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TAG
Treatment Action Group

# tagline

NEWS ON THE FIGHT FOR BETTER TREATMENT, A VACCINE, AND A CURE FOR AIDS

## HIV Vaccine Trial Results: Efficacy and Uncertainty

First Signal of Vaccine-Mediated Protection Against HIV Infection is Both Celebrated and Questioned

BY RICHARD JEFFERYS

On September 24, 2009, the surprising announcemnet that a vaccine combination had shown efficacy in preventing HIV infection was splashed across the world media. The news emerged from a huge trial in Thailand, conducted under the aegis of the Thai Ministry of Public Health, the U.S. Military HIV Research Progam (USMHRP) and the National Institute of Allergy and Infectious Diseases (NIAID), which enrolled 16,402 mostly low-risk individuals (in the Rayong and Chon Buri provinces) and randomized them to receive a combination of two vaccines, ALVAC vCP1521 and AIDSVAX B/E, or placebo shots.

**Modest Efficacy?**

The term most commonly used to describe the result was *modest*; the reported efficacy was 31.2% and it achieved statistical significance by the thinnest of margins. Nevertheless, as the first-ever signal of efficacy in an HIV vaccine trial, the news was widely hailed as historic. In raw numbers, 74 out of 8,198 volunteers who received placebo immunizations became infected, compared to 51 out of 8,197 volunteers who received the vaccines. As a coprimary endpoint, the trial also measured viral load levels in participants who acquired HIV infection, but there was no difference between the vaccine and placebo groups. The reason the total participant numbers didn't quite add up to 16,402 was because 7 volunteers who were randomized and immunized were excluded from the efficacy analyses after it was found that they were HIV-infected at the time of receiving their first vaccination; this type of exclusion is standard in prevention trials. (In the

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## HIV Care and Treatment: A Doctor's Perspective

As the health care reform debate continues, TAGline's Tracy Swan spoke with James Braun, doctor of osteopathy, a pioneering HIV physician, about how the epidemic has changed, and how our health care system can begin to meet the needs of an expanding and aging HIV-positive population.

BY TRACY SWAN

Dr. James Braun started caring for HIV-positive patients in 1982, and still sees patients three days a week at New York City's Callen-Lorde Community Health Center. He is the founding director of the Physicians' Research Network (PRN), a nonprofit organization providing peer support and education to physicians, nurse practitioners, and physician assistants who care for people living with, and at risk for, HIV disease and/or viral hepatitis (http://www.prn.org/).

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## WHAT'S INSIDE

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**Tracy Swan:** This coming year marks the 20th anniversary of PRN. How did it start?

**James Braun**: In the 1980s the [HIV] epidemic was just brutal: clinicians who chose to treat HIV/AIDS and its complications in the early years were burning out from the amount of work and anxiety. Each day was unpredictable, with the surreal cascade of ever-increasing complications of AIDS; the uncertainty that surrounded day-to-day care of patients and the people who loved them; and, of course, the mourning. Despite all our efforts, so many people died, and that made it very difficult to feel good about our work.

**In the 1980's the [HIV] epidemic was just brutal: clinicians who chose to treat HIV/AIDS and its complications in the early years were burning out.**

To cope with all this, a few clinicians began meeting informally in each other's homes for mutual support. There was also a social group for gay and lesbian physicians called New York Physicians for Human Rights [NYPHR] that tried to address HIV/AIDS clinical issues at some of its meetings. And though many of the people involved in the more informal meetings were also members of NYPHR, our straight colleagues were not. So the board of NYPHR—I was vice president at the time—decided to support the creation of a new group focusing on HIV/AIDS for all interested clinicians, and it was from this that PRN was eventually born.

