AIDS ReSearch Alliance

SPOTLIGHT

People & Developments / Spring 2004

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—*One on One at ARA with Herminio Reyes & Michelle Simek*

Herminio "Bob" Reyes, Ph.D. and ARA's Michelle Simek talk about participating in ARA's current vaccine trial.

INTERVIEW: Putting Your Body Where Your Mouth Is

Herminio "Bob" Reyes, Ph.D. is the first participant enrolled in the AIDS ReSearch Alliance current vaccine trial, sponsored by Merck & Co., Inc. He is also a member of our Institutional Review Board, a former participant in the ARA/VaxGen vaccine trial, and a longtime friend of and volunteer at ARA. He is a consultant

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AIDS remains one of the world's most devastating diseases—every day, 8000 people die and another 14,000 women, men and children become infected with the HIV virus. In the United States, about one in 250 Americans are estimated to be living with HIV infection, and one third of them don't know that they are infected. While new medicines have reduced the death rate from AIDS in this country, AIDS has killed 22 million people since the beginning of the epidemic and has infected an

HIV/AIDS Treatment: *The Current State*

estimated 42 million people worldwide. Within six years, the UN projects that the total of infections will double, with an additional 45 million people contacting the virus.

The drug approval process in the U.S. is one of the most rigorous in the world.

The Drug Development Process

In an effort to stem the pandemic, biomedical researchers continue the arduous task of identifying and testing medi-

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ALSO IN THIS ISSUE:

SPOTLIGHT

People & Developments at
AIDS ReSearch Alliance

ARA envisions a future in which HIV and its effects are eliminated from infected individuals, and research yields effective and accessible methods to prevent new infections—eradicating the virus.

ARA's mission is to find and accelerate the development of effective treatments for HIV and its complications. We do this by conducting cutting-edge research and clinical trials in order to improve the longevity and quality of life for all people with immune deficiency.

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Message from the Executive Director

This summer the biannual *International AIDS Conference* will convene in Bangkok. It is the premier scientific meeting on HIV/AIDS in the world. In the past, much of the science unveiled at the meeting has been funded by the U.S. Government and many findings having been made by researchers at the *National Institutes of Health* and the *Centers for Disease Control*.

The Bush Administration has trumpeted U.S. leadership in advancing AIDS research, and made promises (as yet unkept) to provide massive aid to ameliorate this global crisis. The President should be commended for stating that AIDS is a top priority.

Yet, the Administration remains stuck in old-style political arguments that prevent progress. Political debates rage over whether generic drugs should be allowed in developing nations that cannot afford the patented versions.

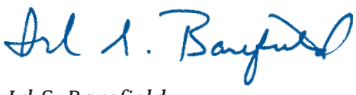
Politics drive whether President Bush will deliver on his promise of 15 billion dollars to the *Global Fund*—an international collaboration aimed at unifying global policy and halting the disease's spread. But recently the administration announced plans for a U.S. initiative that operates entirely apart from the Global Fund—even though the Administration's own Health and Human Services Secretary Tommy Thompson heads the larger effort. This has led to confusion regarding U.S. intentions.

The willingness to play politics with this serious issue undermines President Bush's credibility in leadership and promised assistance to those threatened by HIV/AIDS.

If there were any doubts that politics has replaced both science and sound policy, Secretary Thompson seems intent on removing them. You see, he is limiting the number of NIH and CDC researchers attending the Bangkok meeting to 40 people. Just two years ago, HHS sent hundreds to Barcelona for the same conference, with a budget more than six times that planned for Bangkok. Is this an attempt at efficiency? No. The presence of leading researchers in the same place makes science proceed efficiently, and without usual barriers to collaboration. Why, then, interfere with the ability of its own scientists to present U.S.-funded research to the world and forge collaborations that could build on them?

It turns out that that the pettiest of motives is at the core of this decision. At the Barcelona meeting, Secretary Thompson's address to those gathered was drowned out by a few loud activists. *USA Today* recently reported that a confidential email from one HHS leader to another revealed that as a result of this minor heckling, Mr. Thompson has decided to eviscerate the U.S. presence at this year's meeting.

The willful refusal to prevent America's finest scientists from attending the Bangkok Conference will only be reversed if Mr. Thompson's boss hears from enough citizens who realize that when science becomes political science, lives become expendable. You can reach Mr. Thompson's direct supervisor via email at *president@whitehouse.gov*. If you believe, as we do, that it is not only bad politics but bad logic to punish a few protestors by depriving the world community of U.S.-led scientific efforts, why not write an email today?



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Trial Announcements

Serostim® 24380 / SERONO, INC.

Long-term HIV-disease, as well as the long-term use of Highly Active Antiretroviral Therapy (HAART), are both associated with several metabolic abnormalities. One such abnormality is *lipodystrophy* (fat redistribution), which may consist of *lipoatrophy* (abnormal fat depletion, usually on the face or arms), and *HIV-associated Adipose Redistribution Syndrome* (known as HARS, consisting of abnormal fat accumulation, usually on the stomach, back, or in women, the breasts). One may have both HIV-associated fat depletion and fat accumulation at the same time.

No therapy is currently approved to treat either sort of abnormal fat redistribution. A previous trial suggested that Serostim® can significantly reduce truncal fat accumulations, non-HDL cholesterol and related cardiovascular risk parameters in HIV-infected volunteers; this follow-up placebo-controlled trial is designed to confirm these findings. This study will compare the use of Serostim® with placebo; volunteers will be randomly assigned to one of three groups.

This thirty-six week study is designed for HIV-infected volunteers who have evidence of excess abdominal fat deposits who have been taking antriretroviral medications for at least 30 days prior to study entry.

This study is currently enrolling.

BMS A1424-103/Atazanavir / BRISTOL-MYERS SQUIBB

There are currently six protease inhibitors (PIs) available to HIV-infected patients for use as part of Highly Active Antiretroviral Therapy (HAART). Their usefulness is limited by high pill burden and severe toxicities (lipodystrophy and lipid disorder). There is a clear need for potent PIs with convenient dosing and less toxicities. In addition, many treatment-experienced patients may benefit from a new PI with a different resistance profile which is non-overlapping with current PIs. Finally, some people who are on PI-containing regimens may experience harmful elevated levels of serum lipids (harmful fat in the blood).

