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EXPERTS AGREE AN AIDS VACCINE IS DOABLE

By John Gallagher

In the battle against AIDS, protease inhibitors have held center stage since they were first approved over a year ago. Yet for some, there remains an even better solution to the crisis: a preventive vaccine that stops people from getting infected in the first place.

"The weight of enthusiasm over the past year was treatment and the idea that you could potentially eradicate infection," says Julie McElrath, an associate professor of medicine at the University of Washington in Seattle. "That certainly put a vaccine on the back burner. Now that the excitement has peaked, it's clear what the long-term solution is. Everyone is back to saying we've got to get a vaccine."

Despite recent advances in AIDS treatments, the number of people becoming infected with HIV continues its unabated rise, leading scientists and health care advocates to conclude that a preventive vaccine is the way to cut the epidemic off at its knees. "The old adage is true: An ounce of prevention is worth a pound of cure," says Robert Belshe, director of the division of infectious diseases at Saint Louis University's medical school. "We need a vaccine."

Unfortunately, say activists, the need has yet to translate into strong action. While important research and testing is being done by universities and pharmaceutical firms, overall the effort has been disappointingly small.

"There is not enough going on in *any* sector: not in government or industry or groups that represent affected communities," says David Gold, a member of the AIDS Vaccine Advocacy Coalition, a group promoting the development of a safe and effective vaccine. "We really need a reinvigorated effort."

Surprisingly, most scientists agree that a vaccine is indeed feasible, despite the notoriously complex nature of HIV. "There's a belief that it can be done," says Cladd Stevens, head of epidemiology at the New York Blood Center and lead investigator for HIVNET, a network of domestic and international field sites evaluating prevention efforts, including vaccine research. Still, says Bill Snow, a member of AVAC, "the realistic people say it's going to be a long time" before a vaccine is available.

Although the search for a vaccine began soon after HIV was identified as the cause of AIDS, the few experimental vaccines that have been produced have been confined either to animal testing or to small pools of volunteers. No vaccine has proved promising enough to merit the large-scale testing on thousands of volunteers that researchers call a Phase III trial.

Public apathy is partly responsible for the lack of success, says Chris Collins, an AVAC member and a policy specialist at the Center for AIDS Prevention Studies at the University of California, San Francisco. "People haven't focused too much on HIV vaccines," he says. "They're waiting for a big scientific breakthrough. But the speed at which that scientific breakthrough is accomplished is to some degree determined by public attention, because it affects decisions in both industry and government."

The recent advances in AIDS treatment may be helping to make the task seem less daunting. "Somehow or other the psychology has changed," says Snow. "HIV seems beatable now in a way it didn't before. It's no longer the virus you can't do anything about."

Still, according to a study of industry investment in research released by AVAC in December, "the current HIV vaccine effort is a patchwork of ef- ▶

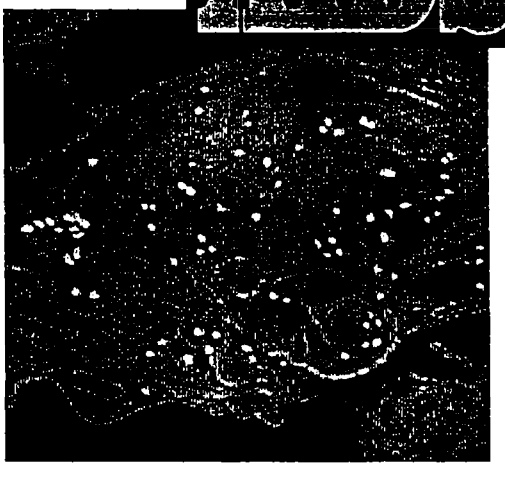
So why don't we have one?

JIM LEVITT/IMPACT VISUALS FOR THE ADVOCATE

forts, not the aggressive, well-funded and well-coordinated international strategy that is required." Why? "One reason," says Collins, "is that the science is difficult. Another is that other investment opportunities are more promising."

AVAC members say that their interviews with pharmaceutical-industry scientists indicate that private-sector researchers are looking for government leadership. They hope the appointment of David Baltimore, a Nobel prize–winning microbiologist, as chairman of a National Institutes of Health vaccine committee, will bring more attention to the effort. "Baltimore is a major figure," says Gold. "His appointment is an important step, but it's only a step."

A vaccine using a live, if modified, version of HIV could result in HIV infection and possibly AIDS



Snow points out that vaccine research "gets the least money" of the areas that the Office of AIDS Research funds. Gold, who is also a consultant on vaccine issues for the American Foundation for AIDS Research, estimates that the entire annual budget, counting federal and private-industry moneys, is at most $150 million. "That's not a whole hell of a lot when you consider that many Hollywood movies spend that much producing and marketing one film," he says.

Yet money alone will not solve the problem. "You can't just take money and throw it at something," says Ellen Blackstone, a health educator at the University of Washington site of the AIDS Vaccine Evaluation Group, an organization conducting clinical tests of experimental vaccine antigens at six university sites. "You need the ideas."

So far, most vaccine research has concentrated on using a genetically engineered version of an HIV protein to try to produce an immune response. Gold contends that the research, while valuable, needs to cast a broader net in order to find an effective vaccine.