In 1990, PRN began as a citywide organization that clinicians managing the care or complications of AIDS could join for peer support and education, and we have been meeting monthly ever since. We were able to create common ground for people all over the city who were interested in HIV, spotlighting advances in research and clinical management. We started publishing the *PRN Notebook* in 1995, and launched our website in 1998. PRN membership grew steadily; by 2000 we had over 600 clinician members in and around NYC, who in turn cared for over 70,000 people living with HIV and AIDS. These days, PRN meetings focus mainly on preventing and managing complications of chronic infection and lifelong drug therapy, diagnosing, treating and preventing coinfections and comorbidities, and the challenges of aging with HIV disease.

**TS:** What is important for us to remember about HIV?

**JB**: HIV is unique, and has been since the early days of the epidemic. First, it was unexpected, and its cause and treatment controversial. This should always serve as a vivid reminder that infectious disease is never static, and is likely to continue to surprise us again in the future. Several elements contributed to the rapid evolution of successful HIV treatment. It would not have been possible without a strong advocacy movement, largely driven by well-educated, insured people who were unafraid to make demands on their doctors, hospitals, insurance companies, and government. The gay community as a whole stood behind the struggle for HIV research, access to care, and fighting the unreasonable fears and stigma associated with AIDS. The government and the pharmaceutical industry conducted studies to find drugs to treat HIV disease, and the advocacy movement pressed for expanded access. People with HIV were willing to take risks to survive. There was a sense of urgency that could not be dismissed.

**Several elements contributed to the rapid evolution of successful HIV treatment. It would not have been possible without a strong advocacy movement.**

Before combination therapy, our patients seemed to grow old before our eyes. Young people who were dying of AIDS looked far older than they were, and they became increasingly disabled and often became home-bound in the final stages. So to be able to say HIV and "aging" in the same sentence is a beautiful thing. With combination therapy, we saw survival and wellness: people were able to go back to work, and focus their energy on things that were important to them.

In New York, many HIV patients are in the performing arts; actors could return to work, and writers could begin writing again. It was wonderful. Before 1996, HIV disease and progression to AIDS were so debilitating that it was impossible for people to be productive. Working people had to go on disability and spend down their assets so that they could qualify for Medicaid. Now people with HIV are offered treatment earlier, and rarely have complications that prevent them from realizing their goals in life, although they still have to deal with a chronic disease.

Much of this history has been forgotten; young people today don't know the horror that we went through in the early days of the epidemic—they aren't losing people they love, and they don't see this happening all around them. As HIV has become what many wish to consider a chronic manageable disease, the urgency we all felt has subsided. But that is a false sense of security.

We need to continue demanding ongoing research, so long as drug resistance continues to evolve. We need to revive some kind of vital advocacy base—if patients are not demanding new and better drugs, research is far less likely to happen.

We need sustained patient advocacy, clinical dedication, organized clinical research, drug research adn development, improved diagnostics, better prevention strategies—and, of course, easier access to care.

**TS:** We now have more effective, safer HIV drugs. So, without a randomized controlled trial, but in the context of other research and your experience, when should people start HIV treatment?

**JB**: We have lost the sense of urgency for treatment. In earlier days, once HIV disease progression was better understood and we had laboratory tools necessary to measure the level of HIV, it was considered unethical not to offer treatment to anyone

with a detectable viral load and treatment guidelines were very aggressive. Then the fear of long-term toxicity from HIV treatment took rein; this led to a very conservative retreat. Guidelines changed, and recommended delaying treatment until there was clear evidence of immune deterioration. In recent years there has been a gradual endorsement of earlier treatment.

The NA-ACCORD (North American AIDS Cohort Collaboration on Research and Design) data, which looks at several large cohorts from 1996 onward, are extremely important in that they point to the survival benefit of starting combination treatment early. Survival was better in people who started therapy with a CD4 cell count of 350 cells per cubic millimeter or more, than in people who started with lower counts. And a more recent analysis shows that starting before the CD4 cell count drops below 500 provides an even greater survival benefit. You really can't beat survival as the most desirable outcome in this disease—or any other, for that matter. And remarkably, this survival benefit was seen in people who took many of the drugs we have worried about the most.