This study primarily looks at the safety and efficacy of atazanavir in supressing viral load and maintaining immune system health in those taking an atazanavir-containing HAART regimen compared with those on a HAART regimen containing another PI; it also studies the reduction of serum lipids in members of both groups. Volunteers will be randomly assigned to one of these two groups.

This ninety-six-week clinical trial is for HIV-infected volunteers currently on or just removed from a NNRTI-containing HAART regimen which no longer serves to suppress their viral load.

This study is currently enrolling.

For information about participation in these studies, or to find out if there are other ARA studies for which you may be eligible, please contact Corie Castro at 310.358.2429.

Interview
One on One

to the clinical laboratory and biopharmaceutical industries, a medical writer, and a patient advocate and educator. Michelle Simek is ARA's Outreach Coordinator and Clinical Research Assistant; she also served recently as Event Media Coordinator for our Vaccine Press Conference *(see story on page 5)*; and she is a state-certified HIV counselor. She is a participant in the Merck vaccine trial, though at the time of this interview, she had not received her first injection.

Michelle and Herminio recently spoke together at length about vaccine trial participation, HIV clinical trials in general, the media and community activism.

MS: Herminio, you are our favorite volunteer in the world, the one that we can count on for everything. I've got some questions for you in your various roles—as a study volunteer, and as someone who knows a great deal about vaccines in your work. I'm also asking about your study experiences on my own behalf; I'm going to be starting on the study and will receive my first injection soon.

Let's start out with this: ever since you've come to us, you've been a blessing. You volunteered for this vaccine study, you were on an earlier vaccine study we did, you help us out at Gay Pride every year, you've spoken and worked at events, you're on our Institutional Review Board (IRB), and you were our "media darling" just recently at our vaccine press conference. Do you remember how you initially heard about ARA?

HR: I'd known about ARA for many years, having worked in the clinical laboratory and biopharmaceutical industries. One of my specialties was infectious disease—HIV in particular. Also as a member of the gay community affected by the AIDS devastation of the 80s and early 90s, having lost dozens of friends and a domestic partner to AIDS, I decided in a personal and professional capacity to become more involved with social services and in volunteering in any possible way—you know, education, outreach, anything else like that that I could do.

I also became aware of all the AIDS Service Organizations out of necessity, partly because most of my friends were becoming ill, they were dying, my partner died in 1990. During his illness, in the 80s, I had to learn about all the available services.

MS: You were a volunteer for us on the VaxGen vaccine clinical trial. Do you remember how you heard about that?

HR: I read about that in a *Frontiers* advertisement, and I'd been wanting to participate in a vaccine study, to "put my body where my mouth is," as it were. It was another way for me to further research and disseminate knowledge.

MS: And is that why you volunteered again, this time to be on the current Merck vaccine study?

HR: The same reasons apply to me being on both vaccine studies. I was, in fact, very happy once the VaxGen study was unblinded and found out that I'd been in the placebo group, because that meant that I could volunteer for this new study. Being a medical scientific professional, I pretty much follow everything related to HIV/AIDS and infectious diseases, and I'd heard about this vaccine candidate. As a member of ARA's IRB, I was invited to Merck's presentation here at ARA. I saw the data, which was very compelling and wanted to volunteer again.

MS: Well, we appreciate your commitment and that of everyone else out there who's volunteering for this study. Let me ask you another question about the VaxGen study. How did you feel when those results came out?

HR: I really wasn't surprised at the VaxGen results. Based on my medical knowledge, I wondered whether a vaccine that produced one single type of antibody against HIV was likely to work. I think that in order to be at least moderately successful, a vaccine must elicit both a cellular (so-called "killer cells") and humeral (antibody) immune response.

MS: Did it make you feel frustrated, or did it just make you ramp up for the next project? Not as a scientist, but as a volunteer and activist—this is an act of not just volunteerism, but activism, by "putting your body where your mouth is," as you put it…

HR: At that point, I just wanted to be unblinded and see if I was able to go on the upcoming Merck study, which looks so promising. I just wanted to get that show on the road & get my first shot.

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Interview photos by Karen J. Wellenkamp

Los Angeles Kick-off of Significant New Vaccine Study

AIDS ReSearch Alliance (ARA) was the first organization in Los Angeles to begin a new, Phase I study of an experimental, preventative HIV/AIDS vaccine. ARA held a press conference on Thursday, March 24th, during which the first vaccine volunteer, Herminio "Bob" Reyes, Ph.D., received the initial study injection. Reyes also agreed to speak to the press about his reasons for joining the study. ARA's Executive Director Irl S. Barefield and Medical Director Dr. Stephen J. Brown represented AIDS ReSearch Alliance at this study kick-off.

There was major media turnout as television stations KNBC-4, KABC-7, KCBS-2, KCAL-9 and news radio station KFWB gathered to record this significant event. These stations ran their coverage periodically throughout that day and the next, hitting the major evening and late night newscasts, as well as the next day's morning shows. The *Advocate's* on-line Healthwatch at www.advocate.com, as well as L.A.'s *Frontiers* magazine, both ran short features covering ARA's participation in this nationwide vaccine trial.

Stephen Brown & Herminio Reyes prepare for the study injection.

Channel KNBC-4 shows the container holding the initial study injection.

The injection is captured by Channel KABC-7's cameras.

Dr. Brown answers a battery of press questions after the initial injection.

Photos by Neil S. Gordon & Karen J. Wellenkamp

Event Media Coordinator Michelle Simek, originally uncertain of media interest, was gratified by the strong media attendance and subsequent coverage. "I was thrilled by the media response to this event. It showed that the general public outside of the HIV/AIDS community is interested in news on HIV vaccines, and therefore the media wants to cover this issue. Reporters in attendance asked us to keep them apprised of developments in the vaccine trial. It was wonderful to see that HIV/AIDS apathy had not affected the local media's concern to report developments in this critical area."

This vaccine, manufactured by Merck Co., Inc., has scientific potential because it may stimulate production of antibodies to HIV proteins and also elicit cellular immunity. The study is scheduled to last five years and additional study volunteers are urgently needed.

Our grateful thanks go to Herminio, ARA's first study participant, Institutional Review Board member, and beloved ARA supporter and friend, for volunteering to be our "media-darling-for-a-day," and for being so public and candid about his study participation.