Another approach is a vaccine based on a subunit of the HIV protein. In the past the federal government has determined that two trials using the subunit approach did not merit Phase III study. The advantage of the approach, however, is that it is safe. "We're not challenging people with HIV," Blackstone stresses. A vaccine using a live, if modified version of HIV could result in HIV infection and possibly AIDS, whereas the vaccine being tested at AVEG sites avoids that danger.

AVEG researchers hope to avoid past failures with subunit vaccines by combining them with another vaccine—for the canary pox virus, which is safe in humans. The vaccine is known as ALVAC-HIV.

"The canary pox vaccine would be a delivery system for genetic material for HIV," says Connie Celum, principal investigator for the University of Washington's HIVNET site. "The hope is that the combination will stimulate both arms of the immune system: an antibody response and a cellular response."

AVEG and HIVNET plan to launch a Phase II trial in April. The trial will not, however, determine whether the vaccine produces resistance to HIV, but only whether it produces a good enough immune response to make a wide-scale trial worthwhile. Within a year scientists will have to decide whether the vaccine is promising enough to warrant a Phase III study. "It's both a scientific and political decision-making process," says Celum. "It will probably be a heated discussion."

One issue concerning scientists is whether any trial in the United States could be big enough to produce the results needed. "The rock-bottom issue is, are infection rates high enough to run a trial?" says Snow. "The only way to have an outcome from a trial is to have two arms, where the outcome in one is higher than in the other." Because infection rates in the general U.S. population are, in mathematical terms, low, the vaccine and a placebo would have to be tested on two huge groups of volunteers for any statistically significant differences to show up between the two groups.

Such an effort would, of course, be costly. "These large-scale clinical trials are very expensive to run," notes Belshe. Moreover, the effort is unlikely to end with just one trial. "Chances are the first vaccine would be only partially effective. Then we would have to run another trial comparing the new vaccine to the old one. It will be an ongoing process."

Yet as important as an effective vaccine would be, it would probably fall short of the kind of overwhelming success people might expect from it. Researchers believe no vaccine will produce immunity in 100% of those injected with it. Still, an HIV vaccine could fall considerably short of that figure and deserve government approval. "The benchmark for success would be a vaccine with a minimum of 60% efficacy," says McElrath, "because that would obviously produce enough cases of immunity to make it worth marketing."

Belshe points out that even a relatively modest rate of efficacy could have outsize dividends, since fewer infected people could produce an exponential reduction in the risk of contracting HIV among uninfected individuals. "Public health authorities say that with 50% efficacy under certain circumstances, you can reduce new cases of infection by 90%," he says. "It multiplies and over time reduces the number of new cases by a much larger proportion."

Ultimately, a vaccine will probably join the arsenal of AIDS prevention weapons, not replace it. "It's part of a broad picture," says Celum. "The key with transmission is that you have to approach it from different angles. You don't let your guard down about safe sex or do away with needle-exchange programs. You have to look at multiple ways to prevent infections rather than looking for the magic bullet." ■

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JAMA
January 1st, 1997

Collaboration Needed for HIV Vaccine Success

A MUCH STRONGER public-private partnership is needed if a safe, effective vaccine against the human immunodeficiency virus (HIV) is going to be developed, says a new report entitled *Industry Investment in HIV Vaccine Research.*

The AIDS Vaccine Advocacy Coalition (AVAC) in San Francisco, Calif, which released the report on World AIDS Day, says working relationships between government and industry have improved in recent years, but many deficits remain. In fact, the report's authors call government leadership the "key ingredient" needed to expedite the creation of a successful vaccine.

"We were surprised to learn that, in most cases, government is the engine that drives industry and that industry research depends on government financing, government leadership, and government support," said Chris Collins, MPP, an author of the report and policy specialist at the Center for AIDS Prevention Studies at the University of California at San Francisco.

Baltimore Appointment Hailed

About a week after the report was issued, Office of AIDS Research Director William E. Paul, MD, announced that Nobel laureate David Baltimore, PhD, would lead the US vaccine research effort for the National Institutes of Health. "I see the appointment of Baltimore as a step toward greater government leadership and coordination, both essential factors toward advancing HIV vaccine research," Collins said.

Other AIDS activists concur. Mark Harrington, policy director of New York City–based Treatment Action Group, said, "[The appointment] is a big shot in the arm for AIDS vaccine research. Dr Baltimore has the experience, the vision, and the insight to reinvigorate the search for a safe and effective vaccine. [His] appointment will raise the profile of AIDS vaccine research in the scientific community."

Harrington added, "We understand that the Office of AIDS Research has also made a commitment to add a major infusion of funds to AIDS vaccine research. With recent breakthroughs in our understanding of the pathogenesis and treatment of HIV infection, vaccine discovery has become the next frontier for AIDS research."

Leading Researchers Interviewed

The 1-year-old AVAC concentrates solely on advancing AIDS vaccine research. Its report is based on interviews with leading HIV vaccine researchers at 23 pharmaceutical and biotechnology companies whose products reach a worldwide market. The report was underwritten in part by the American Foundation for AIDS Research and the Until There's A Cure Foundation, San Mateo, Calif.

One researcher interviewed for the report said the National Institutes of Health (NIH), which oversees a $1 billion-plus AIDS research effort, goes to great lengths to bring knowledgeable scientists together.

Yet others interviewed said a slow governmental bureaucracy and unending regulations get in the way of collaborations. Industry scientists said they would like to be more involved in the NIH planning process and be thought of as more involved than "mere providers of product."

