published stories raising concerns about both the overhead costs and whether a private company should be

making profits from an AIDS charity event.

The *U.S. News and World Report* article, published June 9, created a stir among AIDS activists. The article said the national news magazine conducted its own research and found that overhead costs of all of the AIDS Rides organized by the Pallotta firm appeared to be closer to 50 percent. The magazine also reported that "state investigators" disclosed that Pallotta received "an annual salary and bonus of about \$270,000."

The Washington Post reported in a June 9 story that it conducted its own investigation, too, and found that Pallotta, 36, "lives in a modest home and does not own an airplane, boat, or exotic car."

The Pallotta firm has declined to comment on the profits it makes in organizing the AIDS Rides. Because the firm is privately held, it is not required to publicly disclose its income or profits. ▼

by Wendy Johnson

Two recent studies have found that women may be able contract sexually transmitted diseases from other women, but not many women are practicing safer sex with their female partners.

The studies appear in the premier issue of the *Journal of the Gay and Lesbian Medical Association*, released last month.

One study, conducted by Dr. Nina Carroll at Fenway Community Health Center in Boston, shows that women may be able to contract STDs from other women.

Titled "Gynecological Infections and Sexual Practices of Massachusetts Lesbian and Bisexual Women," the study examined the relationship between the sexual practices and reported gynecological infections among 421 women who have sex with women.

The women answered written questions about their sexual health and sexual practices. The majority of the women (90 percent) identified themselves as Lesbians; 9 percent identified as bisexuals; and 1 percent identified as heterosexual or "other."

Twenty percent of all women said they have never had sex with a male; they were presumed by Carroll to have had sex with women. (This figure is roughly comparable to one from a 1994 Missouri study, which found that 19 percent of Lesbians surveyed said they had never had sex with a man.)

Of these 79 women who had never had sex with a man, 23 percent (18 women) said they had been diagnosed with a gynecological infection. The infections included 13 reported cases of vaginosis, a common vaginal infection; five cases of genital warts; and two reported cases of trichomoniasis, a parasitic vaginal infection.

This incidence of woman-to-woman STDs is higher than is commonly believed among health care providers, who annually record low incidences of STDs in Lesbian-identified women, Carroll reported.

Among 403 women who gave information about their past sexual partners, 47 percent said they had had sex with men but not in the past 10 years; 20 percent had had sex with men but at least five years ago and less than 11 years ago; 20 percent never had sex with a man; and 13 percent had had sex with a man less than four years ago.

Women who had sex with men were twice as likely to have suffered a gynecological infection compared to women who never had sex with men. This held true even for the women who had sex with men more than five years ago. Among the 270 of women who'd had sex with men more than five years ago, 43 percent (116 women) had reportedly been diagnosed with at least one sexually transmitted gynecological infection.

"Either these STDs were acquired by prior heterosexual encounters and remained latent for several years, or they were due to woman-to-woman contact," Carroll concluded. "The true incidence of STDs among Lesbians is underestimated because of ignorance regarding the variety of sexual behaviors that are possible between women."

Monitoring the prevalence of STDs

among Lesbians has been important to researchers, since studies have shown that people with STDs are at greater risk for contracting HIV infection.

HIV risks

High-risk behaviors associated with HIV infection were examined in the second study, conducted by Patricia E. Stevens and Joanne M. Hall of the University of Wisconsin-Milwaukee School of Nursing.

Titled "Emotional and Social Contingencies Affecting HIV Risk Reduction Among Lesbians and Bisexual Women," the study used extensive interviews with women who have sex with women to learn how their attitudes and beliefs about safer sex influence the probability that they will engage in safer sex practices.

A total of 563 women were interviewed at San Francisco Gay bars and Gay community events between 1993 and 1994.

Stevens found that although the women reportedly engaged in sexual activity that put them at risk for contracting HIV and other sexually transmitted diseases, many said they do not engage in safer sex. The reasons ranged from peer pressure and their association of latex barriers with promiscuity, to misconceptions about their own risk of contracting STDs.

ig Lesbians

The purpose of the study was to learn about women's sexual attitudes and practices and participants were allowed to use their own definitions and terminology. Statistical data is not available for all aspects of Stevens's study, since the interviews were conducted as conversations and the women were not asked specific questions, said Stevens.