For information about participating in this trial, or for more information about ARA's other clinical studies, please call 310.358.2429.

INTERVIEW
One on One

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MS: How would you feel if you ended up being on placebo again for the Merck study?

HR: It's going to take five years, at least, before I know. But some research studies require placebo groups. In this study, the chances are that 12 out of every 13 volunteers will be at least getting some dosage of the vaccine. If I were to receive placebo again, I wouldn't be upset. And I hope that no one thinks that by participating in this trial that they are lowering their chances of contracting HIV and can engage in risky behavior. But the study is designed in such a way that if a person answers questions honestly about their risk behaviors, it should provide useful results.

MS: Well, also it is people that are at low-to-moderate risk of becoming infected that are enrolled in this study. And we will be counseling everyone every time they come in for the study.

HR: Which also happened for the VaxGen study. But some people did sero-covert, which means they likely engaged in risky behavior.

MS: Let's look at the Merck study

now. We had a media blitz several weeks ago, and you were our "media darling" for at least the couple of days that the coverage aired. We want to thank you for that, of course. How did you feel about doing that?

HR: It was exciting. I emailed everyone I knew and called everyone I couldn't email. When I came to the press conference and saw the ABC truck, I thought, "Well, at least somebody showed up." And then everybody showed up and there were cameras everywhere. And the coverage… Channel 4 was great, and they actually incorporated part of my interview with Nerissa Witherspoon. They also extended it by going to the Watts Health Foundation and tied it in to people living with and being treated for HIV. This trial is designed for HIV-negative individuals at a low-to-moderate risk of contracting HIV, and I'm glad they tied it together with the HIV-infected community, particularly by going to Watts and doing outreach to minorities, because minorities are really unfortunately under-represented in almost all clinical research and education—not just vaccine research, but every kind of trial for new medications and treatments.

After the press conference, I ran home, threw in a tape and was flipping stations madly back and forth looking for coverage.

MS: Yeah, that was me after I got home that night. I actually had "remote thumb" from flipping the channels so much… So, what was scarier for you, getting the injection or being in front of the cameras?

HR: Actually, I wasn't really afraid of either one. The media people were very friendly and I was quite comfortable. They came prepared, very well-informed, and knew the appropriate questions to ask. They seemed very interested in what I had to say, both as a volunteer and as a medical professional. So that made it very easy.

MS: I'm asking this on behalf of anyone reading the article who may be interested in participating in the Merck vaccine study, and also for myself, going on the study—I get my first injection in about a week. Any side effects or anything else to share with us?

HR: In contrast to any other kind of injection I've had in the past, this one burned a little bit when it went into my arm. Just momentarily, but I was aware of it. You get a vaccination report card, in which you monitor your oral temperature and any other reactions to the injection, and your general health for a period after your injection.

MS: Yes, I'd like to talk about this a little—what are you monitoring, and how much time does it take you every day, is it a hassle?

HS: Starting on the day of the vaccination, for 29 days I have to monitor my oral temperature. For the first five days, I look at my arm to see if there's any swelling or redness or other reaction, and note that on the card. I had absolutely no reaction whatsoever, and no elevated temperature.

MS: I'm interested… I'd like to look at the study diary. What do you think of it?

HR: Here it is. It's very clear and explains everything. It shows you how to grade injection site reactions, on a scale of 1-5.

MS: There's a place here for other complaints or illnesses, for other medications, other non-study vaccinations, so if you got a cold, you would have to write that down.

HR: Yes, I would have to write it all down, because those things all need to be reported as "adverse events." Regardless of whether or not it's study-related, on any study,

anything that happens that's medically out of the ordinary has to be reported to the study sponsor as an adverse event.

MS: As the media coordinator for the day, and also as someone who's been involved in HIV issues for many years, I was very gratified by the media response. Just to know that the media and the community at large are interested in vaccine development was exciting. And also on behalf of the agency—because we are a smaller AIDS organization than some others in the community. And we've had a great response from the media coverage—folks have called in about the study. Which leads me to another question—who would you like to have join you on the trial, to be your "study brethren," as it were. Who do you think it would be important to have on this study?

HR: I think it is important for women and men of color, Latinos, Asians, all ethnicities and races and genders. I would like it to have the most diverse study population, because you know we live in a very diverse geographical area.

MS: And no group is unaffected by HIV/AIDS. Every population is affected and it has the potential to infect anyone. Every socio-political group, every ethnicity, etc. are all affected. I would love to have an extremely varied group on the study… Any advice for me before I get my first injection?

HR: Not really—just relax, be comfortable, there's nothing to be concerned about. You might feel a slight burning sensation… Something I think is important to note is that just because you don't have a reaction (if you don't) doesn't mean that you received placebo.

MS: Exactly. We had that come up with patients during the VaxGen study. Some volunteers came in for their follow-up appointments and indicated that they believed they either did or did not get the vaccine or placebo based on their side effects. We would remind folks every time they came in that they really had no way of knowing, based on their reactions to the injections. I may or may not have side effects.

HR: Yes, it's entirely possible that I had no side effects to this initial injection, not because I received placebo, but because perhaps I had high levels of antibodies to adenovirus, which is a cold virus and the "carrier" in this vaccine. I may have had a cold not too long ago, which means my immune system was primed for it, and so I got no reaction.

MS: You're farther along in the process than I am—I'm going to get my first injection of whatever it's going to be in a little over a week. I wanted to join because I work for ARA so this cause is very important to me. I have friends and colleagues who are infected with this disease so I'm doing this in their honor. I kind of wanted to be an example for straight women. Because straight women are being infected, and women are one of the highest growing infected populations. I don't want to steal your great phrase, putting "my body where my mouth is," but I do believe that volunteering for this vaccine study is a form of HIV/AIDS activism.

HR: It absolutely is.

MS: Back to the day of the vaccine press conference. You mentioned that you called and emailed everyone that you knew to check out the coverage. What was the reaction you received? Was there any negative reaction to your being on the vaccine trial and speaking out for it?

HR: No—everyone reacted positively. I got a lot of emails back saying, "Hey, I saw you on T.V." Right after the Channel 4 cover-

age, both my home phone and my cell phone were ringing simultaneously, ringing back and forth. I still occasionally encounter folks who saw me on T.V.