The AVAC report recommends that NIH funding for HIV vaccine research be increased and managed by the Office of AIDS Research. Currently, it notes, resources are insufficient and are not handled in a coordinated manner. A portion of the funding should go toward answering scientific questions that could establish consensus on the most promising approaches.

Much of the vaccine research conducted to date has concentrated on the use of glycoproteins 120 and 160 or other HIV proteins. But a review of HIV vaccine research sponsored by the companies that participated in the interviews showed they are pursuing many directions—DNA vaccines, live vector strategies, and peptide vaccines—without a cohesive approach.

The report suggests that collaboration among industry and government scientists to determine the best approaches and focus research programs accordingly might entice private-sector investment in HIV vaccine research, which now is lacking.

"Everyone we spoke to was convinced an HIV vaccine is possible and that there will be a strong market for a vaccine, maybe even a multibillion dollar one," said William Snow, also an author of the report and an HIV vaccine advocate who has worked with a number of national advisory groups.

"Yet the profit motive has been unable to drive investment because of the scientific difficulty of the field," Snow added. "Publicly funded research targeted to key scientific questions could reduce the level of scientific uncertainty and stimulate private-sector investment."

As researchers try to tackle difficult scientific issues regarding AIDS vaccine development, the report suggested that President Clinton and Congress develop liability legislation that would spur further investment in vaccine research yet balance the needs of industry and people who would receive the vaccine.

—by Rebecca Voelker

Bay Area Reporter
December 26th, 1997

HIV PERSPECTIVE

AIDS vaccine research in disorder

by Bill Snow, ACT UP/ Golden Gate Writers Pool

According to a report released this month by the AIDS Vaccine Advocacy Coalition (AVAC), entitled "Industry Investment in HIV Vaccine Research," the private-sector search for an AIDS vaccine is grossly underfunded and a low industry priority. The report is based on interviews with top researchers at 23 biotechnology and pharmaceutical companies.

"Less than $40 million of the $135 million spent on HIV vaccine research worldwide each year comes from the private sector. The private sector, particularly the large companies, must take on a greater role in this effort," says report author and attorney David Gold. "By way of comparison, Hollywood spent more on making *Waterworld* than the whole world is spending on HIV vaccine research each year."

There are only five global vaccine manufacturers, and only two of these (Chiron and Pasteur-Merieux-Connaught) have broad-based HIV vaccine programs that are pursuing a number of approaches. A third, Merck & Co., has a substantial program that is currently focused on a single approach.

The remaining companies (SmithKline Beecham and Wyeth Lederle) have insignificant HIV vaccine programs. Several smaller biotech companies have single-approach programs that are not terribly secure.

AVAC's investigation examined the reasons for the low level of commitment to HIV vaccine development, given the enormous financial and human costs to the public of the continued spread of HIV.

Among the first community-based groups dedicated solely to the advancement of HIV vaccine research, AVAC was uniquely positioned to work with scientists from private industry, and was able to conduct confidential interviews with every company that now has or once had an HIV vaccine research and development program. Collaboratively researched by AVAC's five member authors, including myself, the report details some unexpected findings.

The role of government

"Industry scientists repeatedly told us they wanted stronger, more vocal public leadership in this arena, and that this would help them to secure private financing," says UCSF AIDS Policy Specialist and report author Chris Collins. "We were surprised to learn that, in most cases, government is the engine that drives industry, and that industry research depends on government financing, government leadership, and government support."

The primary obstacle to investment identified in the report was the problematic state of the science. While most industry scientists were convinced that a vaccine for HIV was possible, they were not always certain of their own next scientific steps. In every case where a company downsized or eliminated its HIV vaccine program, scientific obstacles were the primary factor, leading AVAC members to call for increased scientific assistance and direction by government sponsored research.

Everyone we spoke to was convinced an HIV vaccine is possible, and that there will be a strong market for a vaccine, maybe even a multi-billion dollar one, and yet the profit motive has been unable to drive investment because of the scientific difficulty of the field. Publicly-funded research targeted to key scientific questions could reduce the level of scientific uncertainty and stimulate private sector investment.

Also noted as a significant impediment to vaccine development was the issue of product liability. "Lawyers and investors are hesitant to back HIV research without some kind of tort reform," said report author Sam Avrett. "Once again, it's a question of government taking a leadership role on the issue in order to stimulate private industry and advance the public health."

Zero of 17 in testing

While 268 therapies for HIV and AIDS have entered clinical trials, only 17 potential vaccines have entered human studies, and none have yet been deemed to merit wide-scale testing. Meanwhile, 10,000 people become infected with HIV every day – and 40 to 80,000 Americans will acquire HIV in the next year alone. Although powerful new AIDS treatments have become available in the United States, these drugs remain unavailable to the American uninsured and to the 90% of people with HIV who live in the developing world. Even an effective vaccine would fail to stem the epidemic in the absence of effective mechanisms for assuring global access.

In the last few weeks vaccines have received some much needed attention from government. Dr. David Baltimore, a Nobel prize winner, has accepted the assignment to lead a cross-NIH vaccine development oversight committee by the Office of AIDS Research; and the President's Commission on AIDS and the president himself have stated that a cure and a vaccine together are our highest priority.

