

AIDS Research Alliance

Board of Directors

Kenneth "Cam" Davis, Jr.
CHAIR
Vice-President
Sanford C. Bernstein & Co.

Arnold Kassoy, Esq.
VICE-CHAIR
Partner
Manatt, Phelps & Phillips

Chuck Williams
TREASURER
Chuck Williams & Associates

Derek Jones, M.D.
SECRETARY

Nancy Bresler

Sandy Bresler
Talent Agent
Bresler, Kelly & Associates

Bruce Cochran, Esq.
Attorney

Tim Corrigan
Executive V.P.
Bates Worldwide

John Dratz, Jr., Esq.
Of Counsel
Hooper, Lundy & Bookman, Inc.

Matt Redman
McCown-Redman Design

Adrian van Deudekom
Manager of So. CA Promotions
Disneyland

Robert Winters, M.D.

Executive Director
Irl S. Barefield

Director of Clinical Research
Stephen J. Brown, M.D.

Medical and Scientific
Advisory Committee

Bisher Akil, M.D.
Peter Anton, M.D.
H. Aaron Aronow, M.D.
Victor Beer, M.D.

Aron Bick, M.D.
Joseph Church, M.D.
Gary Cohen, M.D.
Richard Cooper, M.D.
Jim Corti, R.N.
George Fareed, M.D.
Erik Fleishman, D.O.
Jonathan Goldsmith, M.D.
Michael Gottlieb, M.D.
Edward Grant, M.D.
David Hardy, M.D.
David Hart, M.D.
Scott Hitt, M.D.
John James

A. Kay Kalousek, D.O.
Mark Katz, M.D.
Peter Kraus, M.D.
James Lee, D.O.
Albert Lerner, M.D.
Thomas Magee, M.D.
Ian McGowan, MB, D.Phil., MRCP
Michael Moret, M.D.
Phillip A. Muskanth, M.D.
Gregg Olsen, M.D.

Amit Patel, M.D.
Henry Poscher, Ph.D.
Eugene Rogolsky, M.D.
Peter Ruane, M.D.
Jesse Sanders, M.D.
Karen Sandler, D.O.
Anthony Scarsella, M.D.
Michael Scolaro, M.D.
Bye Singer, M.D.
Brian Smith, D.C.
Brian Terry, M.D.
James Thommes, M.D.
Michael Wensley, M.D.
Daniel White, M.D.
Kevin W. Williams, M.D.
Ronald Wing, M.D.

Founders In Memoriam
Paul Rothman, D.O.
Matthew Rushton

AIDS ReSearch Alliance

SPOTLIGHT

People & Developments / Summer 2001



PHOTO BY BRUNO CALABRANO

Focus on AIDS 9 Coming into focus at Barneys New York

The ninth **Focus on AIDS Foundation** photographic art auction, the largest of its kind in the United States, will be held at **Barneys New York** in Beverly Hills on Friday, November 9th.

This elegant, star-studded event features both live and silent auctions of over 240 rare, vintage and contemporary photographs, offering both the collector and the public an opportunity to view and bid on some of the finest photographs in the world.



continued on page 4

Prostratin A promising natural compound for treating HIV

AIDS ReSearch Alliance targets the viral reservoirs, but what are they?

Highly active antiretroviral therapy (HAART), consisting of at least three antiretroviral drugs, has given us greater control over HIV/AIDS. In fact, using HAART has dramatically improved the lives of many HIV+ people and has led to a substantial decline in AIDS and AIDS-related deaths in the United States and other developed countries.

ALSO IN THIS ISSUE:

- ARA Trials Announcements
page 3
- Clinical Trials 101
page 7
- Thank you to our Donors
page 12

The viral reservoirs are considered to be the major stumbling block to eradication of HIV from infected individuals—in other words, to curing AIDS.

At first, there was great optimism that HIV could be eradicated in HIV+ people who were being aggressively treated. However, eradication relied on the assumptions that the virus would remain completely suppressed and that no unreachable virus existed in infected individuals. Unfortunately, those assumptions proved incorrect.

continued on page 18

SPOTLIGHT

PEOPLE & DEVELOPMENTS AT
AIDS ReSEARCH ALLIANCE

ARA envisions a future in which HIV and its effects are eliminated from infected individuals, and a vaccine preventing new cases eradicates 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.

EDITOR

Karen J. Wellenkamp

EXECUTIVE DIRECTOR

Irl S. Barefield

DEVELOPMENT DIRECTOR

Vincent M. Cummings

CONTRIBUTORS TO THIS ISSUE

Irl S. Barefield

Vincent M. Cummings

Antonio Pisig

Michelle Simek

Karen J. Wellenkamp

SUBSCRIPTION COORDINATOR

Helen Macias

ART DIRECTOR & PRODUCTION

Karen J. Wellenkamp

DIGITAL PRE-PRESS STUDIO

Fontographics

Spotlight is published twice-yearly to highlight recent developments at AIDS ReSearch Alliance of America for the benefit of its donors, supporters, patients and other community members. ARAA, a nonprofit corporation with its principal place of business in California, is solely responsible for its content. Noncommercial reproduction is encouraged provided the appropriate credit is given.

Circulation: 11,500

Copyright© 2001 AIDS ReSearch Alliance
of America

All rights reserved.

AIDS ReSearch Alliance of America
621-A N. San Vicente Blvd.
W. Hollywood, CA 90069

Telephone: 310/358.2423

Fax: 310/358.2431

www.aidsresearch.org

Spotlight is funded in part
by a generous donation from the
Joseph Drown Foundation.

CFC #1704

Printed by Acuprint on recycled paper.



Message from the Executive Director

"I know a little."

This was the quiet answer of Samoan healer Epenesa Mauigoa when ethnobotanist Paul Cox asked her if she knew anything about traditional herbal medicine. The elderly woman then shared 121 herbal remedies drawing on over 90 plant species. Cox now heads the U.S. National Botanical Gardens and was once named a "Hero of Medicine" by *Time Magazine*. But he vividly remembers Epenesa recounting her 37th herbal remedy. She described boiling the bark from the *mamala* tree and giving the liquid to those suffering from *fiva sama sama*—viral hepatitis. Cox reported this to the National Cancer Institute's drug screening program, and in 1992 NCI isolated a part of the plant that demonstrated unique anti-HIV properties.



PHOTO BY WALTER M. ADINA

The compound isolated from the *mamala* tree is prostratin—you can read about ARA's work on this compound in this issue. You will also read about our collaborations with researchers at the National Institutes of Health, the National Cancer Institute, scientists at UCLA, Thomas Jefferson University, and around the world. The aggressive work done under the orchestration of AIDS ReSearch Alliance has so far shown a compound of great promise—a drug that may prevent HIV from infecting cells, as well as purging the hidden viral reservoirs that are a barrier to treatment. This is a welcome change from its limbo status when pharmaceutical companies wouldn't fund its development because plant compounds cannot be "patented".

It shouldn't be surprising that the rich diversity of the Samoan rainforest may hold a key to treating AIDS. Roughly half of the prescription drugs sold in the U.S. at your neighborhood pharmacy come derived from plants, or are synthetic versions of compounds isolated from plants—just one way in which natural diversity has informed and driven our progress in many endeavors.