MS: Okay, about the study itself. I mention this as a person who will be participating in the study and also for the benefit of our readers: there is a likelihood that being on this study will induce a "false positive" using conventional, initial HIV testing (ELISA), which would later be corrected by a confirmatory "Western Blot" test. For some folks that may be a barrier to participating. When you were deciding to be on the study, how did you feel about that? Did the prospect of receiving a "false

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HIV/AIDS Treatment: The Current State

continued from cover

cations to treat HIV/AIDS and its related conditions. The drug approval process in the U.S. is one of the most rigorous in the world. Historically, it took an average of 15 years for an experimental drug to travel from the lab to patients; however, the Food and Drug Administration (FDA)—responding in part to patient-rights activists—implemented regulations in the 1990's to expedite the approval process for drugs treating life-threatening diseases such as HIV/AIDS.

The development process for new drugs includes an initial discovery—or basic research—phase, followed by pre-clinical studies gathering information on the mechanism of action, safety and potency of the drug. If identified as a viable candidate for further study, researchers apply to the FDA for permission to begin human clinical trials. These trials, performed in four phases, involve increasing numbers of participants to demonstrate the safety and efficacy of the drug in people. After obtaining satisfactory results from the clinical trials, a researcher files for approval by the FDA. Only five in 5,000 compounds that enter pre-clinical testing make it to human testing, and only one of those five is approved for use.

New HIV Drugs in 2003

Last year, the FDA approved five new drugs to fight HIV infection

Currently 72 promising new compounds are under investigation for treatment of HIV and its complications, as well as 15 vaccine candidates.

(see chart on page 9), bringing the total roster of antiviral drugs to 24. Added to the 24 antiviral drugs, there are another 53 drugs that deal with HIV related complications—including anemia, systemic fungal infections, oral-facial herpes, genital warts, neoplastic meningitis, anorexia and AIDS wasting, PCP, non-Hodgkins lymphoma, CMV retinitis, nausea and vomiting associated with cancer chemotherapy, toxoplasmosis, Kaposi's sarcoma, and tuberculosis.

That would certainly seem like enough drugs to provide a sufficient number of treatment options, but closer inspection of the list reveals that some of these drugs are simply re-formulations of already-approved drugs. After releasing a drug, a pharmaceutical company conducts additional research to make the drug more effective. Companies may then release a stronger—or weaker—version of a drug already on the market or combine several drugs into one pill to make dosing easier.

Additionally, there are a number of "me-too" drugs on the approved list—drugs released by different pharmaceutical companies that have similar chemical structures and that work in identical ways. In fact, even with all of the antiviral drugs available, we are still only able to attack HIV at four different stages of its life cycle.

The Search Must Continue

Even with this current arsenal of medicine, there is still no cure for AIDS and no vaccine effective against HIV. Current treatments have been effective in slowing the HIV virus and dealing with the nightmare crop of complications that arise, but some of these regimens have severe side effects and their prohibitive costs limit their usefulness in most countries. None of the drugs completely eradicate the HIV virus from the body, so most of them require lifelong use, even though we are still unsure about the toxic effects of long-term drug use. More importantly, the HIV learns how to out-smart these drugs and can mutate, changing its structure so that the drugs are no longer effective.

HIV/AIDS remains a clever and deadly enemy, and research organizations must continue to meet the challenge by continuing an all-out effort to develop novel and more effective treatments—especially antiviral medications—and vaccines to contain the disease. Rising levels of drug resistant mutations force researchers to develop new anti-HIV agents that take aim at novel targets. Side effects force us to develop less toxic and more powerful therapies. And finally, the search for a cure forces us to find strategies to eventually eradicate the

HIV virus from people's bodies and rebuild damaged immune systems.

In the Pipeline

Currently 72 promising new compounds are under investigation for treatment of HIV and its complications, as well as 15 vaccine candidates.

Ultimately, vaccination to protect against HIV infection will be the surest way to stop the spread of HIV, and intensive vaccine research has resulted in a slate of 15 new vaccine candidates in development out of 62 projects that were evaluated in 2003, according to the R&D database, Pharmaprojects. With 14,000 new HIV infections occurring every day, even a partially effective vaccine could save hundreds of thousands of lives each year.

The other compounds that have either reached the human clinical trial stage or are at the FDA awaiting approval, include:

- 33 antiviral drugs, some of which are designed to attack HIV in two new stages of its life cycle.
- 18 drugs that fight various opportunistic infections, AIDS-related cancers and funguses.
- 9 immunomodulators that work to strengthen the immune system, enabling it to continue functioning in the face of HIV's onslaught. This would be key to salvage therapies, as there are currently no immunomodulators approved by FDA to help restore HIV-ravaged immune systems.

Approved in 2003

Lexiva® — GlaxoSmithKline/Vertex

This newest protease inhibitor (PI)—a class of HIV meds that includes Crixivan® and Viracept® —is a cleaned-up cousin of Agenerase® that cuts the pill count from eight twice-daily doses to two twice-daily doses. Studies have shown Lexiva® is easier on the digestive tract and the pill count adds up to an easier dose. There are no food restrictions, and resistance to other PIs does not necessarily rule out the use of Lexiva®.

Emtriva® — Gilead Sciences

The newest Nucleoside Reverse Transcriptase Inhibitor (NRTI)—the oldest class of HIV meds and the backbone of most combination therapies—has a long half-life, which means it stays in the body longer. While some treatment advocates aren't excited by this drug because of its practical similarity to Epivir® (3TC), they are looking forward to the combination of Emtriva® with Viread® in one pill, which could be a significant treatment advance.

Reyataz® — Bristol-Myer Squibb

This new PI has a once-a-day dosing schedule and does not require another drug to "boost" its effectiveness. It doesn't appear to raise cholesterol like other PIs and may have a resistance profile that is slightly different from other PIs. Reyataz® is good for people who need a once-a-day treatment, although some treatment advocates still recommend a Norvir® booster for better efficacy.

Viracept® — Pfizer/Agouron

A new formulation of the PI Viracept® that cuts intake from five 250 mg pills twice a day to two 625 mg pills twice a day.