The AIDS Vaccine Advocacy Coalition was founded in December 1995 to advocate for the development of a safe, effective, and accessible HIV vaccine. It seeks to promote increased funding and investment in HIV vaccine research by government agencies, private industry, and non-governmental organizations; to identify barriers to the development of a vaccine; and to increase public awareness about the need for a well-funded, coordinated HIV vaccine research program. It seeks to promote increased HIV vaccine advocacy efforts by community-based organizations and increased awareness about HIV vaccine development among AIDS-affected communities. It is committed to the principle that funds for HIV vaccine research are not to be taken from basic HIV research, drug development, or prevention efforts.

The AVAC report proposes five key steps that would lay the foundation for making significant advances in HIV vaccine research and development. They are: increased government funding for HIV vaccine research, targeted scientific research to stimulate industry investment, expanded commitment by large pharmaceutical companies, increased commitment by affected communities, and expanded public leadership. It emphasizes that two key principles are essential to ensuring an ethical, sustainable, and ultimately successful HIV vaccine research effort: maintaining aggressive research effort in HIV prevention and treatment, and addressing international access issues. AVAC will press for these recommendations in the months to come.

"The president and vice-president must make the development of an HIV vaccine a national priority," said report author Garance Franke-Ruta, "if we are to prevent AIDS from becoming the scourge of two centuries." ▼

You can order a copy of the AVAC report by sending $9.50 to the AIDS Vaccine Advocacy Coalition, 2215R Market Street #501, San Francisco, CA. 94114.

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San Francisco's vaccine vanguard

by Bill Snow, ACT UP/ Golden Gate Writers Pool

More than 40 years ago, the children who participated in polio vaccine trials got a souvenir button saying, "I Was a Polio Pioneer." In all the literature that surrounded those trials, the words "volunteer," "experimental," and "test" were never used. Parents had to "request" that their children participate in the trial. Millions did, and fortunately it all worked out well. Because of this vaccine, polio has essentially been eradicated in the developed world, and there is a plan to continue to eradicate it worldwide, as smallpox has been.

Today, an important step forward in preventive HIV vaccine research is happening at the Department of Public Health with much less fanfare and a great deal more openness and caution. For the last two years, DPH AIDS Office Research Branch has followed a group of 791 sexually active HIV-negative gay and bisexual men as part of a Vaccine Preparedness Study. Now some of those men are being asked if they wish to join a safety and immune response trail of two candidate vaccines. The trial, HIVNET 014/AVEG 202, is being conducted at 14 sites around the country to see if this vaccine combination approach is ready for further testing to determine if it will prevent HIV infection. That "efficacy" trial could start in 1999.

Testing a potential vaccine begins with small safety trials in a few low-risk individuals. Over the last ten years, about 2,000 people have participated in Phase I trials of about 15 experimental HIV vaccine products. In the early 1990s, some San Franciscans were participants in early safety trials of rgp120 at San Francisco General. They were our first HIV vaccine pioneers.

The current trial is only the second Phase II Trial of a preventive HIV vaccine (the first was with one of these products alone), and the first Phase II trial for San Francisco. No vaccine has moved beyond this safety stage to testing for efficacy, Phase III. The vaccine candidates are known as ALVAC vCP205 and rgp120. The ALVAC vaccine has HIV genes engineered into a live canarypox virus which doesn't reproduce in humans; the rgp120 vaccine is a copy of proteins from the outside coat of HIV. Both of these candidate vaccines appear to be quite safe, and have been genetically engineered, so there is no risk of becoming infected from vaccination.

A randomly ordered list has been made of the Vaccine Preparedness Participants, and they are being asked in order if they wish to participate in this trial. The trial will enroll 420 participants nationwide, of whom 30 will be from San Francisco. Nationwide, 1/3 will receive both experimental vaccines, 1/3 will receive the ALVAC vaccine and a dummy vaccine known as a placebo, and 1/3 will receive two placebos; no one in San Francisco will know until the end of the study who got vaccine and who got placebo. The study will continue for two years, but some results will be available after one year to help decide whether to move to larger trials. The process of informing, screening, and getting the consent of participants before they ever get an injection of vaccine or placebo is underway.

Risk factors

There are risks from participating in this trial for any potential participant. Perhaps most important is that we have no idea if these vaccines will provide any protection against HIV infection, and that some participants will receive placebo. Therefore, participants must not increase their risk behavior or expose themselves to HIV because they are in this trial. Later, if these vaccines continue to appear safe and appear to stimulate immune responses, prevention would have to be tested in a much larger trial. At this stage any new HIV infections would only cloud the questions that are being studied. In addition, for this and for efficacy trials, becoming HIV-infected would have the usual serious personal ramifications. It is even a theoretical possibility that vaccination may make one more likely to become HIV-infected, although the opposite is the desired outcome and more likely. Therefore, everyone will be encouraged to avoid exposure from unsafe sex or needle sharing.

Also, as with any medication or vaccine, the vaccine candidates may cause side effects. In previous safety studies, these have been minor and short-lasting if they happen at all. Participants could develop allergic reactions, which could range from mild reactions to life-threatening ones. Since this trial is an experiment, even though these vaccines have been tested safely in animals and humans in Phase I safety trials, there may be other side effects – even serious ones – that haven't been seen yet.