Now that we have drugs that are safer and easier to take over the long term, we need to get back to treating HIV disease, not waiting until people get an AIDS diagnosis or are moving irrevocably in that direction. We know that therapy stops and even reverses HIV disease progression, and even if a "cure" is not yet possible, we may be missing the best opportunity for providing responsible care to our patients. So why wait? By starting therapy earlier, we may be able to preserve subtle immune function that affects long-term survival, but we will also be able to decrease risk of transmission, which could help end this dreadful epidemic.

**TS:** In New York, at least a third of HIV diagnoses are in people who have already developed AIDS. How can we get people diagnosed and into care sooner?

**JB**: I worry about the capacity of our system to provide HIV care and treatment as all the undiagnosed people out there gain access to medical care through health care reform. Even in New York, where we have the heaviest burden of HIV in the U.S., physicians are not required to have HIV-specific knowledge for licensure.

We are going to have to normalize basics of HIV management by including HIV disease in the curriculum of every medical school, and virtually every residency program, because there is hardly any medical subspecialty that does not or will not see complications associated with HIV disease.

Every practicing primary care doctor needs to know basic components of HIV medicine, because clinicians will not run diagnostic tests unless they know what to do if the result comes back positive. How many times must people with undiagnosed HIV disease seek medical care for one problem or another without being appropriately tested? How far does their disease have to progress until their diagnosis becomes obvious? If health care reform succeeds, we are unlikely to have an efficient response to the multitude of previously uninsured and undiagnosed HIV-positive patients until all primary care clinicians—and by that I mean any clinicians that see patients in a first-point-of-care setting—understand the diverse signs, symptoms, and associated conditions of HIV disease and how to diagnose both acute and chronic HIV disease. They also need to understand the limits of what they can appropriately manage, and develop good working relationships with different subspecialists so that they can appropriately refer their patients when necessary.

**How many times must people with undiagnosed HIV disease seek medical care for one problem or another, without being appropriately tested?**

**TS:** How can we improve HIV care and treatment?

**JB**: Once people are diagnosed with HIV, they will need guaranteed ongoing access to health care, and by that I mean continuity of care for the rest of their lives. The optimal treatment of HIV disease does not include treatment interruption. But health care delivery in this country is so chaotic and fragmented that it is almost impossible for people to maintain continuity of care—employers change insurance policies, people move, they may lose jobs and insurance, some are in and out of prison, and the list goes on and on. Continuity of care is crucial, because interrupting HIV treatment can accelerate HIV progression, result in greater likelihood of complications, and increase the risk of HIV transmission. Access to health care and long-term adherence to treatment allow people to realize the full survival benefit of long-term viral suppression. With treatment secure and in place, people can get on with the rest of their lives.

**TS:** As health care reform looms, how should we think about changing our health care system so it is ready for an aging HIV-positive population?

**JB**: Clinicians who do not have extensive training in general medicine will need additional training to deal with the complications that their HIV patients will undoubtedly face as they age. Just think for a moment how few geriatricians we have in this country. And now tack on HIV disease.

Patients with HIV disease will be facing problems with health care delivery as they age, since it is rare for a single doctor to oversee medications, and help people coordinate and make sense of their total health care. There is little emphasis on the value of good primary care services, and primary care providers are not adequately compensated or respected for much of the work they do. Many patients themselves don't understand the value of having one primary health care provider as an advocate and partner in their long-term health care.

We need to emphasize the critical inportance of qualified, accessible, and reliable primary care providers in health care reform. Everybody needs one that they can trust, whether they have HIV disease or not. ●

***HIV Vaccine Trial***, continued from page 1

previous two efficacy of trials of AIDSVAX, there were 14 and 19 such exclusions, respectively.) The exclusion of these seven participants was not, however, made clear in the September 24 announcement; trial investigators Jerome Kim and Merlin Robb both stated in their presentations that 16,395 individuals were randomized. This issue would rear its head again when the results were eventually published in the *New England Journal of Medicine (NEJM)*.