Fuzeon® — Roche Laboratories/Trimeris

Technically called a "fusion inhibitor," Fuzeon® is the first of a brand-new class of HIV drugs that keeps the virus from entering healthy cells. It should bypass the resistance that people have built up to existing drugs. Fuzeon® has shown a fair amount of punch, but at $20,000 each year, it is the most expensive HIV drug available, must be very carefully prepared and injected twice daily.

continued on next page

HIV/AIDS Treatment: The Current State

continued from page 9

- 13 other types of compounds, including a buffer gel to prevent the sexual transmission of HIV, and drugs that treat neutropenia, lipodistrophy and HIV-associated neuropathy.

ARA's Current Research Agenda

AIDS ReSearch Alliance is conducting clinical trials on 14 of the anti-HIV medicines and vaccines currently in development. One such study is the experimental Merck vaccine candidate that was developed in the mid-1990's. This vaccine uses a weakened common-cold virus—known as adenovirus—that has been modified to carry several HIV genes into the body. Once injected, cells surrounding the injection site internalize the DNA into the nucleus, where viral genes will be translated into viral proteins. Protein fragments are then transported to specific molecules and are expressed at the cell surface. The recognition of the viral protein by the immune system and specific T cells will hopefully induce an immune response against HIV. We have begun inoculating the first few volunteers with this experimental vaccine *(see page 1 for an interview with two of our volunteers.)*

We are also investigating several compounds to combat peripheral neuropathy—the often-disabling degenerative nerve damage experienced by nearly 35% of all HIV+ people. Neuropathy causes numbness, burning or tingling of the feet and hands, and if left untreated can become so severe that it permanently interferes with a person's ability to walk. It is historically difficult to treat, and there are currently no FDA-approved therapies available. One compound we are studying, *prosaptide*, is a nerve regeneration agent that may actually repair some of the neural damage that causes neuropathy. The other treatment now in Phase III clinical trial is C107, a topical patch containing three prescription analgesics.

AIDS ReSearch Alliance is conducting clinical research on 14 of the anti-HIV medications and vaccines currently in development.

Moving Forward

The search for a cure for HIV infection must go beyond treatments that merely slow the production of new virus. We must find ways to target the hidden pockets of HIV—or viral reservoirs—that remain dormant for decades in HIV+ people and escape the reach of current anti-HIV drugs. One of the most exciting compounds we are studying is *prostratin*, a natural compound isolated from a Samoan rainforest plant which has shown the unique ability to both activate HIV production in these dormant pockets and prevent the virus from entering uninfected cells. We are using our exclusive license from the federal government to develop prostratin, and by collaborating with researchers worldwide, we will see if prostratin's abilities in the lab can be translated into an efficient anti-HIV therapy targeting the elimination of viral reservoirs in HIV+ people.

As AIDS continues its global destruction, research organizations—like AIDS ReSearch Alliance—must continue to aggressively search for new and more potent therapies and vaccines to combat the disease. We must find new antiviral compounds that have strong and durable properties, unique resistance patterns, patient-friendly dosing schedules and less toxicities. We need drugs that more effectively handle complications that arise not only from HIV infection itself, but also from long-term use of the very medications that fight AIDS. Treatments to repair immune systems that have been ravaged by the disease and vaccines that prevent its further spread are incredibly critical. And ultimately, if we ever hope for a cure, we must find strategies to eradicate HIV from people living with HIV/AIDS.

We fully understand that 42 million people all over the world are depending on us.

INTERVIEW
One on One

continued from page 7

positive" result on an initial HIV testing bother you?

HR: No. For one thing, the study sponsor, Merck, has guaranteed to give us vaccination cards. With this study, there's a good chance that study participants who receive some dosage of vaccine will have sustained HIV antibody responses for many years. By conventional initial HIV tests, they will test positive…

MS: … but there is a law on the books here in California that those participating in HIV vaccine trials specifically cannot be discriminated against. This definitely pertains to employment, and also to insurance coverage.

HR: Well, let me ask you, Michelle. How do you feel about being on the study and the fact that you could become "false positive"?

MS: I haven't dwelt so much on being concerned about getting a "false positive." But it's not something I'm going to let deter me from being on the study.

HR: Now, here I am, interviewing you, Michelle! You're participating in the study, so potentially, you could get the vaccine instead of the placebo. Say you enter into a relationship and you're going to be monogamous. You'll probably both want to get HIV tested. How would you feel about that? How would you handle that? Would you feel comfortable telling them? And would you feel compelled to provide proof of your HIV status, or your HIV vaccine trial participation?

MS: That stuff is never really easy. Even as an HIV counselor. But, anyone who knows me knows what I do for a living and knows what I believe in and what I'm about. If any potential partners have a problem with me being on this study, then they would have a problem with me as a person. Again, I do believe that volunteering for this study is a form of HIV/AIDS activism.

HR: Some people don't always understand—being on a vaccine trial, it's doesn't mean you have HIV—you can't start on this trial if you are HIV positive. When I was on the VaxGen study, my parents especially asked me, "This is for a preventative vaccine, right?" Meaning, you're not HIV positive, right? And again, when I said I was going on this Merck vaccine trial, my mother again asked the same thing. Just making sure.

MS: You felt that it was important to be on this study and speak out about it, regardless of the potential for negative reaction from people you know?

HR: I'm so deeply concerned about the HIV/AIDS complacency that is happening in the community. I have this conviction that everybody under the age of 30, say, should read or see the films *And The Band Played On* and *Longtime Companion*. Because they didn't live through that awful period in the 80s and the early 90s, which was absolutely devastating for me. Many young people have missed that decimation. I also unfortunately even at this stage of the pandemic know HIV-positive people who have unprotected sex with multiple partners. I want people to know that they can become re-infected, most likely with multi-drug resistant HIV strains.

And the drug company advertisements for HIV meds all over TV and magazines make people think people that HIV/AIDS is completely treatable and that there's no problem—you know, people climbing mountains and looking completely fine. What those ads don't show is the percentage of people who don't respond to treatment, or are failing meds, or who have horrible, horrible side effects from the treatments. The ads don't show people who get extremely virulent or multi-drug resistant strains, or people whose vital organ systems are just so overworked and tired from the medications. And now there is the high frequency of multi-drug resistant HIV strains being transmitted as new infections. This complacency is dangerous, in which people think HIV completely treatable, but they have a very high chance of getting infected with a strain of HIV that is resistant to whole classes of drugs. Even if they don't have any side effects with the drugs, the drugs just might not work on them anyway. We have to find a vaccine and continue educating people.