Shortly after Paul Cox learned of prostratin from Epenesa Mauigoa, a logging company arrived to clear cut the part of the Samoan rainforest where Mauigoa gathered the bark of the *mamala* tree. Cox's influence in the U.S. prevented that. But it might have been different. In Hawaii, for example, half of native plant species are threatened with extinction. If they go, what unknown benefits will go with them?

Nature has yielded potential new therapy for HIV. Its story shows the real, practical value in difference and diversity. We should take a hint from the value found in the diversity of the world's plant species, and the different environments in which they thrive. Our differences—whether cultural, ethnic, socioeconomic or political—create the need for the kind of dialogue that moves us towards new ways of thinking about AIDS. HIV has exploded globally and crossed cultural barriers in the U.S. We must recognize and listen to the diverse populations facing this crisis, and address their varying needs by attacking the epidemic from different perspectives.

The epidemic is at a unique point. What was true for the late Samoan healer Epenesa Mauigoa is also true for us. If each of us admits as openly as she that we only "know a little," we will be poised to learn a great deal more from one another as we confront the third decade of this crisis.

With respect,

Irl Barefield,
Executive Director
irl@aidsresearch.org

Trial Announcements

Serono's Lipodystrophy Study, OraSure's Hepatitis C Test and GlaxoSmithKline's APV30002.

Lipodystrophy Study **(Fat redistribution)**

Many people who are HIV+, and those taking HIV medications, experience fat redistribution, among other "metabolic complications". This fat redistribution is also known "lipodystrophy". Symptoms can consist of fat loss in the face and elsewhere, an increase in abdominal and neck girth, abnormal fat accumulation in the back of the neck, significant increases in breast size and *lipomas* (tumor-like fatty deposits)*.

Serono's Serostim®, already FDA-approved for treatment of HIV/AIDS-associated wasting, will be tested on HIV+ volunteers currently taking anti-HIV medications and suffering from abdominal lipodystrophy to see whether the drug can induce improvements in body shape. This is a 24-week study.

This study is currently enrolling.

*It is thought that these changes in body fat may increase the risk of cardiac disease in those experiencing them.



Hepatitis C Assay **(Hepatitis testing)**

ARA is investigating OraSure's new oral assay for Hepatitis C, which tests for the presence of Hepatitis C antibodies in saliva and epithelial (cheek) cells.

Blood assays for the detection of Hepatitis C antibodies already exist, but this test, if successful, would allow an oral test instead, encouraging those at risk to be tested for this serious and chronic illness, and protecting healthcare workers from exposure to needle-stick infection.

Those interested in joining the study must bring proof of their infection with them to the initial screening appointment. Volunteers will receive \$20 for their inconvenience.

This study does not involve a drug; it consists of a single clinic visit during which the volunteer will have one oral specimen and one blood draw taken, and have a 15-minute confidential interview.

This study is currently enrolling.



APV30002 **(Antiviral therapy)**

This clinical trial represents a different approach to anti-retrovirals. It studies the safety and effectiveness of the experimental *prodrug* formulation of Agenerase® (amprenavir), a protease inhibitor which was recently approved by the F.D.A.

Prodrugs are precursor versions of medications which are changed within the body to the parent drug. They are not fully potent until after the medication has been metabolized by the body to some extent.

The study compares the combination of the prodrug amprenavir when combined with ritonavir, abacavir and 3TC to the combination of nelfinavir, abacavir and 3TC.

This medication, if successful, may create fewer side effects than amprenavir and thus be better tolerated than Agenerase® in its current form.

This study is currently enrolling.



(For information about participation in any of these studies, please contact Corie Castro at 310/358.2429.)

SPOTLIGHT EVENTS

Focus on AIDS 9

cover story continued

The Focus on AIDS Foundation, founded by **Hossein Farmani** over eleven years ago (*see box below*), has successfully raised over \$1,000,000 in support of non-profit agencies fighting AIDS. These agencies have conducted cutting-edge research on new treatments or provided critical services to both the photographic community and adults

and children affected by AIDS. The Focus on AIDS Foundation is assisted by a celebrity host committee chaired by **Anthony Edwards** and his wife **Jeanine Lobel**. This year's FOA9 beneficiaries are **Caring For Babies With AIDS**, **AIDS ReSearch Alliance** and the **Focus on AIDS Foundation**.

Photos will be on view at Barneys beginning with the *VIP & Artists*

continued on next page



FOCUS ON AIDS 6: Melvin Sokolsky, "Bubble du Taxi", 1963, Courtesy of the artist.

FOCUS ON AIDS ONE (1)/HOW IT ALL BEGAN

Antonio: *Inspiration & Friendship*

Antonio Lopez, fashion illustrator and innovator, died in March, 1987 of AIDS-related illnesses. Published in *Vogue* and the *International Vogues*, *Elle*, *Harper's Bazaar*, *Marie Claire* and numerous other publications, he was considered by many in the fashion & art worlds to have changed the face of fashion illustration. Antonio's dynamic and eclectic style liberated fashion art in the 60s and helped open its doors to models of color and diverse ethnicities.

Susan Baraz was his close friend of many years, modeling for him in the 60s and 70s, and finally nursing him in her home until his death. When Antonio died, a grief-stricken Susan struggled with her loss and expressed her feelings of helplessness in the face of



Antonio in New York, 1976

AIDS. She spoke with her good friend **Hossein Farmani**, who had come to know Antonio through Susan, and who, with **Candace Falk**, had conducted Antonio's last press interview in 1987 for his magazine at the time, *International Vue*.

Hossein responded with the idea for the Focus on AIDS Photography Auction to commemorate Antonio's death, and to combat the illness that struck him down. He set about organizing FOAF1 with Candace, who eventually served with Hossein as co-chair of the first four Focus on AIDS auctions. Susan Baraz has served as co-chair for Focus on AIDS 5 up through the present auction.

AIDS ReSearch Alliance has been the primary beneficiary & co-organizer of the event since Focus on AIDS 7 in 1997.

Last year, both FOAF and ARA Boards were moved to discover that ARA Medical Executive Committee Chair and Board Member **Dr. Robert Winters** had served as Antonio's physician during his final illness. It seems fitting that ARA should have become involved in the event that was inspired by Antonio's memory, bringing the story full circle.

Of Antonio, Susan says, "His life touched thousands of people. He helped everybody do or be the best they possibly could, and made people feel beautiful both inside and out. When he died, it was like a light went out in the world."

For more information on Antonio and his art, please visit this Smithsonian-hosted website: <www.hispanicdesigners.org/antonioB.html>



Susan Baraz with an Antonio drawing featuring herself as model



An illustration by Antonio for Fashion of the Times, 1967



FROM LEFT TO RIGHT: *FOCUS ON AIDS 7*: Douglas Kirkland, "Golden Boy", 1997, Courtesy of the artist & G. Ray Hawkins Gallery; *FOCUS ON AIDS 8*: Martine Barratt, "After The Service, Sunshine—Harlem", 1983, Courtesy of the artist; *FOCUS ON AIDS 8*: Yul Brynner, "Tony Perkins", 1997, Donated by Victoria Brynner; *FOCUS ON AIDS 8*: Henri Mandel, "Untitled (10)", c. 1900, Courtesy of Stephen Cohen Gallery.