Aside from the physical risks, there are social risks to consider as well. After vaccination, participants may test HIV antibody positive on standard tests. This may be an indication that the vaccine is producing a desirable immune response, but it will require special tests to rule out actual HIV infection. Those extra tests will be available from the Department of Public Health at any time for participants who need or want them. But there is the possibility that participants could be discriminated against if they appear to be HIV antibody positive. In the past these problems have included: getting insurance, hospitalization, traveling to other countries, employment, military/Peace Corps service, and relationship problems with friends or family. If any of these problems occur, participants will be helped to address and remedy them by the study staff and National Institutes of Health.

It is also possible that knowledge of participation in the study alone might prompt discrimination simply based on being from a risk group. In California, there are legal protections against such discrimination.

Practically, the study involves four vaccination visits and about 14 visits to SF General for injections, blood draws, interviews, and counseling.

So the big question is, why bother? Certainly not to protect yourself. Perhaps the best, maybe the only good reason is what's known as altruism: the need some people have to make a contribution, to take some action, to be part of an effort they believe in. We all take risks, some are selfish, some are stupid, some are calculated, some are irrational. They're all human, and we choose our own.

For the sake of getting an AIDS vaccine, many in our community will ultimately have to step forward and take these risks. Is that good enough? The answer is up to each individual. There are no right or wrong answers. For this trial we need 30 volunteers from an existing study; down the line we'll need thousands.

What would you do? ▼

For the sake of getting an AIDS vaccine, many in our community will ultimately have to step forward and take some risks. Down the line, we'll need thousands more volunteers.

For additional information, e-mail joe_wright@dph.sf.ca.us or call (415) 554-9065

ACTion UPdate

Vaccine and heard in San Diego

There will be a one-day National HIV Vaccine Advocates Forum on November 8 in San Diego (attached to the National AIDS Treatment Advocates Forum November 9-12). This forum should be a great place for people to get connected with other activists who are interested in the issue. For more info, call the AIDS Vaccine Advocacy Coalition at (415) 248-1330. ▼

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Bay Area Reporter
September 11th, 1997

5TH STORY of Level 1 printed in FULL format.

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SECTION: NATIONAL/FOREIGN; Pg. A5

LENGTH: 785 words

HEADLINE: Report faults pace of research on AIDS;
No plans made for Clinton's 10-year goal

BYLINE: By Richard A. Knox, Globe Staff

BODY:
In the year since President Clinton set a 10-year timetable for developing a vaccine against AIDS, experts say, not much has happened.

Invoking John F. Kennedy's 1961 man-on-the-moon goal, Clinton pledged last May 18 to "do all I can" to achieve a practical AIDS vaccine by 2007. But scientists and AIDS vaccine advocates said yesterday that there are still no coordinated efforts, no interim goals, no project director, no major new infusions of money, and no presidential jawboning of drug companies to gin up the effort.

In a report released yesterday, a group called the AIDS Vaccine Advocacy Coalition summed up the past 12 months as "a year of good words and gradual advances.

"In 1997, a goal was established by the president, but without a coordinated plan to achieve it," said the San Francisco-based coalition.

SmithKline Beecham, the world's largest vaccine maker, has "watched the epidemic from the sidelines," the group observed.

"Industry doesn't want to get involved," agreed Dr. Jose Esparza, vaccine development adviser of UN AIDS, the UN agency coordinating global efforts against the epidemic.

Industry officials are spooked by ethical issues certain to swirl around AIDS vaccine experiments, he said. But the real deterrent is the uncertain economic payoff.

"No vaccine is a moneymaker and the science is not clear," Esparza said yesterday after giving a lecture in Boston about prospects for an AIDS vaccine. "Every time a famous scientist gets up and says 'No current concept is valid and we need to go back to the drawing board' - and many scientists are saying that - it goes right back to the boardrooms of pharmaceutical companies. 'Even the scientists can't agree,' " they say.

There is fierce debate among scientists about whether the AIDS vaccine approaches in early phases of human testing are ready for full-scale efficacy tests involving 5,000 to 10,000 volunteers and $ 20 million to $ 30 million per trial.

On one side are "trial and error" advocates, who believe progress will be made only by concurrent trials of many experimental vaccines. That view is scoffed at by scientific sticklers who insist it is immoral to do widespread human tests of vaccines without even knowing what kinds of immune responses are likely to protect against infection or disease.

Dr. Seth Berkley, president of the New York-based International AIDS Vaccine Initiative, represents the impatient empiricists. "It is unacceptable that 17 years into the epidemic, not a single vaccine . . . has been put into widescale efficacy trials, even though 25 candidates have been shown to be safe and most have demonstrated some degree" of immune response, he said.

On the other side are doubters such as Jean-Paul Levy, chief of France's AIDS research. "Some highly dubious trials in human subjects have been announced," Levy wrote in Science's May 8 issue. "The empirical, quasi-religious approach, neglecting half a century of science or more, could be dangerous."

The debate is likely to intensify, since small-scale human tests of a vaccine type that federal officials rejected in 1994 as unlikely to be effective are nearing completion.

The US Food and Drug Administration is said to be nearing approval of widespread human trials of the vaccine, developed by a California company, VaxGen. It consists of genetically engineered pieces of the AIDS virus's outer coat, which is made of a protein called gp-120.

"Hopefully, before the end of this year or early in 1999 we will see the beginning of large-scale efficacy trials" of VaxGen's vaccine, Esparza said. Results would be available around 2003. He said the new-generation gp-120 vaccine is improved in several respects over the version that was shelved four years ago.