Not all responses to the initial announcement were euphoric. A great deal of skepticism about the vaccine candidates had been expressed prior to the trial's start, with 22 scientists publishing a perspective piece in the journal *Science* arguing that it should not go ahead. TAG also had a letter published in *Science*, noting the design precluded any understanding of the contribution of the individual vaccines and suggesting that AIDSVAX should be dropped. For skeptical observers, the wide 95% confidence interval (CI) around the efficacy estimate was the most frequently cited cause for concern. Spanning 1.1% to 51.2%, the CI suggested both the marginal efficacy (a lower bound less than 1 indicates a lack of statistical significance) and a great deal of uncertainty about the reproducibility of the result. TAG issued a statement calling for caution in interpreting the findings until more details were available, and positing that the results might be better described as marginal rather than modest.

**A Cloud of Controversy**

A little over a week after the initial announcement, the views of the skeptics appeared to be bolstered when news began to leak out about additional analyses of the trial results that did not achieve statistical significance. Specifically, an analysis of only those individuals that fully complied with the protocol and received all immunizations on schedule—called the "per-protocol" analysis—reduced the number of infection endpoints from 125 to 86 and led to a lower efficacy estimate of 26.2% that was no longer statistically significant. These reports were widely cited as undermining confidence in the overall result and created the suspicion that the investigators had deliberately put their best analysis forward in the original announcement (which did not mention anything about the per-protocol finding).

**The Data Revealed**

Finally, after nearly a month of sturm und drang, a fuller report of the trial results was presented at the AIDS Vaccine 2009 conference in Paris and simultaneously published in a peer-reviewed paper in the NEJM on October 20. These presentations went a long way to clarifying the previous confusion. The apparent drop in efficacy in the per-protocol analysis was largely a consequence of the fact that the greatest difference in the numbers of infections between vaccine and placebo groups accrued during the first 12 months of the study, including during the period participants were receiving immunizations (the regimen involved ALVAC shots at weeks 0, 4, 12, and 24 with AIDSVAX added at weeks 12 and 24). Because the per-protocol analysis excluded any infection that occurred during the first six months, the efficacy estimate was consequently reduced. The loss of statistical significance reflected both this early difference in infection rates and the overall loss of statistical power associated with reducing the overall number of participants included in the analysis. Around one-third of the total trial population was excluded from the per-protocol analysis, due to issues such as immunizations not being received exactly on schedule.

**The data do appear to support some marginal efficacy of the vaccines in preventing HIV infection, but there is a strong suggestion that this efficacy is short-lived.**

There was one final wrinkle in the controversy over the results, however. The NEJM paper listed an "intent-to-treat" (ITT) analysis first, and this includes the seven individuals excluded from the September 24 announcement because they were infected at the time of first immunization. Because five of these individuals were in the vaccine group and two in the placebo group, their inclusion renders the efficacy result a nonsignificant trend ($p = 0.08$). But since exclusion of these cases is standard (a vaccine cannot protect someone already infected), it is unclear why the paper lists this analysis first. In all prior HIV vaccine efficacy trials, individuals later found to be infected at baseline have been excluded from the ITT analysis.

After the ITT, the next result reported in the paper is the nonsignificant per-protocol analysis, and the originally publicized statistically significant result is listed last; it's called the "modified ITT" (mITT) and the $p$ value is 0.039. To someone reading the paper who hasn't read other vaccine efficacy results, it's easy to get the impression that the mITT analysis is somehow less rigorous than the ITT analysis because it's left until last, but this is not the case. In prior trials, the mITT was presented as the primary analysis with no controversy whatsoever, and it remains unclear why that didn't occur here. Ultimately, it seems that what should have been a nonissue has added an extra layer of confusion to the story.