Opening and Preview Party on Saturday, November 3rd at 7:30p.m. VIP ticket packages start at \$500. Photographs will remain on view at Barneys until the auction on November 9th, and the beautiful 50-page collector's catalogue will be available for \$20 the week preceding the auction.

Tickets for the *Focus on AIDS 9* photographic auction can be purchased in advance for \$65 by calling 310/358-2423, or at the door for \$75. Included with admission are a complimentary catalogue, a martini bar, and live music. Exquisite hors d'oeuvres, coffee and gourmet desserts will also be provided.

Event sponsors include **The Walt Disney Company, Bruce Kramer/5th & Sunset, A & I Photography Laboratories, David Hunt/Merrill Lynch, and Tamron USA, Inc. (Bronica).**

The country's most important photographers, photography galleries, reps and framing companies help us create one of

America's largest and most prestigious fundraisers of vintage and contemporary photographs by world-renowned photographers.

Participating photographers from past auctions have included **Richard Avedon, Tom Bianchi, Michel Dubois, Jeff Dunas, Greg Gorman, George Hurrell, Diane Keaton, Andre Kertesz, Annie Liebovitz, Mary Ellen Mark, Bill Robbins, Melvin Sokolshy, Sebastiao Salgado,**



FOCUS ON AIDS 8: Alistair Thain, "John Hurt, London, 1982", Courtesy of the artist.

Jean-Loup Sieff, Peggy Sirota, Francesco Scavullo, Edward Steichen, William Wegman and Andy Warhol.

The *Focus on AIDS* auction embodies the glamorous and hip side of Southern California, as well as its capacity for caring. Over 5000 entertainment industry leaders and celebrities, artist and photography communities, people-in-the-know, philanthropists, trend-setters and media representatives will flow through the week's worth of events at Barneys New York. These high-profile events are extraordinary opportunities to view some of the hottest photography in the world by some of its most distinguished photographers.

For further information **Focus on AIDS 9**, see our sponsorship opportunities (following on page 6) or contact Vincent Cummings at AIDS ReSearch Alliance, 310/358.2423.



Focus on AIDS 9 *Sponsorship Opportunities and Benefits*

Event Title Sponsor \$25,000

- Title Sponsor listing in all event materials, promotional print pieces, event advertising, press releases and tee shirts • Prominent coverage as Title Sponsor in ARA's Spotlight publication • Title recognition during the event • Title listing on Catalogue cover and 1 full premium page ad in Catalogue • Title host of *Preview Artist/VIP Reception* • 30 Tickets to both *Artist/VIP Reception* and *Auction* • 30 Keith Haring Tee-Shirts

Presenting Sponsor \$10,000

- Presenting Sponsor listing in all event materials, promotional print pieces, event advertising and press releases • Presenting Sponsor recognition during the event • Presenting Sponsor listing and premium full page ad in Catalogue • Presenting Host of *Preview Artist/VIP Reception* • 20 Tickets to both *Artist/VIP Reception* and *Auction* • 20 Keith Haring Tee-Shirts

Producing Sponsor \$5,000

- Producing Sponsor listing in all event materials, promotional print pieces, event advertising and select press releases • Sponsor recognition during the event • Full Page Ad in Catalogue • 14 Tickets to both *Preview Artist/VIP Reception* and *Auction* • 14 Keith Haring Tee-Shirts



FOCUS ON AIDS 6: Annie Liebovitz,
"Greg Louganis", 1991,
Courtesy of the artist.

Event Partners \$2,500

- Partner recognition listing in event materials and promotional pieces, along with Event Partner recognition during the event • Half Page ad in Catalogue • 10 Tickets to both *Preview Artist/VIP Reception* and *Auction* • 10 Keith Haring Tee-Shirts

Event Angels \$1,000

- Mention in Catalogue and during the event • Tribute page listing • 6 Tickets to both *Preview Artist/VIP Reception* and *Auction* • 6 Keith Haring Tee-Shirts

VIP Ticket \$500

- Mention in Catalogue • Tribute page listing • 2 Tickets to both *Preview Artist/VIP Reception* and *Auction* • 2 Keith Haring Tee-Shirts

Individual Event Tickets \$65



FOCUS ON AIDS 6: Phil Borges, "Yama",
1994, Courtesy of the artist.

FOAF9 AUCTION CATALOGUE Advertising Information

Ad Rates

Premier Page* / B&W.....	\$ 1200
Full page / B&W.....	\$ 800
Half page / B&W.....	\$ 500
Quarter page / B&W.....	\$ 300
Tribute page listing.....	\$ 50

* Inside front cover, inside back cover, outside back cover (if available)

Color: For 4-color ads, please add \$1200. For 2-color ads, please add \$350

Clinical Trials 101

A Crash Course in Clinical Trials



ARA's Outreach Coordinator Michelle Simek, using suggestions and feedback from area service organizations and the HIV community, prepared the following information to acquaint prospective trial volunteers with the basics of trial participation and to dispel common misconceptions about clinical studies. Michelle has offered live presentations of this mini-course to such diverse groups as the **Minority AIDS Project**, **Women Alive**, **AIDS Project Los Angeles**, **Common Ground** and the **Foothill AIDS Project**. We present it here for the benefit of new subscribers and other interested readers.

What Is A Clinical Trial?

A clinical trial is a research study in which experimental drugs or treatments are tested in volunteers under the close supervision of a doctor and clinical staff. Clinical trials can be conducted at universities, hospitals and research centers (non-profit, governmental, or private). Clinical trials determine if experimental drugs are safe and effective. All drugs, from penicillin to AZT, go through clinical trials before they are approved by the government and made available to the general public.

What Is An HIV/AIDS Clinical Trial?

An HIV/AIDS clinical trial is a study of new drugs or treatments specifically for HIV infection and AIDS. Some HIV/AIDS clinical trials study medications for specific symptoms or opportunistic infections; other studies focus on decreasing viral load and/or raising T-cell counts.

Why Should I Participate In A Clinical Trial?

People participate in clinical trials for a variety of reasons that may include:

- You may have a disease for which there is no cure or effective treatment.
- Your disease might not respond to current medication options.
- You might join a clinical trial hoping to get improved medical care.
- You can get medical care through participation in a clinical trial even if you are uninsured.

What Is A Study Protocol?

A study protocol is the "map" of how the study will be conducted and describes every step of the study. The protocol lists what the comparison groups will be, what tests will be done, what dosages of the drug are being studied or what drug combinations are being studied.

What Are The Inclusion/Exclusion Criteria?

The Inclusion/Exclusion criteria are certain requirements that you have to meet before you are allowed to join a study. Each clinical trial has a different set of Inclusion/Exclusion criteria.

What Is A Placebo And Why Is It Used?

A *placebo* is essentially a "fake" pill that is a harmless substance given to some study volunteers instead of the actual drug. A placebo is used to compare results with the study drug so that researchers know if the drug actually works. Usually, neither the patients nor the clinical staff know who is receiving a placebo and who is not (This is called a "double-blind" study). Study participants receive the same level of medical attention and care whether they receive the placebo or experimental drug. Frequently, the study patients who receive the placebo are given the opportunity to take the experimental drug if it is shown to be safe.