While this first set of field trials will undoubtedly yield crucial data, no one expects the gp-120 vaccine will fulfill Clinton's goal of an effective and practical AIDS vaccine.

For one thing, the gp-120 vaccine can only stimulate the production of antibodies against the human immunodeficiency virus, HIV, which causes AIDS. But many scientists believe that a vaccine must also produce a different type of response called cellular immunity in order to be truly protective.

Another experimental vaccine, which uses a live canary pox virus that has been loaded with HIV genes followed by a booster shot of gp-120, is on the drawing board. But large-scale human tests will stretch further into the remaining nine years of Clinton's vaccine timetable.

"Development of an HIV vaccine is not going to be easy and it's not going to be fast," Esparza told several hundred AIDS researchers at the Hynes Convention Center yesterday. "But we all need it."

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The National Journal

.May 9, 1998

SECTION: ADMINISTRATION; Pg. 1062; Vol. 30, No. 19

LENGTH: 1209 words

HEADLINE: The AIDS Initiative, One Year Later

BYLINE: Garance Franke-Ruta

BODY:

From Viagra to a potential cancer cure, breakthroughs keep coming from modern medical science. But the good news doesn't extend to the effort to create a vaccine against AIDS.

Last May 18, in a commencement speech at Morgan State University, President Clinton declared the development of an AIDS vaccine a national priority, saying, ''I am prepared to do all I can do to make it happen.'' He called for the development of a vaccine within a decade--likening the endeavor to the race to land on the moon.

One year later, the National Institutes of Health (NIH) has yet to name a director to set up the new Vaccine Research Center Clinton announced. The search process had to be reopened after everyone in the first crop of candidates was deemed inadequate or withdrew from consideration. And that's not the only important vacancy at NIH: The Office of AIDS Research (OAR) has not had a permanent director since November, when the former head, William E. Paul, decided to return to his immunology lab. And the directorship of the vaccine and prevention research program at the National Institute of Allergy and Infectious Diseases (NIAID) has been empty ever since Patricia Fast left last November to join Aviron, a California-based biotech firm.

''The Administration has been slow to fill positions throughout the government, and this is just another example of that,'' said Jeff Jacobs, director of government affairs at AIDS Action, a Washington-based advocacy group. ''If the Administration has an intent to have this vaccine on line, they need to move as quickly as possible to make sure the director of the vaccine center is on line at the NIH.''

While the appointment of an OAR director is said to be imminent, the Vaccine Research Center position is proving harder to fill. Some blame the job's structure. ''Would you take a job that reported to three bosses and had no control over budget or staffing?'' asked Sam Avrett, executive director of the AIDS Vaccine Advocacy Coalition, a nonprofit group that promotes private-sector investment in vaccine research. The Vaccine Research Center's staff will be hired, supervised and paid by the National Cancer Institute and NIAID. Congress designated $ 26

million from the NIH budget for the facility's building, but ground will not be broken until late this year.

NIH director Harold Varmus, who made the decision to reopen the search for an AIDS vaccine chief, ''was not completely satisfied with the array of candidates,'' explained NIAID director Anthony Fauci. Said Varmus: ''This is a very important appointment. It requires special qualifications. It is crucial to find someone of great stature and competence, and this consideration is as important as speed. . . . We hope to have a Vaccine Research Center director on campus this year.'' Varmus emphasized that vaccine science ''is progressing well'' despite the vacancy. Indeed, much of the vaccine science is conducted outside NIH.

Meanwhile, NIH took applications for Fast's former position until the end of March. Said Carole Heilman, deputy director of the NIAID's AIDS division and acting associate director of its vaccine and prevention research program: ''Some of those names would be very good, if they are serious about the position. I'm really hoping that these people are serious.'' Government positions can be less attractive than the positions in academic research or the pharmaceutical industry, she added, and senior scientists sometimes submit frivolous applications to NIH out of a sense of duty. ''It takes a special person to really want to do all of this,'' she added. ''We're keeping our fingers crossed.'' Others are starting to point theirs, over the perceived delays in vaccine development.

Jonathan Mann, founder of the World Health Organization's Global Program on AIDS and now dean of the school of public health at Allegheny University of the Health Sciences, spoke pointedly to the Presidential Advisory Council on HIV/AIDS on March 20. He charged that NIH scientists were unethically stalling HIV vaccine studies by holding them to a higher scientific standard than has historically been used. ''It is as if the U.S. government had decided that the AIDS epidemic could be controlled in this country without a vaccine,'' declared Mann.

Many scientists had hoped trials using a French formula, Pasteur Merieux Connaught's vaccine candidate, could begin this year. Late last year, however, the manufacturer tanked its product in favor of a more advanced prototype, delaying future large-scale trials by two to five years. The 10-year deadline for developing a vaccine, originally a challenge, appears to hinge on the fate of the French formula and on that of one being developed by California-based VaxGen--which NIH decided not to test in 1994 after concluding it was unlikely to work.

Still, a letter published in the May 8 issue of Science magazine and signed by nearly 50 scientists gently reprimands critics for their impatience. ''The worldwide epidemic creates a compelling urgency for developing an effective vaccine. Slow progress is frustrating to all concerned, but attacking NIH and the scientists who are working on the problem serves no useful

purpose,'' a draft of the letter stated.