Yet with the publication and presentation of the results, the clouds of controversy and confusion are beginning to clear. The data do appear to support some marginal efficacy of the vaccines in preventing HIV infection, but there is a strong suggestion that this efficacy is short-lived. Subgroup analyses are also included in the NEJM paper, and while the numbers are too small to draw firm conclusions, infections among higher-risk participants were equivalent in the vaccine and placebo arms, indicating that the limited efficacy was concentrated among those at low and medium risk. Although the majority opinion among observers is that a small but real effect has been detected in the Thai trial, some statisticians have stressed that the possibility of a fluke result remains. This is the fourth HIV vaccine efficacy trial, and even though the result is statistically significant, there is around a 1 in 21 possibility of this occurring by a simple play of chance.

**The Next Steps**

There is unanimous agreement on one issue: the marginal efficacy observed in the Thai trial is not sufficient for licensure of the

vaccines (the investigators set 50% as the minimum threshold). Discussions are being held regarding whether the vaccine should be offered to placebo recipients in the trial, but a decision has not yet been made. The priority for researchers is attempting to identify immune responses that may have been associated with protection ("correlates of immunity," the holy grail for vaccine scientists), but the study was not powered with this in mind and samples are limited. At the AIDS Vaccine 2009 conference in Paris, investigator Nelson Michael explained that subcommittees have already been formed to look at various aspects of the immune response in the trial outcome; due to the apparent short-lived nature of the vaccine effect, there is particular interest in studying innate and antibody responses on the basis that they would be most likely to wane over time. The USMHRP will also solicit ideas from independent investigators via its website (http://www.hivresearch.org/).

In the longer term, many additional issues will need to be addressed, including:

- The reproducibility of the finding (this does not mean repeating the trial, but instead attempting to reproduce the outcome in other settings, including animal models).
- The contribution (if any) of the AIDSVAX component, which failed to show even a hint of efficacy in two large prior trials. (Claims made by the manufacturer of efficacy in subgroups were entirely spurious.)
- The role of the subtype specificity of the vaccines. (Both constructs included envelope antigens from the most common circulating strain in Thailand, CRF01_AE, formerly known as subtype E.)
- The relevance of the finding, if any, to higher-risk populations.

Currently it is uncertain if additional trials of ALVAC and AIDSVAX will occur, or whether similar vaccines that induce immune responses more consistently will take their place. Future issues of *TAGline* will provide updates as the story unfolds.

**The Analyses:**

| | Modified intent-to-treat (mITT) | Strict intent-to-treat (ITT) | Per-protocol (PP) |
|---|---|---|---|
| Total number | 16,395 | 16,402 | 12,452 |
| Cases of HIV infection | 74 placebo, 51 vaccine | 76 placebo, 56 vaccine | 50 placebo, 36 vaccine |
| Efficacy (95% confidence interval) | 31.2% (95% CI, 1.1 to 51.2) | 26.4% (95% CI, -4.0 to 47.9) | 26.2% (95% CI, –13.3 to 51.9) |
| *p* value | 0.04 | 0.08 | 0.16 |

**The Vaccines**

ALVAC vCP1521 vector is a modified version of a bird virus called canarypox. While the natural form of the virus can be harmful to birds, it can only enter human cells and not replicate in them. ALVAC vCP1521 contains the gene encoding the HIV-1 gp120 protein from a virus code-named 92TH023 that was isolated from a Thai individual in Bangkok. The virus was originally designated as belonging to subtype E, but it has since been recognized that this subtype is largely a circulating recombinant form now known by the name CRF01_AE. The 92TH023 virus isolate uses the CCR5 coreceptor to enter cells, like almost all primary HIV isolates. In the ALVAC vCP1521 construct, the 92TH023 gp120 protein is linked to a portion of the gp41 protein from the first HIV ever isolated, LAI (originally misnamed LAV). Part of the gp41 protein is deleted to make it easier to distinguish vaccine-induced antibodies from those induced by HIV infection. LAI belongs to subtype B and uses the CXCR4 coreceptor to enter cells. The other two HIV-1 proteins encoded by the ALVAC vector are Gag and Protease, also derived from LAI.