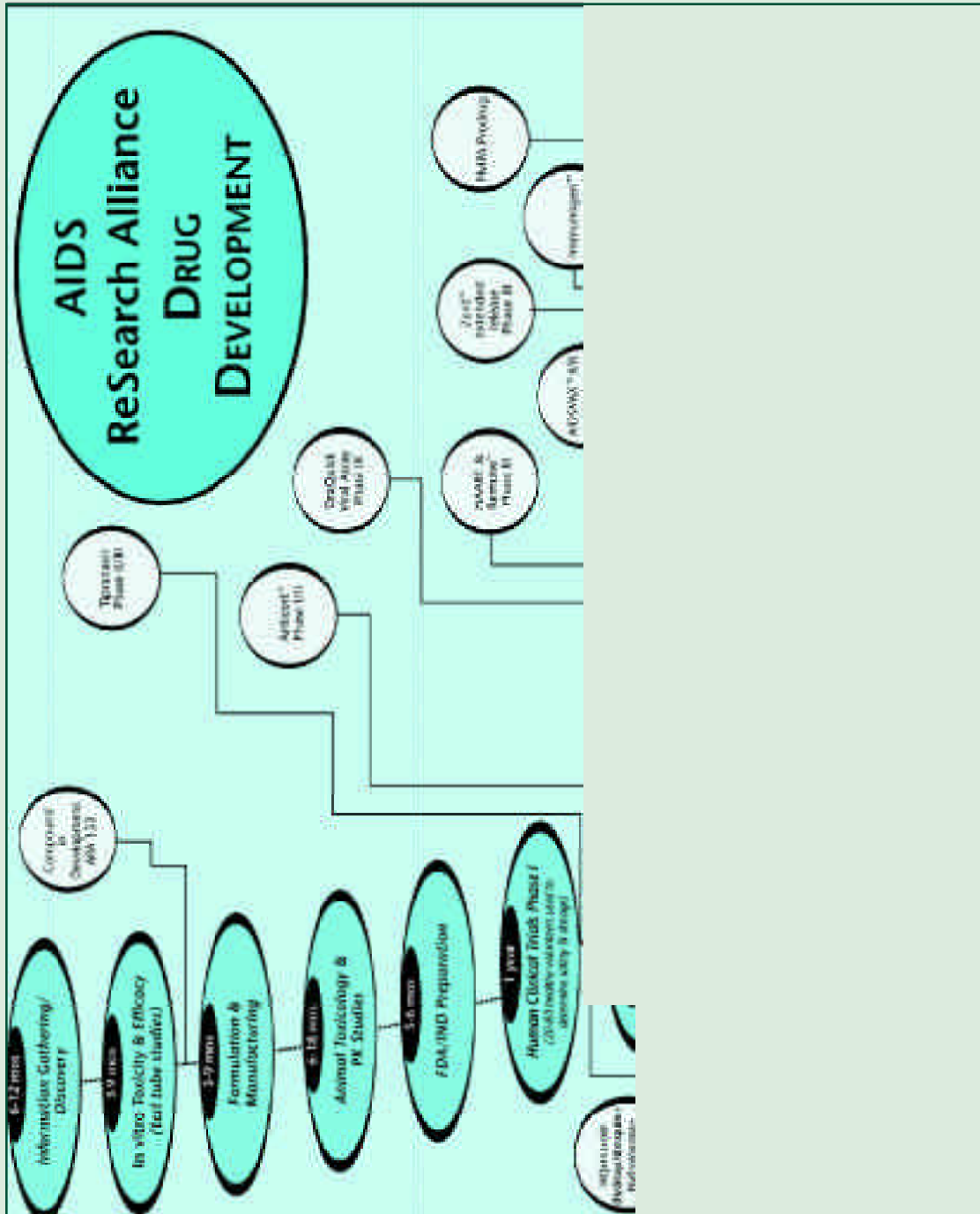
What Is The Informed Consent Form?

The Informed Consent is a document that you are required to sign prior to participating in a study. The Informed Consent explains the study protocol, including possible risks and benefits, what tests will be performed and what you are agreeing to do as a participant. Signing the Informed Consent indicates only that you understand the clinical trial, that all of your questions have been answered and that you have decided to participate. The Informed Consent is *not* a contract—you may leave the study at any time and are not obligated to stay in the study because you signed the consent form.

continued on page 9

medicine cabinet (see article pages 7 & 9). That process can take anywhere from 7 to 15 years.

This time-line chart of our current/recent research will give you an overview of our work, and where we are with each of these promising therapies. Research is all we do. Your dollars fund this important effort to move effective HIV treatments forward swiftly and safely.



Clinical Trials 101

continued from page 7

What Is An Institutional Review Board?

The Institutional Review Board is a panel of outside experts and community members who make sure that the clinical trial is safe and will not hurt or harm its participants. The Institutional Review Board (also known as the “IRB”) has to approve the study protocol before the study may begin.

What Are The Different Phases Of A Study?

Drug studies have many phases before they are approved by the Federal Drug Administration (FDA) and made available to the public.

Pre-clinical research is the first step of a study. The drug is first tested in a test tube to see if it is effective. The drug is then tested on animals.

Phase I Studies test the drug to see if it is safe in humans, and if so, what amount (e.g., milligrams) is safe. These studies are conducted in a small number of patients (usually 10-30) for a short period of time (usually 2-12 weeks). Phase I trials have the most risks for patients because this is the first time that the drug has been tested in humans.

Phase II Studies look at the ongoing safety and effectiveness of the drug and involve a moderate number of patients (50-100).

Phase III Studies are a larger evaluation of the drug’s safety and effectiveness. This usually involves a large number of patients (300-5000). Phase III studies are the final step before the FDA approves the drug. The FDA must approve all drugs before they go on the market and can be prescribed by doctors.

Phase IV Studies take place once the drug has already been approved by the FDA and is allowed to be marketed by the drug company and prescribed by physicians. Usually studies at this level involve looking at long-term side effects of the drug and its use in combination with other drugs.

What Should I Expect When I Participate?

You should expect the following:

- The clinical staff will answer all of your questions and address all of your concerns about the study.
- The study site will protect your confidentiality.
- You may have many appointments at the clinic — and it is important for you to keep all of them!
- You must take the study medication exactly as directed.
- You will need to be honest with the clinical staff and answer all of their questions concerning how you feel and whether you’ve been taking the study medication correctly.
- You will be informed of any changes to the study protocol.
- You are able to leave the study for any reason at any time. **You can not and should not be forced into participating or continuing in a clinical trial.**

What Are The Benefits Of Participating In A Clinical Trial?

- You may receive potentially effective new drugs that are not available to the general public. These drugs are free to you while you are on the study. You may even continue to receive drugs after the study ends.
- You will receive free medical care while on the study.
- If you participate in an HIV/AIDS clinical trial, you may receive free viral load and CD4 tests, along with other lab tests.
- You may receive specialized tests that you and your doctor have no other way of obtaining.
- You will be helping to insure that the study drug is safe and effective in people like you—some drugs act differently in women and people of color.
- You will be contributing to the advancement of medicine by helping to develop new medical therapies.

What Are The Risks Involved In Participating In A Clinical Trial?

- The drug being tested may not work.
- The drug being tested may have unknown side effects or be unsafe.
- You might receive a *placebo* (fake pill or treatment) instead of the drug.
- The required blood draws may be uncomfortable.
- Some drugs require injections that may be uncomfortable.

What Happens After The Study Ends?