Interview photos by Karen J. Wellenkamp

SPOTLIGHT DONORS'04

The families, individuals, foundations and companies listed below recognize that AIDS won't end without medical research; they form the bedrock upon which our vital work rests. Their generosity enables AIDS ReSearch Alliance to continue searching for better treatments against HIV and innovative ways to stop its spread. Regardless of dollar amount, they are making the difference in this epidemic.

(Donor list covers from 1/1/04 to 4/16/04.)

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"For the cause that lacks assistance,
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For the future in the distance,
And the good that I can do."

-- George Linnaeus Banks

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"What really distinguishes this generation in all countries from earlier generations ... is its determination to act, its joy in action, the assurance of being able to change things by one's own efforts."

-- Hannah Arendt

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That's right, go ahead and buy something for yourself—a new CD, the latest bestseller, essentials like toothpaste or vitamins, even a computer. But first sign-up at www.iGive.com/ARA. Every time you shop at one of the over 500 name-brand stores in the Mall at iGive.com, we'll receive a donation of up to 26% on each purchase you make, at no cost to you. You may even save money on exclusive deals to iGive.com patrons!

Remember, helping AIDS ReSearch Alliance this way won't cost you a thing. Just begin all your online shopping at iGive.com. Why not visit www.iGive.com/ARA right now? Membership is free and your privacy is guaranteed.

STUDY	DESCRIPTION	STATUS
Pre-clinical & basic research AIDS ReSearch Alliance	ARA is engaged in a number of ongoing preclinical and basic research projects not ready for human clinical trials. We include this information here to ensure that our supporters know that this chart reflects only a part of our mission-driven work to ameliorate and, we hope, one day end the epidemic. *(Various)*	Ongoing
BMS AI424-103 Bristol-Myers Squibb	A study to see if a regimen containing the experimental protease inhibitor atazanavir will maintain viral suppression while lowering serum lipids (harmful fat in the blood) in volunteers who are experiencing virologic failure on their first NNRTI-containing HAART regimen. *(Antiviral therapy)*	Enrollment initiated
Serostim® 24380 Serono Laboratories	A study testing the safety and effectiveness of a growth hormone in treating HIV-associated lipodystrophy. *(Fat redistribution therapy)*	Enrollment initiated
C107 NeurogesX	A study testing the safety and effectiveness of a new treatment called a capsaicin patch for the relief of HIV/AIDS-associated neuropathic pain. *(Pain alleviation)*	Enrollment ongoing; study ongoing
Experimental HIV Vaccine Merck & Co., Inc.	A study to test the safety and efficacy of a new anti-HIV vaccine. *(Preventative HIV Vaccine)*	Enrollment initiated
C0603 Savient Pharmaceuticals, Inc. and the Neuro-AIDS ReSearch Consortium (NARC)	A study testing the safety and effectiveness of a new medication called prosaptide for the relief of HIV/AIDS-associated neuropathic pain. *(Pain alleviation)*	Enrollment ongoing; study ongoing
A4301010 Agouron Pharmaceuticals, Inc.	A study testing the safety and effectiveness of a new Viracept™ formulation as a component of HAART for antiviral treatment of treatment-naïve volunteers. *(Antiviral therapy)*	Enrollment ongoing; study ongoing

STUDY	DESCRIPTION	STATUS
BMS AI424-067 Bristol-Myers Squibb	A study to see if replacing volunteers' current protease inhibitor (P.I.) with the experimental protease inhibitor atazanavir will lower serum lipids (harmful fat in the blood) while maintaining viral suppression. *(Antiviral therapy)*	Enrollment ongoing; study ongoing
BMS AI266-406 Bristol-Myers Squibb	Vest-QD: a study to see if Sustiva™, a non-nucleoside reverse transcriptase inhibitor (NNRTI), will maintain viral suppression in volunteers who switch to Sustiva™ from a protease inhibitor (PI). *(Antiviral therapy)*	Enrollment ongoing; study ongoing
Micronutrient Neuropathy Study Integrative Health Consulting, Inc.	A study testing the effectiveness of a broad-spectrum micronutrient supplement in the treatment of those volunteers who have developed neuropathic pain while taking stavudine and/or didanosine antiviral therapy. *(Pain alleviation)*	Study completed; report pending
Zerit® (Stavudine, d4T) Bristol-Myers Squibbs	A study to evaluate and compare the safety and efficacy of extended-release stavudine compared with standard stavudine for antiviral activity. *(Antiviral drug/improved dosing)*	Enrollment completed; study ongoing
Serostim® 22388 Serono Laboratories	A study testing the safety and effectiveness of a growth hormone in treating HIV-associated lipodystrophy. *(Fat redistribution therapy)*	Study completed; report pending

For information about enrolling in any of our studies, contact ***Corie Castro*** *at* **310.358.2429**. *Transportation to our clinical research facility is usually available on request. For priority notification of new or enrolling clinical trials, sign up for our* ***Priority Notification Program*** *by calling the above number or visiting our website at* **www.aidsresearch.org**. *Para informacíon en español, llame 310.360.3876.*

ARA in the Community

On January 21st, in collaboration with **Being Alive LA**, ARA presented a clinical trials medical update to the 80 people in attendance at the West Hollywood Auditorium.

Deon Claiborne, Outreach Coordinator at the **UCLA Care Center**, presented an overview of clinical trial phases and the drug development process. Using slides to illustrate, she spoke in detail about the research process, and in particular, about the research currently ongoing at UCLA and the AIDS Clinical Trials Group.

ARA's Outreach Coordinator **Michelle Simek** spoke to the audience about what to expect in a clinical trial, covering the paperwork and time committment involved in a typical study, as well as a trial colunteer's rights and responsibilities. She explained why some studies are able to compensate for study participation while others are not, and outlined some questions that anyone considering clinical trial participation should ask before entering a study. She also used slides to underline her main points, and offered a handout "Clinical Trials 101" that covered the basics of her talk.