The AIDSVAX B/E vaccine contains two gp120 proteins. One is from the subtype B HIV-1 isolate MN, a CXCR4-using virus originally isolated from a child with AIDS-related complex (as it was then known) in 1984. The other gp120 is from a CRF01_AE virus isolate name A244 or CM244 that was obtained in northern Thailand (CM = Chang Mai) in 1990. The source of the isolate was a young Thai man who tested HIV-positive after being randomly selected for military service. Like 92TH023, CM244 is an R5-using isolate. ●

Resources:

*New England Journal of Medicine paper:*
http://content.nejm.org/cgi/content/full/NEJMoa0908492.

AIDS Vaccine 2009 Conference webcast and press conference:
http://www.hivvaccineenterprise.org/conference/2009/webcasting.html.

**The Value of Volunteerism**

Irrespective of the various controversies that have surrounded the trial, the commitment and dedication of the volunteers and supporting organizations deserves to be recognized and saluted. According to a presentation at the 2004 AIDS Conference in Bangkok, more than 70% of trial participants cited altruism as their primary motivation for participation.

# Scientific Thrills and Activist Chills in Cape Town

"The Vancouver of Implementation Science" meets the "Fund the Fund" Demonstration at the Cape Town AIDS Conference

BY MARK HARRRINGTON

**The Difference of a Decade**

For anyone who had been at the Durban, South Africa, AIDS Conference in mid-2000, when virtually no one with HIV in developing countries was receiving antiretroviral therapy (ART), the Fifth International AIDS Society Conference on HIV Pathogenesis, Treatment, and Prevention, held in Cape Town, South Africa, on July 19–22, 2009, showed the breathtaking progress that has been made in the past nine years—and the daunting challenges still ahead.

In 2000, then South African president Thabo Mbeki opened the conference with a long and rambling defense of his policy of refusing to provide ART for either the prevention of mother-to-child transmission or the nation's estimated five million people then living with HIV.

In 2009, after a historic, unprecedented, and exhausting campaign by the Treatment Action Campaign, South Africa now has the world's largest HIV treatment program, with over 600,000 South Africans receiving ART. The program has now been so effective that in some places—such as the township called Gugulethu just outside of Cape Town—HIV-associated tuberculosis (TB) rates, which have increased fivefold since the advent of HIV, were shown to decrease by up to 80% after the introduction of ART. This showed that HIV treatment, when combined with a decent TB program, can reverse the toll taken by HIV-associated TB disease. (A recent report from the World Health Organization indicates that TB kills at least 25% of people with AIDS globally.)

Another study, from Uganda and Zimbabwe, similarly showed that HIV treatment reduced malaria incidence among ART recipients by 75%. And a host of studies have shown that treating pregnant women with triple antiretroviral therapy during pregnancy and through breastfeeding could reduce the transmission of HIV to 1% or less.

These studies all demonstrate that the scale-up of ART—which now is reaching four million people around the world, according to the World Health Organization and the Joint United Nations Program On HIV/AIDS—is bringing benefits across the continent of Africa, particularly among mothers and their infants; ART is saving lives and reducing diseases such as TB and malaria.

**Scientific Progress, but a Grim Outlook for Future Funding**

The implementation science at Cape Town was as breathtaking in its way as was the therapeutic revolution that marked the International AIDS Conference in Vancouver, British Columbia, in 1996, when highly active antiretroviral therapy (HAART) was dramatically presented at an international meeting.