Several things might happen when a clinical trial ends. The pharmaceutical company might continue to provide the study medications to those patients that are responding well. Sometimes, a patient will no longer receive the investigational drug and will have to wait for the drug to become available to the general public.

Where Do I Find HIV/AIDS Clinical Trials?

Many AIDS service organizations list enrolling clinical trials in their newsletters. You can also check **The Trials Search Guide: HIV Clinical Trials in California** (published quarterly, 800/492.5777). There are web sites that list clinical trials across the country:

<www.actis.org>
<www.centerwatch.com>
<www.natap.org>



*For more information about HIV/AIDS clinical trials in Southern California, please consult the **Clinical Trials Update** on pages 16 & 17, call us at 310/358.2429 or visit our website at <www.aidsresearch.org>. To schedule a live presentation of this material in English or Spanish, please contact ARA’s Michelle Simek at 310/358.2423.*

Profile

ARA Institutional Review Board

In addition to scientific reviews and approvals that must be achieved prior to the initiation of new research projects, all clinical trials conducted at **AIDS ReSearch Alliance** must also be approved by a human subjects protection committee known as the Institutional Review Board (IRB). The IRB ensures the ethical and equitable treatment of all study participants by carefully reviewing prior to initiation (and on an on-going basis) all research protocols, informed consent documents and advertisements used to promote study participation. We introduce **Danny Ruiz**, one of the most recent additions to our IRB.

Danny has been a Staff Pharmacist at **StatScript Pharmacy** in



PHOTO BY ARMOND BAGASABAN

Danny Ruiz
ARA Institutional Review Board

West Hollywood since January, 1999. He joined our IRB in the summer of 2000.

A member of the **American Pharmaceutical Association**, he has practiced as a pharmacist since he received his degree from the **University of Texas** in 1989.

He moved to California from Texas in 1990 and managed the

Payless Drug Store pharmacy in Manhattan Beach. His next move was to South Carolina, where he served as Staff Pharmacist for **Rite Aid** in Hanrahan from 1992 until 1994. He lived next in Columbus Ohio, working as Staff Pharmacist for **Merck-Medco Rx Services of Ohio**.

Danny returned to California in 1997, working as Pharmacy Manager for **Capitol Drugs** in West Hollywood, and receiving numerous employee awards for outstanding performance. He joined StatScript in 1999.

According to Danny, "I work closely with the HIV/AIDS community every day, and I see what patients can go through in dealing with treatment side effects. On the IRB, I have the patient's best interests at heart, and I'm here to see that the experiment goes well, with participants deriving the most benefit possible."

Transitions

ARA Bids Good-bye & Thanks to Outgoing Board Members Tim Engel and Lou Sawaya



PHOTO BY JILL MARR

Tim Engel receives ARA's 1997 Paul Rothman Founder's Award for Distinguished Achievement.

We're sad to announce the departure from the Board of Directors of two long-time HIV/AIDS activists and AIDS ReSearch Alliance supporters.

Tim Engel, Senior Vice-President of Feature Animation at **Walt Disney Studios**, joined our

Board in 1994, serving as its Treasurer until 1995, as Board Chair until 1997, and Board Secretary until 1999.

He was tireless in his efforts on our behalf, and, as a person living with HIV, brought a deep personal commitment, as well as considerable organizational and financial skills, to the Board.

Lou Sawaya's involvement in HIV/AIDS activism dates back to the early 80's when his partner, the late **Nancy Cole Sawaya**, helped found **AIDS Project Los Angeles**. Lou joined our Board in 1999.

While they're no longer on the Board, both Tim and Lou continue

to serve ARA and support AIDS research in any way they can. The Board and staff are grateful that they shared their time, boundless energy and personal and professional skills with us. We wish them well in their future endeavors.



Making it all possible ARA Volunteers

PAUL KAPLAN Volunteer/Development

Paul was diagnosed with AIDS in 1996; after seeking treatment, he was stabilized on medications and has stayed relatively healthy since. He suffers from neuropathy, but is able to live a full and active life despite this disability.

Paul lost his brother Herb to AIDS in 1998, and this loss, as well as his own HIV status, sparked Paul to look for a way to help out with the HIV/AIDS crisis. His friend **Richard Bloch**, an ARA volunteer since 1993, suggested that Paul join him and work with us.

He joined our volunteer staff in March, 1999 and has proven to be a vital force at ARA. Initially helping with administrative tasks, Paul now plays an active role in corporate solicitation and assisting Director of Development **Vincent Cummings**. Just recently, Paul joined the **Focus on AIDS Executive**



PHOTO BY ARMOND BUGALSKIAN

Paul Kaplan
ARA Volunteer
Development Assistant

Committee, which is overseeing the upcoming **Focus on AIDS Photographic Auction** (see article page 1).

Paul brings a wealth of entertainment and retail knowledge to his development work through his experience as a writer's agent for the **William Morris Agency** in New York City, and later as Home Fashion Director for **Bullock's Department Stores** here in Los Angeles. These positions introduced him to fashion and industry leaders with whom he has maintained relationships.

"I love working here," says Paul, "and ARA's mission is of the utmost importance. Out of the 17 anti-HIV medications the FDA has approved, ARA has worked on 14. I hope that any of my friends reading this article will use the donor envelope included in the magazine to send in a donation. With your interest and financial help we can do even bigger and better things. I'm very anxious to find a cure."



PHOTO BY WALTER MIAJONA

Michael Ashby
ARA Trial Participant
Viracept® study

MICHAEL ASHBY Volunteer/Trial Participant

When Michael tested positive in 1991, he was devastated and wondered how long he had to live. His only knowledge of HIV/AIDS was through watching a friend in the early 80s waste and die. After he was diagnosed, his long-term partner, also in-

fectured, became critically ill, and Michael made the decision to nurse him at home. After caring for him until his death, Michael, who had put his own health care on hold, decided to visit his partner's doctor.

His doctor was **Wilbert Jordan, M.D.**, (at the time, a member of ARA's Board of Directors and currently on our Medical Executive Committee). Michael's viral load was quite high and Dr. Jordan referred him to ARA for the then-experimental Viracept® (nelfinavir) in a "cocktail", which was proving to be a most effective method of treating HIV/AIDS.

Michael joined ARA's Viracept® study when it opened

in February, 1996 and remained in the study until it closed recently at the end of 2000. Michael's health improved significantly and he has been able to maintain his health and quality of life since that time. Viracept® was shown to be one of the most effective and tolerated protease inhibitors developed to date.

Michael was a most responsive & helpful participant, always upbeat, never missing an appointment and responsible in taking his medications. Study volunteers like Michael make it possible for ARA to continue running trials to increase the HIV/AIDS medication arsenal.

Michael says, "The improved health I've experienced need not be exclusively mine. The first step is to get tested. Once you know, you have an array of choices. You have to get past the insecurities and stereotypes associated with disease and new medications. You have to love yourself enough to take control of your life's situations."

Our deep thanks go to Michael for his long-term assistance with our study and for his always cheerful cooperation.

SPOTLIGHT DONORS

THANK YOU THANK YOU

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 out 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 12/00 to 6/01; Circle of Hope Donor List is for entire year.)