All of the 563 women reported having had sexual activity with other women. Some also reported sexual activity with men. None of the women were directly asked whether they have sex with men and women, and none were asked to define their sexual orientation.

"We didn't ask specific questions, but used conversations to find out about women's strategies and their knowledge of the issues," said Stevens. "It's a rapport-building strategy and one well-used in women's health research."

Fifty-six percent of all women interviewed for the Stevens study said that when they have sex with other women, they have unprotected sex. Twenty percent of all women said they have unprotected sex when they have sex with men. The remainder of those interviewed did not say whether they use barriers.

A similar study Stevens conducted in 1993 shows little difference in Lesbians' concern about safer sex. In that study, 50 percent of the 626 women interviewed said they did not use latex barriers when having sex with women; 15 percent did not use condoms when they had sex with men.

At least 20 percent of the women interviewed for the current study said they sometimes use barriers during sex but that they forgo the barriers when their "intuition" tells them it is safe to do so.

"I can always tell if a partner is a risk," said one woman. Another believed she had a "built-in sense about women, so [she] can feel when it's OK to be wild."

When discussing safer sex practices, women reported varied definitions of what "safe" sexual practices were.

For example, although 31 percent felt that unprotected sex in monogamous relationships was an ideal strategy for preventing HIV infection, definitions of monogamy varied widely.

Some defined monogamy as limiting sex to just that partner, but for some women, these relationships lasted only a few weeks to a few months, so, while they were monogamous sexually, they had a number of sexual partners in the space of a few months or years. Others said they considered relationships monogamous even if they had sex outside the primary relationship, provided that latex barriers are used with the secondary partner.

At least 20 percent of the women interviewed said they were tested regularly for HIV infection as a way to "prevent" infection. Half of these women said they were concerned about their own sexual practices or their partner's.

At least 12 percent of all women interviewed gauged their own risk for acquiring HIV infection by gathering information about their partners' sexual and drug histories. This information, however, was often obtained during vague conversations and, in some cases, after sexual activity had occurred.

Ten percent of all women interviewed said they avoided certain "categories" of sex partners as a way to lower their own risk for HIV infection. Some of these categories included strangers, people with "worrisome lifestyles," and "people who aren't honest."

Some women in their 20s believed they could lessen their HIV risk by having sex with younger women only — presuming they had less experience sexually.

Some women said they avoid having sex with women who identify as bisexual, saying that women who identify as Lesbians are not likely to engage in sex with men and are therefore less likely to be HIV-infected. This reasoning appeared flawed, since some women who

identified as Lesbians also said that they also have unprotected sex with men.

Women also described some of the difficulties they encounter when attempting to reduce their risk for HIV infection. Some said they lack access to information; others have poor communication with their partners, and some have concerns that safer sex will hamper their enjoyment of sex. At least 28 percent of the women interviewed said they are frustrated with the "how-to's" of practicing safer sex with other women: dental dams were either too small or difficult to obtain, and condoms were too small and too clumsy to handle.

Eighteen percent of the women denounced latex barriers as a constant reminder of "death" and said that "too much apparatus" hampers sexual intimacy and romance.

"In the middle of passion, I hate to worry about all the negative things, you know, deal with death," said one woman.

Education was also a factor. At least 22 percent felt that they lacked the basic knowledge necessary to prevent HIV infection, and others said they felt embarrassed by their lack of skill in using latex barriers. Some women said they did not know where to get information, what information to believe, or whether they should bother.

Some articulated grossly inaccurate beliefs, including the notion that oral sex is safe because "saliva kills the virus." One woman believed that contact with "some blood" is safe.

"There's a difference between venous and arterial blood in terms of HIV," she said. "HIV doesn't live in oxygenated environments." Another woman said she "prevents" HIV infection by "using the toilet after sex and drinking lots of water to flush [her] system."

At least 15 percent said they did not like to discuss safer sex practices with their sexual partners. Some felt that *talking* about sex was more intimate than *having* sex and were less likely to discuss safe sex with a casual sexual partner. When they did broach the subject, 14 percent said they encountered resistance from their partner and found it difficult to be assertive with them. One woman said her partner became angry when she brought up the use of barriers.

"She said, 'I hate that shit.' So we didn't talk about it again."

Others associated condoms with "sleazy" or "promiscuous" sex.

"I wouldn't practice safe sex with my girlfriend, unless I *thought* she was cheating on me," said one woman. "If my girlfriend started practicing safe sex, I would *know* she was cheating on me."