Finally, **Michael Ashby**, longtime volunteer in ARA's Viracept trial with Agouron/Pfizer and friend of AIDS ReSearch Alliance, spoke at length about his experiences on the study and with ARA's clinical staff. He talked about his partner, who he lost to AIDS many years ago, his own original HIV diagnosis in 1991, his referral to ARA through his doctor **Wilbert Jordan, M.D.** (currently on ARA's Medical Executive Committee), and his gradual return to health and viral stability on antiretrovirals. He credited ARA and his study participation with saving his life, and encouraged folks to get HIV-tested, educate themselves about the disease, and if infected, take steps to ensure that they get the best possible treatment available and stay informed about emerging, experimental treatments.

The team took questions from the lively audience, whose comments ranged from specific questions about the drug development process to voicing concerns about the state of HIV/AIDS treatment available to those lacking health insurance.

In addition to ARA and Being Alive, representatives were also available from the UCLA Care Center, **National Neurological AIDS Bank**, **Health Research Associates**, **UCLA Behavioral Health**, and **USC 5P21 Clinic** with information about their current research projects. Being Alive's able facilitator **Kevin Kurth** coordinated the forum and arranged for the appetizing dinner offered to forum attendees. The evening was underwritten by a grant from **Abbott Laboratories.**

PHOTOS: (Top) ARA's Michelle Simek, (Middle) Study participant Michael Ashby, (Bottom) Forum presenters Michael, Michelle and Deon Claiborne take questions from the audience.

The ARA Team: Say Hello...

The Board of Directors (BOD) is proud to welcome newest member **Garfield Ricketts** of **Round2 Communications**. BOD member and former Chair **Cam Davis** helped bring Garfield on board and we thank him for this exciting and latest member of our Board team.

He is Chief Executive Officer and founder of Round2 Communications, a media agency he started in 1993, which currently has offices in Los Angeles, San Francisco and the U.K.

Garfield was born in Kingston, Jamaica and grew up in New York City, the first generation of his family to be raised in the U.S., a place he considers to be an "great place for growth and opportunity."

Photo by Kimberly Kusler

Garfield Ricketts

He has spent over 25 years in the media business, working for New York firms **Young & Rubicam**, **William Esty & Co.**, **Ogilvy & Mather**, as well as **keye/donna/pearlstein** of Los Angeles, and later serving as Director of Media at **L.A. Gear**.

Garfield is committed to sharing his advantages and expertise with the community, glad, as he says, "for a chance to give back, and never forgetting where I came from, nor the times when I had to operate on a shoestring. I have been fortunate, and I believe that it's important to promote the spiritual and physical well-being of our global community."

He enjoys travelling and recently attempted to climb **Mt. Kilamanjaro** in Africa with his partner, Terry, who did complete the arduous climb. They live in a house in Bel-Air which they are in the midst of renovating and landscaping and share their home with what Garfield calls their "big old English sheep dogs," Daisey and Wally.

...& Wave Good-bye

Sergio Codina, R.N., Manager and Coordinator of ARA's clinical trials for nine years, has left Los Angeles and AIDS ReSearch Alliance with his partner Peter Samuels and moved up north to settle in the small town of Eureka, California.

Originally hired in 1995, Sergio came to us from USC as a skilled nurse with both HIV and research experience, expertly filling ARA's expanding and demanding Trials Coordinator/Manager position at a time when HIV/AIDS research and treatment was undergoing some of its most radical and profound developments.

He coordinated pharmaceutical industry and independent trials that ranged from innovations in antiretroviral and combination therapies to complementary treatments for HIV/AIDS and its opportunistic infections. He worked successfully with such companies as **Merck, GlaxoSmithKline**, **Agouron/Pfizer**, **Bristol-Myer Squibb** and **Pharmacia & Upjohn** and collaborated with organizations that varied from **UCLA** to the Chinese Government.

He is sorry to leave ARA, where he found his position satisfying and challenging and enjoyed his relationships with both colleagues and trial volunteers, but moving to Eureka with

Photo by Arnond Bagdasarian

Sergio Codina, R.N.

his partner of 11 years is, as he says, "fulfilling a dream of buying a house in a small community where the Redwoods meet the Pacific, and getting back to both of our backgrounds of living in a small community, where the pace of life is slower."

Sergio will be working at **St. Joseph's Hospital** in Eureka in their Intensive Care Unit and E.R., while his partner Peter will continue to draw inspiration for his art from the scenic beauty of the region. They both have longtime friends in the area, and have visited and loved this part of the coast for the past ten years.

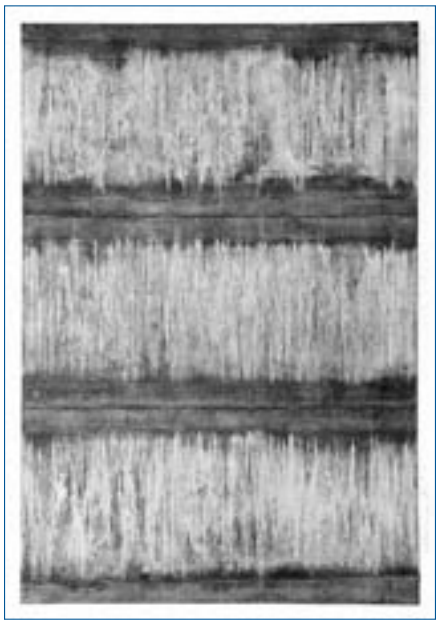
From ARA's Executive Director **Irl Barefield**: "Without exception, everyone at ARA will miss Sergio. He dedicated nine years of his life to coordinating the highest quality research, and did so because he knew one person could make a difference. For the majority of ARA's history, Sergio made that difference in all the clinical trials that led to the powerful medications that have resulted in longer, healthier lives for those with HIV. The fact that he did this job for so long with unequalled efficiency and fierce compassion is simply remarkable. Countless people owe their health and well-being in large part to his efforts."