CIRCLE OF HOPE

FOUNDER'S CIRCLE (\$25,000 and above)

MacDonald Family Foundation

CHAIRMAN'S CIRCLE (\$10,000-\$24,999)

Ruth Ganz
Richard Gere/The Gere Foundation
Estate of Matthew Rushton

PRESIDENT'S CIRCLE (\$5,000-\$9,999)

Cecile & Fred Bartman Foundation
Daniel H. Renberg
Grace Jones Richardson Trust
RockCares Foundation
The Walt Disney Company
Charles R. Williams

DIRECTOR'S CIRCLE (\$2,500-\$4,999)

Tim Corrigan

Leland Johnson
Jane Langley
Jean Senuta Peppard
Diann & David Sant
Marie A. Tallmadge

FRIEND'S CIRCLE (\$1,000-\$2,499)

Anonymous
Irl S. Barefield
Mary C. & Brian M. Beitner
John Bishop & Jill Goodson Bishop/
Jill Goodson Family Foundation
The Challenge Fund
The Christian Service Charities, Inc.
Philip Citron Charitable
Foundation Trust
John W. Gilbert/Gilbert Heritage
Foundation
Bonnie & David Gould
Eliot P. Graham
Starr Harwin Bleimeister & Rand
Bleimeister
Richard W. Haskamp
John & Rose Herman Support
Foundation
Lenore & Fred Kayne
John Lee Fund
Kristine & Frank Lazaro
Lee R. Lyon
Macy's West, Inc.
Forrest E., Deborah C. Mars &
Edith Long Mars, Jr.
Marianna Clemson McAfee
David McK. Smith
Bradley W. Segal

CALIFORNIA SHOPPERS/MACY'S DISCOUNT COUPONS

MACY'S
PASSPORT 01
IN STORE

More Fashion.
More Compassion.

Save on shopping and help save lives.

AIDS ReSearch Alliance will once again participate in **Macy's Passport In-Store**, a day-long shopping event designed to raise money for local HIV/AIDS organizations. **Passport In-store 2001** will be held on Saturday, September 22, 2001 at the Macy's Department Store in the Los Angeles Beverly Center and the Costa Mesa South Coast Plaza. The day's activities will include product demonstrations and other events sponsored by **Mega 92.3 Radio, Men's Health, Odwalla**, and **Peet's Coffee**, among others.

Tickets for the event are \$10 each and all funds raised from tickets purchased from ARA will go directly to our organization to fund our research. Macy's will also donate an additional \$3 per ticket for ticket redeemed in-store on the day of the event. The ticket entitles the holder to discounts on almost all purchases, including items already on sale. You can even shop at participating stores during the two weeks prior to the event, have items put on hold, and be charged for your purchases on the day of the event. **Virgin Megastore** on Sunset Boulevard is also participating in the event, offering 10% off all purchases on the day of the event.

For more information on Macy's Passport In-store and to buy tickets, please call Antonio Pisig at 310/360-3871 or e-mail him at antonio@aidresearch.org.

DONORS

Donors \$500-\$999

A & I Photography Laboratories
Michael Becker
Richard Bloch
Imogene & Dan Carter
Laura & Michael Corrigan
Vincent Cummings
Randall Drain

THANK YOU THANK YOU THANK YOU THANK YOU

The Faultline/Nick Golden, Mngr.
 Claudine Gerson
 Connie & Robert Gordon
 Linda S. & Robert Graven
 Sandra & Alvin R. Haveson
 Alan Heppel
 Mark Allen Itkin
 Eugene Kapaloski
 Paul Kaplan
 Steve Kasloff
 Patrick L. Kastein
 Harvey Kauffman
 Bernard Markowitz, M.D.
 John McDonald & Rob Wright/
 McDonald Wright Foundation
 David McGavran
 Susan T. & Cory Nakashima
 Dean Pitchford
 Lillian & Arnold Rubin
 John R. Sealy, M.D.
 Susan Smith

Donors**\$100-\$499**

Ellen & Lewis Anten
 Mildred J. Atkinson
 Jackie Banchik
 Vicki Baral & Gerry Hariton
 Jason M. Barrett
 Lewis Baskerville
 John Beezley
 Bunni Jadd Benaron & Richard
 Benaron
 Jennifer & Michael Bergquist
 John D. Berl
 Karen & Charles Berteau
 John C. Bonkoske
 Lloyd A. Bookman
 David C. Bright, O.D.
 Kenneth L. Burgess
 Michael J. Buster
 Nancy Carnon
 Douglas A. Chadwick, Jr.
 Hilton Chodorow
 Carl Stewart Chronister
 Lawrence Chrysler
 Diane Connors
 Cornelia R. & John H. Corrigan
 Robert Crewe
 Charles Cruz
 Jack R. Culley
 Cunningham, Escott, Dipene &
 Assocs., Inc.
 Philip D. Dagort
 Charles E. Davis
 Robert Deschene
 Sunny Deutschman/Deutschman
 Family Trust

Mary J. Dicks
 Betty & John Dratz
 Tim Engel
 Kevin Erskine
 Marcia & Robert Finkel
 Bonni & Murray Fischer
 Sam Forney
 Martin Gage
 David H. Gardner
 Laurence D. Getzoff
 Dwila & Jack Gilbert
 Beverly & Barry Gold
 Bert Goldberg
 Robert C. Gould
 Randi & Warren Grant
 John C. Graves
 Ricky Tovim Gross & Byron Gross
 Mark Gundacker
 Bryan W. Harper, Jr.
 Jane & David Harris
 Marcia & David Harrow
 Jay Hartz
 Ellen Hein
 John R. Hellow
 David P. Henniger
 Leonard Hill
 Patric Hooper
 Jack E. Howard
 Linda G. & Roger H. Howard
 Robert Hurowitz
 Jeff Iorillo
 Mark Katz, M.D.
 Keith G. Kauhanen & James Petrone
 Cynthia C. Kazarian
 Edward J. Kennedy
 Maryellen Kirchen
 Robert N. Kohman

Linda Kollar
 Edward La Fuente
 Lillian & Erwin Lehmann/
 Lehmann Family Trust
 Elaine & Jay Levy
 Bernard Lewis
 Edward F. Limato
 Barry H. Lippman
 Richard T. Lira & M. Gretchen Taylor
 Nancy & Walter Lob
 Brian Lucky
 Robert W. Lundy
 Michael Margules
 Patricia J. Marvin
 Marilyn Lovell Matz & Peter Matz
 Robert M. Mazza & Michael
 Palmieri/Mazza Palmieri Prods.
 Meid & Macfarlane Foundation
 Angela A. Mickelson
 Lawrence A. Mirisch
 Mildred Naatz & Richard Habic
 Elly & Jack Nadel/Elly & Jack
 Nadel Foundation
 Troy Nankin
 Kurt J. Nelson
 Guy Nemiro
 Mary E. Nichols
 Sarah Jessica Parker
 Brian Pendleton
 Arthur Porter
 Gregory A. Pospisil
 Thomas C. Puckett
 Rich Ratkelis
 Mark E. Reagan

IN-KIND THANKS

Two Donors Helping Us Get It All Taped

ARA would like to thank the following donors whose in-kind contributions of materials and services were invaluable:

Ray Haugland of Post Logic, for editing and donating multiple copies of ARA publicity videotapes for distribution at events associated with the 20th anniversary of HIV/AIDS.

Fred Bercovitz of Video 10 Distributors, for donating 14 videotapes as raffle prizes for ARA's use at monthly "Proof Positive" fundraisers held the third Wednesday of each month at the **Faultline** bar in Silverlake.