''It's not that the science is stuck,'' said Seth Berkley, president of the Rockefeller Foundation's International AIDS Vaccine Initiative. ''The science is moving forward. We know more about HIV than any other virus.'' While the vacancies at NIH should be filled, Berkley added, important steps can be taken without additional costs to taxpayers.

Berkley has undertaken negotiations with the World Bank to set up a vaccine-purchase fund, backed by the Group of Seven nations, with an eye to creating a credible vaccine market in the developing world, where 90 per cent of at-risk people live. Currently, most experimental vaccines, because they use HIV strains found mainly in the United States and Europe, are not expected to be much help to at-risk people in developing countries. The World Bank has formed a task force to explore the idea, and the Clinton administration is also considering the proposal. Said Berkley: ''If the Administration focused on this the way we're focusing on this, the president could have a huge, huge policy success. He just got back from Africa. Why not launch this initiative for the globe?''

The Administration itself is not yet sure how to mark the anniversary. A radio address by the President has been discussed, but plans haven't been finalized. The White House Office of National AIDS Policy, swamped with reactions to the Administration's decision on needle-exchange programs, has been focusing its attention elsewhere. Said Todd A. Summers, deputy director of the AIDS office: ''Personally, I was disappointed that--in trying to find something to say about the vaccine initiative--there ain't a lot of flashy news out there.''

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TECHNOLOGY & HEALTH

Clinton Is Failing to Fulfill a Pledge On AIDS Vaccine, Activist Group Says

By MICHAEL WALDHOLZ
Staff Reporter of THE WALL STREET JOURNAL

An AIDS activist coalition said the Clinton administration is failing to live up to its pledge made last year to aggressively spur the development of a vaccine against HIV, the virus that causes AIDS.

In a report out today, the AIDS Vaccine Advocacy Coalition said the administration's initiative to mobilize and coordinate vaccine efforts by creating a new AIDS Research Center "will flounder" if a director isn't named soon. Moreover, the group said government isn't doing much to boost the limited efforts by the pharmaceutical industry to find a vaccine.

The report comes one year after President Clinton made a speech committing his administration to do all it could to make a vaccine available in 10 years. The coalition, formed in late 1995 to lobby the government, academia and industry to focus on vaccine research and development, said that a year after the president's speech little has been done to get the new research center running or to push for greater industry action.

"Unless Clinton is able to elicit real commitments from industry and other countries' governments, and the U.S. research effort is further reinforced and streamlined, the pace of research and development will continue at a snail's pace," said Sam Avrett, AVAC's newly appointed executive director.

A spokesman for the government said a building for the vaccine center is expected to be built soon at the National Institutes of Health campus in Bethesda, Md., and the government is in the process of seeking a director. The government is also expected to soon fill the vacant post of director of its Office of AIDS Research, which coordinates all AIDS programs at the NIH.

AIDS vaccine researchers said that despite the center's lack of director, much is going on in basic research these days. "I think the frustration is understandable," said John Moore, an HIV researcher at the Aaron Diamond AIDS Research Center, New York. Dr. Moore said he believed a federal research center would significantly help coordinate the federal government's own research operations. But he said, "researchers in numerous [academic] institutions and several companies are pressing ahead very actively to try to understand the very difficult science" needed to make a truly effective vaccine.

Dr. Moore, one of the foremost experts in the field, added: "The scientific challenges facing us are not trivial. [But] I do believe it's possible to have a vaccine in 10 years."

In particular, scientists largely are in agreement these days that in order for a vaccine to work it must trigger an immune system that generates white blood cells, called killer T-cells, that can seek out and destroy blood cells infected with HIV. Most experimental vaccines produced over the years don't produce such a response.

Dr. Moore said a government advisory committee headed by David Baltimore, the president of California Polytechnic Institute, has done a good job over the past year in "bringing scientists together, sharing ideas, and coordinating different research efforts," he said. "That's beginning to make a difference."

Still, the AVAC report shows that only two major corporations, **Merck** & Co. and Pasteur Merieux Connaught, a French-American unit of **Rhone Poulenc** SA of France; and **Chiron** Corp. a biotechnology concern, are putting large resources into creating an AIDS vaccine. The report, however, criticizes **SmithKline Beecham** PLC, a major vaccine company, for not conducting any AIDS-vaccine research.

SmithKline wasn't available for comment.

AVAC is based in San Francisco and Washington. Its report can be read at the Internet Web site of http://www.vaccineadvocates.org.

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06/26/98 10:45:00 AM

Record Type: Record

To: Daniel C. Montoya, Sandra Thurman

cc:
Subject: NY Times Editorial on AIDS Vaccine

Dear All,

The New York Times published an editorial yesterday (June 25, copied below). They came out for a "broadened and greatly intensified" AIDS vaccine effort -- a great endorsement for what PACHA, IAVI, AVAC, and others have been advocating.

Best regards,

Bruce

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New York Times, June 25, 1998, Thursday
Section: Editorial Desk

The H.I.V. Plague

The latest figures on the global AIDS epidemic are frightening beyond expectations. A country-by-country analysis by the United Nations AIDS program has found that H.I.V., the virus that causes AIDS, is running wild through many parts of the developing world, especially the impoverished nations of Africa south of the Sahara. The virus has infected one in four adults in Botswana and Zimbabwe, and almost one in five adults in several other African countries. Most do not even know they harbor the virus, but virtually all are doomed unless modern science or their own beleaguered governments can pull off some miracle not yet in sight. As it stands now, the AIDS pandemic is destined to rival the Black Death of the Middle Ages and the influenza pandemic of 1918-1919 as a global horror.