We are pleased to welcome **Grace Gachanja, R.N.** to our clinical staff. Grace will be serving as a Trials Coordinator, while **Michele Vertucci, PA-C** of our medical team will step up to fill Sergio's Coordinator/Manager position. Grace comes to us from Nairobi, Kenya by way of Iowa, and is an experienced nurse with over ten years of experience. *(See our next issue of* Spotlight *in Fall, 2004 for Grace's complete biography.)*

A Tribute to the Art of Bob Crewe

Retrospective Exhibit & Charity Sale Benefits ARA

This past March, ARA was the beneficiary of **A Tribute to the Art of Bob Crewe:** ***A Retrospective Exhibition and Charity Auction*** that raised over $35,000 to fund our 2004 research agenda. The exhibit celebrated the prolific art career of **Bob Crewe**, who is represented in Los Angeles by the **Jan Baum Gallery**, and featured nearly 140 works of art spanning the past sixteen years. A number of these works had never been shown publicly.



"Excavation Triptych"/Bob Crewe

Photo by Johnny G. Photography

Bob Crewe, Lenore Marshall, Gavin & Patti McLeod

Hundreds of celebrities, visual artists, philanthropists, art-collectors, gallery owners and guests flowed through the exhibit—including **Nancy Sinatra**, **Jerry and Rita Vale**, **Gavin and Patti McLeod**, **Gil Garfield**, **Michael Allen**, **Jan Baum**, **Jim Morphesis**, **Alison Arngrim**, **Charlotte Rae**, **Joan Worth**, **Aloma**, **Christopher Showerman** and **Tom Ellis**.

Photo by Johnny G. Photography

Jan Baum, Bob and Michael Allen

Photo by John Bernard

Nancy Sinatra, Tom Ellis and Jan Baum

While Bob Crewe is, in the words of *Rolling Stone* magazine, "a pioneering architect of pop music," he is also a major American painter. As a well-known songwriter, composer and producer, Bob's success was established with countless hits, including "Can't Take My Eyes Off You," one of the most frequently played songs of last century, "Lady Marmalade," "Big Girls Don't Cry" and "My Eyes Adored You."

Photo by Johnny G. Photography

Seth Manlove, Bob and Ric Murray

Photo by Johnny G. Photography

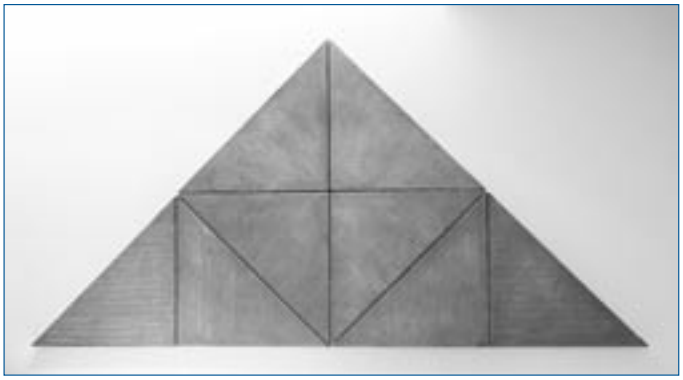
Aloma, Jerry Vale, Cathy Chamales and Rita Vale

Photo by Johnny G. Photography

Rita & Jerry Vale and Charlotte Rae

Photo by Johnny G. Photography

Bob's Hollywood studio the night of the auction



"Triangle Eight"/Bob Crewe

But even while performing on shows with the **Everly Brothers** or **Della Reese**, scoring for performers like the **Four Seasons** and **Frank Valli**, or composing soundtracks for such movies as *Barbarella*, Bob's passion for painting never waned. His abstract work—ever inventive and disarming—has found a wide audience who are inspired and challenged by it.

Bob has been a key supporter of AIDS ReSearch Alliance for the past decade and we were thrilled when he choose ARA to be the recipient of the proceeds from this special tribute. "AIDS ReSearch Alliance is a group that's really on the cutting edge of research and backs up its mission with solid accomplishments. Ever since my good friends, **Nancy and Sandy Bresler**, introduced me to ARA's work, I've watched these researchers come up with innovations in the field that are long overdue."

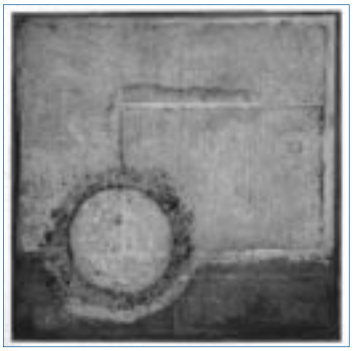
ARA would like to acknowledge the generous support of **Manatt, Phelps & Phillips, LLC** for helping to underwrite this event. Thanks also to our Media Partners: **K-EARTH**, **KABC**, **KLOS**, **KZLA**, **ESPN Radio**, **KJLS**, **94.7 The Wave**, **KLAC**, and **Round2 Communications**, as well as the Bar Sponsor—**Vox Vodka**.

Photo by John Bernard

Bob surveys the crowd below assembled for his tribute.

Photo by John Bernard

ARA Board members Sandy & Nancy Bresler with Bob.



"Mystic Canyon"/Bob Crewe

Bob Crewe Tribute

Honorary Host Committee

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AIDS ReSearch Alliance

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Michael Becker: *From El Rio de la Plata*
Dean Jones & Steve Feldstein & Dan Busbin & Robert Shabkie & Dan Kough: *The Pajama Party*
Bruce Brown & David Wood & Steve Oratowski & Tom Hogg: *Queer Food For The Gay Guy*
Chris Easton & Wayde Westling: *Sex In This City*
David Anderson & Greg Kotler: *Flannel Chic*
Bruce Mink & Mark Farndale: *Retro Chic TV Dinner*
Marc Borzelleca & Monika Reti: *Casablanca in the Canyon*
Terry Cunningham & Garfield Ricketts: *Stone Canyon Renovation & Some Southern Hospitality*
Jody Jackson & Bill Mueller & Jay Richards: *If It Ain't Baroque... A Night at the Opera*
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Dessert Reception Partners

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Dr. Wes Wheadon Optometry, E! Entertainment, The Farm of Beverly Hills , Kevin Hees Photography,
Le Merigot Beach Hotel, Maggiano's Little Italy, Pearl Dragon, Scott Campbell, SoapNet – ABC Networks,
St. Regis Resort, Urth Caffe, Waldorf Astoria, Wood Ranch BBQ and Grill

To find out how you can become involved in upcoming events at AIDS ReSearch Alliance, please call the Development Department at 310.358.2423 x.150. We'd love to have you on-board!

AIDS ReSearch Alliance
www.aidsresearch.org

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