However, the mood in Cape Town among activists and some policy leaders was grim. Activists held a meeting with Dr. Michael Kazatchkine, executive director of the Global Fund to Fight AIDS, TB, and Malaria, who noted that in the coming year 2010 the Global Fund was likely to face a gap of at least US$3 billion between the needs identified by recipient countries and the amounts likely to be available from donors. The global economic crisis has taken its toll, but other pressures have also become acute, such as a backlash among donors, development "intellectuals," and even some high-burden countries, where the momentum of the past seven years of ART scale-up is beginning to flag.

Global HIV activists held a demonstration on the conference's last day demanding that the world "Fund the Fund" and "Fill the $3 Billion Gap." A brilliant campaign by the AIDS and Rights Alliance of Southern Africa (ARASA) pointed out the amounts that could be spent on saving lives if only African leaders and donor countries such as the United States had the right priorities. For example:

- the US$686 billion spent on the war in Iraq is more than 140 times the money needed to close the Global Fund's funding gap for HIV and TB
- the US$48 million spent by Ugandan president Yoweri Museveni on a new private jet would provide 229,524 person-years of ART
- the US$500,000 spent by Swaziland's king Mswati III on a new luxury vehicle could subsidize 21,000 treatment courses for his subjects suffering from TB
- the US$250,000 spent by Zimbabwe's president Robert Mugabe on his 85th birthday party would cover TB treatment for 10,501 Zimbabweans with tuberculosis

Activists from south and north united in a campaign to show the human costs of the current economic crisis, and the consequences for people living with HIV if we fail to achieve universal access to HIV, TB, and malaria prevention, treatment, and control by the end of the year 2010.

Policy makers have often told AIDS activists that our goals are unrealistic. The track record of the past three decades show that what is held to be unrealistic in one decade becomes reality in the next. In the 1980s, HIV was untreatable; in the 1990s HAART became available. In the 1990s, AIDS treatment was considered too expensive; in the first decade of this new century, over four million people received it. To turn the epidemic around, in the next decade, we must make history by achieving the goals of universal access while expanding and intensifying research to discover a cure and a vaccine.

# Policy Corner

## AIDS Drug Assistance Programs Face a Dire Situation as Waiting Lists Expand for HIV Treatment

In the midst of increasing state health budget cuts and service eliminations, people living with HIV/AIDS and advocates are worried about increasing AIDS drug assistance program (ADAP) waiting lists, formulary reductions, and eligibility constrictions throughout the country. ADAPs provide lifesaving HIV treatment to low income, uninsured, and under-insured people living with HIV/AIDS throughout the United States. In 2004, 1,629 people were on ADAP waiting lists and a number of people died as a result of lack of access to HIV medications in several states.

Advocates say that a number of factors are contributing to the crisis, including the higher demand for ADAP services due to unemployment, flat funding of federal monies toward ADAP programs over the last couple of years, and higher drug costs. According to the National Alliance of State and Territorial AIDS Directors, it is "increasingly apparent that demand for ADAP services has increased as a direct result of lost employment and medical coverage due to the national economic downturn."

By October 2009, eight states had already established waiting lists totaling over 245 individuals. These states include Arkansas, Iowa, Kentucky, Montana, Nebraska, South Dakota, Utah, and Wyoming. Some states, including Arizona, Arkansas, Iowa, and Washington, have already instituted cost containment measures generally in the form of formulary reductions. Twelve more states will not be considering waiting lists, reductions in formularies, or lowered eligibility levels until March 31, 2010. Those states are Arizona, Arkansas, Hawaii, Idaho, Indiana, Iowa, Ohio, Mississippi, Missouri, North Dakota, Tennessee, and Washington. Finally, California will be considering such measures after March 31, 2010.

Activists worry that if the trend is not reversed there may be over 500 people on waiting lists by the end of 2009 and hundreds more by mid-2010. They are calling for increased federal awards to maintain services for existing clients and for expansion of services for new clients.