SPOTLIGHT DONORS

THANK YOU THANK YOU

Matt Redman
Gina Reese
Kevin P. Reilly
Pamela & Paul Riley
Jeffrey S. Robin
Lynn & Lana Ruch
Bruce & Dessi Schachne
Cyrille Schiff
Chris Schoeneman
William C. Selover
James J. Shopp
Louise H. & Charles D. Silverberg
William E. Simon Foundation
Carolyn Skorneck
Peter John Sotiriou
Frederick Specktor
Tony Sproule
Joel Stahl
Alan Strasburg
Todd Swanson
Marjorie & Arthur Talbot
Christopher Teasley
Michael F. Thibert
Jeffrey Thomas
Darren J. Thomas
W. Bradley Tully
Kim Warner Valencia & Robert
Valencia
William Vaughn
Vance Walker
Karen & Edward Weil
William E. Weinberger
Dennis E. White & Joan R. Onffroy
Margaret & Patric Wilson
David Winckoski

Donors

\$100 or under

Barbara S. & John R. Abbott
Howard J. Amsterdam
Spencer & Helen Andrews
Anonymous
Martin Ansell
Helen & Bernardino Arellano
Mark Arnold
Ann & Robert Avery
David Bales
John R. Barnaby
Craig Barnhart
Richard A. Bell
John Bowab
Gary Bruneel
Kenneth Bullock
Patrick L. Cain

W. Scott Campbell
Christopher Casey Charles
Jean Chubb
Mary Corrigan/for Corrigan
Family Trust
Kenny Cortland
Steve Darmis
David E. Dassey
Don Diers
Fern & Mike Dorman
Brad Dunning
Elisa Estremera
Charlotte Evans/Evans Family
Trust
Bob Fabian
Manuel Flores-Esteves
Sam Flowers
J. Denise Fuller
Timothy Gales
Thomas Gass, DDS
Cassandra Gauer
Dr. William George
Kenneth M. Gildin
Paul J. Glackman
Mr. & Mrs. Robert Glasspiegel
Roger Goode & Kenny Siegel
Stuart E. Goodnick &
Robert A. Schmidt
Jesse Gulbro
Dave L. Hanson
Spencer Rathus/Harcourt, Inc.
Jennifer Harrigan
Georgia & John Hayashi
Marcus Hernandez
Hirsch Electric, Inc.
David Holsapple
Joseph Isam
Carl J. Johnson
Mary & John Kazmer
Patricia R. Kellogg
Sabrina Kogel
Andrew Kraus
Gloria Kriegler/The Kriegler
Family Trust
Michael Krumme
Alice F. Kuhns
Peter Laura, Esq.
Ken Lautsch
Glen Lawrence & Stephen Thomas
Mark E. Lehman, Esq.
Harlan Levinson
James Loughlin
Martha Maas
Hiwot Haddis Mariam
Mary E. Marvin & Paul Gronseth
Natalie Masliyah
Cynthia L. & Ronald Mason
Hank McCann

Robert Megredy
Debra & Gregory Mertes
Christopher C. Miller
Brian J. Miller
Bruce Mink
Elaine T. Mirsky
Dixie Moore
Jack Moshein, M.D.
Charles Neal & Scott Sites
Randall M. Nerwick
Michael Orloff
Steven R. Paxton
Frank J. Pfizenmayer
Charles Pleshek
Rebecca Poole
C. Allen Posten
Margaret Y. Purves
Myron Dean Quon
Kathleen & Richard Rice
Robert N. Rigdon
Alberto Riveron
Joan Robb
Pedro Romanach
Brian Roskam & Mike Werb
Richard Ross
Martin D. Royer
Judith & Joseph Rubin
Dennis Safren
David J. Shapiro, Esq.
Michael S. Shaw
Peter Shepherd
Michelle Simek
James W. Simey, Jr.
Frank Smedley
Joshua Sparks
Andrew Stancliffe
Sue L. Steinberg/Sue L. Steinberg
Revocable Trust
Elizabeth & Herbert Sussman
Thomas Terlecki
Catherine & Jonathan Tuerk
Mario Valdez
Michele Vertucci
Betty Victor
Heinrich Videnieks
Margarita Visvydas
Susan & Mitchel Wainer
Elise Warner & Robert Bernard
Stephen Wenker
Keith White
Marshall Wong
Mark T. Wood
Frank Young & John Guagenti
Edward G. Zeigler



GRANTS

MacDonald Family Foundation

We received a \$50,000 grant from the **MacDonald Family Foundation** in support of ARA's prostratin project (*see article on cover and pages 18-20*). We offer our heartfelt thanks to the Foundation's Trustees and to **Robert Winters, M.D.**, Chair of ARA's Medical Executive Committee for making this much-needed donation possible.

Ruth Ganz

Ruth Ganz made a significant donation to AIDS ReSearch Alliance for research in the form of a DST Systems stock transfer. Our deep appreciation goes to Ms. Ganz for this extremely generous gift.

Cecile and Fred Bartman

The Cecile and Fred Bartman Family Foundation recently donated \$7,500 to ARA in support of our work. Our profound thanks go to **Mr. and Mrs. Bartman** for their contribution, as well as to Board of Director members **Nancy and Sandy Bresler** for facilitating this gift.

RockCares Foundation

Our appreciation goes to **The RockCares Foundation** for their kind \$5,000 gift in support of our medical research. We would like to thank Mr. Richard J. Rocaberte of RockCares, as well as **Arnold Kassoy, Esq.**, member of ARA's Board of Directors, for introducing our work to the foundation.



THANK YOU TO CFC DONORS

A Member Organization of

**Giving every paycheck—
Combined Federal Campaign Donors**

Postal workers in Des Moines. Marines stationed in Kosovo. Forest Rangers in Yosemite. Nurses in Tucson. Chemists in Atlanta. Judges in Washington D.C. Diplomats abroad. Teachers in Fort Lauderdale. Engineers in Alaska. They're Soldiers, Veterinarians,

Architects, Mathematicians, Calvary Scouts, Engineers, Cartographers, Researchers, Firefighters, Clergy. Living on aircraft carriers, in embassies throughout the world, national parks, or next door, the women and men who work for the U.S. Federal Government—as well as State and local governments—have donated hundreds of thousands of dollars to find a cure for AIDS.

The **Combined Federal Campaign (CFC)** is the annual fund-raising drive conducted by Federal employees in their workplace each fall. And each fall, Federal employees and military personnel designate a portion of their hard-earned paychecks to come each month to AIDS ReSearch Alliance. Similar campaigns are run by individual States and local municipalities for their employees. ARA participates in these campaigns, as well as in workplace giving programs in private corporations, through a federation of researcher charities located throughout the U.S.—**Medical Research Agencies of America (MRAA)**.

The generous employees who donate through their workplace account for 30% of our private dollars. Their gifts make a huge difference in the fight against HIV/AIDS. We want to extend a very special thanks to the Federal, State and local government employees who continuously prove to be some of the most generous people in the world. Our mission to find more effective treatments against HIV/AIDS depends on you!

They—like all of our donors—are bringing hope to all living with HIV/AIDS in their neighborhoods, across the country and around the globe.

If you work for a local, State or Federal government, look for AIDS ReSearch Alliance in our MRAA federation—CFC ID#1704.