Stevens said her study sheds light on the emotional and social complexities involved with teaching Lesbian and bisexual women about HIV risk prevention and risk reduction.

"It helps us know what issues we might need to address in an HIV prevention program," she said. "In the past, approaches in HIV prevention have focused on teaching women how to use condoms, as if [safer sex] is all about cognitive decision-making. But we're finding that it involves all kinds of social pressure and very little decision-making." ▼

Activists demand better access to AIDS drugs *Washington Blade*

NEW YORK, N.Y. — Demanding that drug companies

make more experimental drugs available to people with AIDS, 300 AIDS activists protested three pharmaceutical companies during an AIDS health fair held in New York by POZ magazine.

Holding signs that read "Release experimental drugs now," members of ACT UP/NY and other AIDS activists protested at the POZ Life Expo May 31. The protesters demanded that the pharmaceutical companies create more expanded access programs for promising drugs that are awaiting approval by the Food and Drug Administration.

The companies targeted included Abbott Laboratories, Gilead Sciences, and Glaxo-Wellcome, all makers of protease inhibitors, a newer class of AIDS drugs.

The activists said these three companies have recently scaled back their expanded access programs, which make experimental drugs available to people who have failed conventional forms of treatment. The activists contended the scale-backs are an effort to maximize profit from drugs that are already widely available.

The protest included peaceful confrontations with representatives from Gilead and Abbott, and a large "die-in" at the empty health fair site of Glaxo-Well-

come. The pharmaceutical company withdrew its participation from the two-day health fair after ACT UP announced it would protest Glaxo-Wellcome, according to a written company statement.

The free, two-day health fair, a consumer fair for people with AIDS, will, according to POZ magazine Publisher Megan Whiting, travel to several other cities this fall, including Washington, D.C., Atlanta, Chicago, and Los Angeles.

*File
Jacine*

VIA FAX

TO: DR. SANDRA THURMAN

FROM: VAXGEN INC.

ATTN:

TO: FAX PHONE#: 2024562439

Job Number: 42968005-009-85-0010

TIME: Thu Jul 30 07:14:39 1998

3 pages including cover sheet

Washington, D.C. Clinic Begins Inoculations in Phase III Trial of AIDSVAX

SOUTH SAN FRANCISCO, Calif.--July 30, 1998--The Center for Immunization Research at the Johns Hopkins University School of Hygiene and Public Health today will begin inoculating volunteers in the North American trial of AIDSVAX, the first-ever vaccine against HIV to be tested in Phase III human clinical trials, at D.C. General Hospital in Washington, D.C. The vaccine unit at D.C. General is the third to participate in the trial sponsored by VaxGen, Inc., the developer of AIDSVAX.

The North American Phase III trial got under way last month at clinics in Philadelphia and St. Louis and is projected to expand to 30 to 40 clinics and 5,000 volunteers at risk for HIV infection.

"We are eager to participate in this study because we see it as a milestone in the effort to prevent HIV infection," said Clayton Harro, M.D., Medical Director of the Johns Hopkins Center for Immunization Research and Principal Investigator of the study being conducted at D.C. General.

"AIDS is to our generation what smallpox was to previous generations," Dr. Harro continued. "And what stopped the suffering and death from that epidemic? A vaccine. This study offers the opportunity for those in the communities most affected by this epidemic -- especially gay men -- to take a leadership role in developing a preventive HIV vaccine."

Phase III studies are designed to test the vaccine's efficacy in a real-life setting. Trial participants will be selected from among volunteers who are at risk for HIV infection but who are currently uninfected. Over the course of 30 months, volunteers will be given seven injections, but neither volunteers nor researchers will know which volunteers are given the vaccine and which receive a placebo (inactive substance).

In the North American trial, the volunteers will be selected from among individuals at risk through sexual transmission -- primarily gay males and women with HIV-positive partners.

VaxGen anticipates beginning the Phase III trial of a separate formulation of AIDSVAX in Thailand later this year, following approval by the Thai Ministry of Health. That trial will involve volunteers at risk of HIV infection through injection-drug usage.

Throughout the three-year trials, volunteers will be counseled on methods to avoid HIV infection and cautioned not to construe their participation in the trial as protection against infection. Follow-up with volunteers will continue for at least six months after the last injection is administered.