Unfortunately, there are no sure-fire weapons to bring the epidemic under control. Drugs to treat the disease have become increasingly effective. But they are prohibitively expensive for poor countries where the virus is most prevalent. Although it is heartening that several drug companies are planning huge price cuts for poor nations, even that will leave the cost too high for

most Africans.

Prevention programs stressing health education and condom use have helped some countries slow transmission of the virus. But the best hope would be a vaccine to prevent infection. The first full-scale

clinical trial of an AIDS vaccine is just getting under way in the United
States and Thailand, but many experts believe the vaccine being tested is not very promising. The message in the latest U.N. estimates is that efforts to secure an effective vaccine must be broadened and greatly intensified. Otherwise, today's shockingly high H.I.V. infection rates will only get worse.

# # #

New Effort Is Launched to Develop an AIDS Vaccine — The 'Best Hope'

Reuters

GENEVA — A new global plan to speed up AIDS vaccine development was launched at the start of the 12th World AIDS conference on Sunday.

The International AIDS Vaccine Initiative, an independent nonprofit scientific organization, released its "scientific blueprint" designed to advance progress in preventative vaccines against the HIV virus, which causes AIDS, and to get them into trials in developing countries where they are needed most.

"Only a vaccine has any chance of ending the global AIDS epidemic," Dr. Seth Berkley, the organization's president, told a news conference. "However," he said, "the world is not on track to meet the goal of a safe and effective AIDS vaccine in the next decade."

"The purpose of this program outlined here is to put vaccine development back on a fast track. This is our best hope of stopping the epidemic that has continued to gallop along with the current 16,000 newly infected persons each day."

The organization plans to identify gaps in scientific development, provide technical assistance in poorer countries and encourage public and private collaboration in vaccine research.

It is also recommending the creation of up to six international product development teams to identity promising vaccines and get them into trials quickly.

The first large-scale human trials of a vaccine against the HIV virus began in the United States earlier this month, but there are no other drugs in the pipeline that are due to enter phase III, or late-stage, efficacy trials before 2000.

The vaccine, AIDSVAX, developed by the California biotechnology company VanGen, is being tested in several centers in the United States and is also being considered for trials in Thailand, where the virus is spreading fast.

More than 40 potential vaccines are being tested but AIDSVAX is the first to go into human trials.

■ Third World Would Get Tests Sooner

An ethics panel convened by the United Nations is recommending major changes in the way experimental vaccines are tested in people, Lawrence K. Altman of The New York Times reported from Geneva.

The recommendation comes in response to impassioned pleas from developing countries desperately seeking a vaccine to fight the AIDS epidemic.

Earlier guidelines, intended to prevent exploitation, called for testing any experimental AIDS vaccine in the country where it was made before testing it in a developing country.

But on Saturday, after a two-day meeting, the panel recommended that such trials be allowed to take place in any country, including those in the Third World, even if not tested first in the manufacturer's country.

The old guidelines were having the unintended effect of impeding possible vaccine trials in many developing countries, said panel members from developing countries such as Zambia, Thailand and Uganda.

"We are asking for more flexibility in the guidelines right now," said Sophia Mukasa Monico, director of an AIDS support organization in Uganda.

Reflecting a widespread view on the panel that American ethical standards should not be imposed on developing countries during an epidemic, Major Rubaramira Ruranga, who works at a research center in Kampala, Uganda, asked rhetorically, "Who should be a guinea pig for whom?"

"What is ethical in one place is not always what is ethical in another," he said, pointing out that 90 percent of the people infected by the AIDS virus every day around the world are in developing countries.

The discussions came at what Dr. Peter Piot, the head of the UN AIDS Program, said was the first international meeting on the ethics of AIDS vaccines. The United Nations has sponsored six regional meetings on the issue during the last two years.

The panel's actions are expected to be largely adopted by the UN AIDS Program and thus by researchers worldwide. They represent a shift from older attitudes of paternalism and protectiveness to greater empowerment by developing countries and a victory over what leaders in such countries regard as cultural imperialism, Dr. Piot said.

"People in Africa are not as ignorant as they were 10 to 20 years ago, and they know their rights," said Dr. Nkandu Luo, the minister of health for Zambia.

In the past, drug companies and scientists have conducted research on people in the Third World that led to development of drugs that were not made readily available to people in the countries where the research was done. In allowing the first trials of a vaccine to take place in developing countries, the panel said, the host country had to have adequate scientific and administrative ability to avoid harm to volunteers.

To help guard against exploitation, the panel called for requiring informed consent from each individual before that person is enrolled in a vaccine trial. The new recommendation could end a widespread practice of allowing a village chief or local leader to give blanket approval for the participation in vaccine trials of all those living in a village.

AIDS ASIA

Voice of Asian Solidarity against AIDS

An IHO Publication

AIDS ASIA is a bimonthly Newsletter, the first of its kind from Asia, independently published since December 1993 by the Indian Health Organisation (IHO), an Non Government Organisation(NGO) spearheading the fight against AIDS since 1985 and responsible for bringing India on the AIDS control map of the world. AIDS ASIA is the Voice of Asian Solidarity Against AIDS(ASAA), a network NGOs from the region, to further strengthen the ties between Governments and NGOs and among NGOs themselves.

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