**For more information about ADAP waiting lists in your state, visit http://www.nastad.org**.

## National HIV/AIDS Strategy

For more than a decade, HIV advocates have been calling for the creation of an outcomes-based, comprehensive national HIV/AIDS strategy (NHAS) to address the epidemic in the United States. Now, President Barack Obama's pledge of working toward the reduction of HIV incidence, increasing access to care for people living with HIV, and the reduction of HIV-related health disparities, the long-overdue process toward the development of NHAS has finally begun.

During the last couple of months, the White House Office of National AIDS Policy (ONAP) has been conducting town hall meetings across the country to solicit broad public input about what the strategy should look like. And although thousands of people have attended and testified at these town hall meetings, some community members expressed frustration that ONAP has not gone far enough to ensure substantive community collaboration, especially considering the format and geographical limitations of the town hall meetings and the fact that a draft of the strategy has not yet been released for comment. ONAP is now also soliciting community testimony online, and will be receiving feedback from the soon to be reconstituted Presidential Advisory Council on HIV/AIDS as well as through the establishment of a special interagency task force that will ultimately draft the strategy.

TAG, in collaboration with amfAR and other community advocates organized an independent process of developing NHAS recommendations through discussions with members of the Federal AIDS Policy Partnership and sponsored a meeting of researchers and research advocates (held on 5-6 November 2009) specifically aimed at developing recommendations on HIV/AIDS research for the NHAS. TAG is also collaborating with hepatitis B and C advocates on developing NHAS recommendations specifically related to viral hepatitis comorbidity in the United States. Recommendations from these consultations will be sent to ONAP later this year.

**More information about ONAP, dates and times for future town hall meetings, or to submit your comment online can be obtained at http://www.whitehouse.gov/administration/eop/onap/**

# TREATMENT ACTION GROUP
## 2009 RESEARCH IN ACTION AWARDS

Sunday, December 13

**6:00 pm**
Cocktails and
Hors d'oeuvres

**6:30 pm**
Awards Presentation

The Gallery of the
historic Astor Center
399 Lafayette Street
(at East 4th Street)
New York City

Hosted by

**Jenna Wolfe**
Coanchor of NBC's Weekend *Today*
and *Today* correspondent

Honoring

**Simon Doonan**
Creative Director for Barney's New York,
Author, and Columnist

**Roy M. "Trip" Gulick, MD, MPH**
Professor of Medicine; Chief, Divison
of Infectious Diseases; Weill Cornell
Medical College and New York-
Presbyterian Hospital

**Professor Michael Kazatchkine, MD**
Exexcutive Director
The Global Fund to Fight AIDS,
Tuberculosis and Malaria

**David Hyde Pierce**
Tony® and Emmy® Award Winning Actor

TAG

*TAG Limited Edition*

This year's TAG Limited Edition is *Enlarged Hypothalamus*, an edition of 20 by artist ***Donald Moffett***. Moffett's work has been shown widely across the United States and Europe. A 20-year survey of his major projects will open at the Andy Warhol Museum in Pittsburgh in 2010 and will culminate at the Contemporary Art Museum in Houston in 2012. Donald Moffett was a founding member of the artists collective Gran Fury, which created work in the late 1980s and early 1990s addressing issues of the AIDS catastrophe. Courtesy of the artist and Marianne Boesky Gallery, Stephen Friedman Gallery, and Anthony Meier Fine Arts.

# TAG NEW WAYS TO CONTRIBUTE

## About TAG

Treatment Action Group is an independent AIDS research and policy think tank fighting for better treatment, a vaccine, and a cure for AIDS. TAG works to ensure that all people with HIV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end AIDS.

Program areas include antiretroviral treatments, basic science, vaccines, prevention, hepatitis, and tuberculosis.

## Join TAG's Board

TAG is always seeking new board members. If you are looking for a great place to invest your time and talents, please call Barbara Hughes, TAG board president, to learn more about board opportunities with TAG.

Call 212.253.7922 or email:
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