At the end of the trial, the rate of infections in the group that received the placebo will be compared to the rate of infections, if any, among volunteers who received the vaccine. That comparison will be used to determine the efficacy of the vaccine.

"We are pleased to have D.C. General and Johns Hopkins join the AIDSVAX study," said Dr. Donald P. Francis, President of VaxGen, "especially considering the deep ties to the community and rich history of vaccine research and development represented, respectively, by these institutions. The support of the volunteers, researchers and hospitals like D.C. General is essential to VaxGen's goal of developing a vaccine against HIV."

On June 3, 1998, VaxGen announced that it had received clearance from the U.S. Food and Drug Administration to begin the U.S. portion of Phase III clinical trials of AIDSVAX. Phase III trials are a critical step in the strictly regulated and monitored process by which a new vaccine or drug is tested and precedes application to the FDA to license and market the product. The first two volunteers in the Phase

III North American trial were given injections at the Philadelphia FIGHT clinic on June 23, 1998.

Each AIDSVAX formulation is bivalent -- that is, created from recombinant copies of the gp120 protein from the surface of two types of HIV. The vaccine to be used in test sites across North America is formulated to protect against infection by the major types of HIV-1 virus most typical of infections in the Americas, Western Europe and Australia. The formulation of the vaccine to be used in the Thai trial is designed to protect against the major types of the virus typical of infections in Southeast Asia.

Earlier clinical trials have shown that AIDSVAX is safe for use in humans and induces a strong immune response. AIDSVAX cannot cause HIV infection or AIDS.

VaxGen, based in South San Francisco, Ca., is a biotechnology company committed to making an HIV vaccine for worldwide use.

Additional information is available on our web site at:
<http://www.vaxgen.com/>. NOTE: For information about volunteering in the D.C. study, phone (877) 243-7829.

CONTACT: Donna K.H. Walters, (Pager 888-443-0055)
Anne George, (Pager: 800-686-7073)
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Slow pace of AIDS vaccine draws fire

A microbial killer is roaming the globe, killing 11 people a minute. The killer is HIV, the AIDS virus.

Though a vaccine could arrest its march, researchers complain that the intensive search for ways to treat people who are already sick has eclipsed the vaccine research effort.

Sixteen years into the epidemic - with 30 million HIV-positive people worldwide and 11.7 million dead - not one of 20 experimental vaccines shown to be safe in small studies has completed testing for effectiveness in full-scale human trials.

Disturbed by the lagging *pace* of clinical vaccine research, many advocates and researchers have begun to demand that such trials be carried out.

A vaccine will do more than simply alleviate human misery, they say. It is the only hope of halting a pandemic that has already begun to change history.

"We continue to confront an epidemic that, in many parts of the world, is wiping out the development gains that so many have worked so hard to achieve over many decades," says Peter Piot, director of the United Nations' AIDS program (UN/AIDS).

By the year 2000, HIV could erode economic production in several African countries by 10%, according to a report by the International AIDS Vaccine Research Initiative, a Washington-based advocacy group.

That estimate may prove conservative in Botswana and Zimbabwe, where one adult in four is infected with HIV. In South Africa, at least 3 million people are infected with the lethal virus.

Ninety percent of infected people live in developing nations. Few, if any, can afford to pay for expensive new antiviral drugs.

Geographic distribution of people with HIV/AIDS

North America	860,000
Caribbean	310,000
Latin America	1,300,000
Western Europe	480,000
North Africa & Middle East	210,000
Sub-Saharan Africa	21,000,000
Eastern Europe & Central Asia	190,000
South and Southeast Asia	5,800,000
East Asia and Pacific	420,000
Australia & New Zealand	12,000

Even if patients could, doctors in Africa and India lack access to necessary, sophisticated tests that monitor a person's response to treatment by measuring the amount of virus in the blood.

"We're not putting a thumb in the dike. All we're doing is catching water at this point," says Mary Lou Clements-Mann, a vaccine researcher at Johns Hopkins School of Public Health in Baltimore. "We're treating people who are infected, but we're not stopping the inflow of new cases. That's most obvious in places where people can't afford treatment."

"Last year, 5 million people worldwide became newly infected with HIV. Each year, in this country, 40,000 people get newly infected with HIV. We've got to do something to prevent that," says Jonathan Mann, dean of public health at Allegheny University of the Health Sciences in Philadelphia. "An AIDS vaccine has to be our No. 1 scientific priority."

Mann, founding director of UN/AIDS, in March told the U.S. Advisory Council on HIV/AIDS that failure to proceed with vaccine trials "violates basic human rights."

He notes that cultural factors may have played an important role in shifting priorities from developing vaccines to producing treatments.

For one thing, advocates have not pushed vaccine research as intensely as research into new treatments. Also, the disease is concentrated in people who often don't know how to demand what they need.

"If the 40,000 new HIV infections we expect this year were occurring among middle-class college students," Mann says, "we would have been in field trials; the whole process would have been accelerated."

He and others have taken to task many prominent researchers for focusing on trying to answer every question about what it takes to produce an HIV vaccine rather than testing those that are available.

"Let's stop waiting for a perfect candidate vaccine," Piot says. "Rather, let us push ahead with effectiveness trials of the best candidates we have today."

But the absence of clear evidence that existing vaccine candidates will protect against HIV has prompted such prominent *scientists* as Nobel Prize winner David Baltimore, president of the California Institute of Technology and chairman of the National Institutes of Health's AIDS vaccine advisory committee, to call for more research into the biology of HIV and ways to elicit potent immune responses.

"We need the best of basic research to go forward because the present (vaccine candidates) are not likely to be sufficient to provide the necessary immunity," Baltimore says. "I want, as much as anyone, to see materials brought into clinical trials as fast as possible. However, I do not want to totally give up a rational

approach to analyzing and acting on scientific evidence."

The search for an effective vaccine began 14 years ago with a promise by the Reagan administration to produce a vaccine in two years. But the clamor for treatments, which are much more profitable than vaccines, diverted *scientists'* attention.

A year ago, President Clinton challenged *scientists* to produce a vaccine by 2007.

In June, the International AIDS Vaccine Initiative (IAVI) produced a proposal for meeting the president's 10-year deadline.

The plan would cost \$350 million to \$500 million to establish and fund three to six research teams around the world. IAVI has raised \$15 million, \$1.5 million of it donated by Microsoft billionaire Bill Gates.

In addition, IAVI is negotiating with the World Bank and other funding agencies to create a \$1 billion vaccine purchase fund as an incentive for profit-driven drug companies.

Although there are almost two dozen vaccine candidates, just one - made by San Francisco-based VaxGen - is being tested for effectiveness, in a 5,000-person trial that began last month.

There are several reasons for this:

► All of the vaccine candidates, except two, were designed to combat HIV strains circulating in the USA and Europe, where it may be difficult to find enough high-risk subjects for full-scale human trials. No vaccines in the development pipeline are designed to work against strains circulating in Africa.

► Companies that do plan to conduct effectiveness trials of a vaccine candidate must first invest in a manufacturing plant that will produce enough vaccine to meet the demand once it is approved. Such facilities may cost as much as \$15 million to design and \$150 million to build, which can take four or five years.

► Preliminary human trials of existing vaccine candidates have failed to convince many *scientists* that the vaccines will work.

Most vaccines work by stimulating the body to produce microbe-killing proteins called antibodies. But recent research indicates that it will take more than antibodies to eradicate HIV. Indeed, antibodies may not work at all, because the wily virus uses a sugar coating to disguise proteins an antibody could recognize.

In addition, laboratory-produced virus strains stimulate the production of antibodies that do not work at all against HIV strains that are circulating among humans.

This evidence prompted VaxGen to add a "wild" strain to its vaccine.

Critics of the VaxGen trial note that, while its vaccine does stimulate the production of antibodies, it doesn't provoke an onslaught of white blood cells, called killer T-cells, that attack HIV-infected cells.

Many researchers argue that even if VaxGen's trial fails, it might generate information that could lead to effective vaccines.

"You can only develop a vaccine and learn answers to critical questions by moving into large-scale trials," says Clements-Mann, of Johns Hopkins. "We have a number of successful vaccines that turned out to be beneficial for widespread inoculation in children - yet we still don't understand how they work. We can perhaps answer some of those questions by research in humans."

Max Essex of the Harvard AIDS Institute agrees. "If we in the West had a 25% infection rate among adults, the way Botswana and parts of South Africa do," he says, "we wouldn't be having this debate about testing experimental vaccines that are already proven safe."

By Steve Sternberg, USA TODAY

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