BEQUESTS

The Estate of Matthew Rushton

We received an additional \$13,0555.27 in funds from the **Estate of Matthew Rushton**, one of AIDS ReSearch Alliance's founders and former Chairman of the Board of Directors. This brings the total amount received from this continuing bequest to over \$236,300 in service of the work Matthew began in 1989.

Matthew was the Executive Producer of the blockbuster movie *Mrs. Doubtfire*, and passed away from complications arising from AIDS in 1995. Our appreciation goes to **William Zimmerman**, trustee of Mr. Rushton's estate and former ARA Board member, for facilitating these disbursements. We also extend our continuing thanks and best wishes to Matthew's parents, **Marjorie and Arthur Talbot**, for their ongoing support of our work.

STUDY	DESCRIPTION	STATUS
Pre-clinical & basic research AIDS ReSEARCH ALLIANCE	ARA pursues an extensive pre-clinical research agenda not reflected in this chart. 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. <i>(Various)</i>	Ongoing
Serostim® SERONO LABORATORIES	A study testing the safety and effectiveness of a growth hormone in treating HIV-associated lipodystrophy. <i>(Fat redistribution therapy)</i>	Currently enrolling
Hepatitis C Assay ORASURE TECHNOLOGIES, INC.	A study testing the effectiveness of Orasure's new oral Hepatitis test using both HIV+ and HIV- volunteers known to be infected with Hepatitis C. If approved, this test would be able to determine when someone is infected with Hepatitis with an oral test. <i>(Hepatitis C testing)</i>	Currently enrolling
APV30002 GLAXOSMITHKLINE	A study testing the safety and antiviral efficacy of an experimental formulation of Agenerase® combined with other background antiretroviral drugs in HIV-1 infected volunteers. <i>(Antiviral therapy)</i>	Currently enrolling
Tipranavir™ PHARMACIA & UPJOHN	A study comparing combination therapy (tipranavir and ritonavir vs. saquinavir and ritonavir) used with two nucleoside reverse transcriptase inhibitors in single protease inhibitor-experienced HIV-1 volunteers. <i>(Antiviral therapy)</i>	Currently enrolling
Remune™ AGOURON PHARMACEUTICALS	A study to compare the virologic and immunologic effect of Highly Active Antiretroviral Therapy (HAART) plus REMUNE™ versus HAART plus Incomplete Freund's Adjuvant (IFA) on antiretroviral-naïve volunteers infected with HIV-1. <i>(Antiviral & immunologic therapy)</i>	Currently enrolling

STUDY	DESCRIPTION	STATUS
Hydroxychloroquine (in combination with hydroxyurea and didanosine) AIDS ReSEARCH ALLIANCE	A study of the safety and antiviral efficacy of hydroxychloroquine in combination with hydroxyurea and Videx® (ddl or didanosine) in HIV-1 infected volunteers. <i>(Antiviral therapy)</i>	Currently enrolling
Zerit® (Stavudine, d4T) BRISTOL-MYERS SQUIBB	A study to evaluate and compare the safety and efficacy of extended-release stavudine compared with standard stavudine for antiviral activity. <i>(Antiviral drug/improved dosing)</i>	Enrollment complete, study ongoing
Anticort™ STEROIDOGENESIS INHIBITORS, INC.	A pharmacokinetic and safety study of Anticort™ (an oral procaine formulation) in HIV-infected volunteers. <i>(Anti-inflammatory drug)</i>	Enrollment complete, study ongoing
PMPA Prodrug GILEAD SCIENCES, INC.	A study of the safety and antiviral activity of the addition of PMPA Prodrug to combination antiretroviral regimens in treatment-experienced HIV-infected volunteers. <i>(Antiviral therapy)</i>	Enrollment complete, study ongoing
AIDSVAX™ B/B VAXGEN, INC.	A trial to evaluate the efficacy of the AIDSVAX™ B/B vaccine in adults at risk of sexually transmitted HIV-1 infection. <i>(Preventative HIV vaccine)</i>	Enrollment complete, study ongoing

For information about enrolling in any of our studies, contact **Corie Castro** at **310/358.2429**. Transportation to our clinical research facility is available on request. For priority notification of new/enrolling clinical trials, sign up for our **Priority Notification Program**. Para información en español, llame 310/360.3876.

Prostratin

cover story continued

It's now believed that HIV can persist for decades within long-lived blood cells. The virus is dormant within these cells, so the cells appear "normal" and escape the reach of anti-HIV drugs. These "reservoirs" of HIV hide throughout the body, including the brain, lymphoid tissue, bone marrow, and genital tract. Even in HAART patients with "undetectable" viral levels in their blood, these reservoirs last for prolonged—possibly indefinite—periods of time. When someone stops taking HAART, the sleeping virus springs into action and floods their bodies with millions of new copies within hours.

The viral reservoirs are considered to be the major stumbling block to eradication of HIV from infected individuals—in other words, a necessary step if we are ever to "cure" AIDS.

The reservoir problem has not yet been solved.

There is currently no way to clear the body of HIV. People infected with HIV have treatments that slow down the production of new virus, but with reservoirs of virus always present in their bodies, no amount of drugs currently available can cure HIV. So there is intense interest in the nature of viral reservoirs, how they are established, and why they persist, as well as in strategies aimed at their containment or elimination.

There is also an on-going debate among scientists and activists about the feasibility of pursuing the goal of viral eradication. Others have certainly argued that eradication should not be the focus of AIDS research. However, AIDS ReSearch Alliance believes that the goal of long-term containment of the virus can not be abandoned and remains committed to searching for all ways to attack HIV and its hidden reservoirs.

By activating the production of HIV within dormant infected cells that form the reservoirs, it's believed that the cells could then be recognized by anti-HIV drugs and eliminated. Other researchers have tried to attack HIV reservoirs. The methods that seemed most promising were an attempt using interleukin-2, and another that used IL-2 along with anti CD₃ antibodies. Despite promising early results, the virus rebounded in patients once treatment was stopped.

ARA applied for the exclusive license from the U.S. Federal Government to develop prostratin.

Can prostratin be used against the reservoir?

On a research trip to Western Samoa, a scientist from *Brigham Young University* came across healers who were using a small native tree known as the *mamala* to treat a disease they called *fiva samasama*—yellowing fever, or hepatitis—made from its stem.

The bark was being used to treat viral infections, the leaves were used to treat back pain and the root to alleviate diarrhea.

Samples of these native remedies were sent to scientists at the U.S. National Cancer Institute (NCI), where plant-derived substances are routinely screened against different diseases. Dr. Michael Boyd and his colleagues at NCI isolated the active chemical from the remedy—prostratin—and discovered its powerful effects against HIV. Prostratin both inhibits *and* stimulates HIV production in infected cultures, depending on the dose, which suggested that prostratin could be used to activate viral reservoirs.

Prostratin acts like an entry inhibitor—which is exciting because it attacks the virus at a different stage than the other three classes of FDA-approved anti-HIV drugs.

AIDS ReSearch Alliance investigates prostratin's potential.

Based on encouraging preliminary data, ARA applied for the exclusive license from the U.S. Federal Government to develop prostratin. Based on our drug research expertise, our leadership position in the community and our proven reputation for facilitating between many different groups of researchers and scientists, the license was granted this spring.

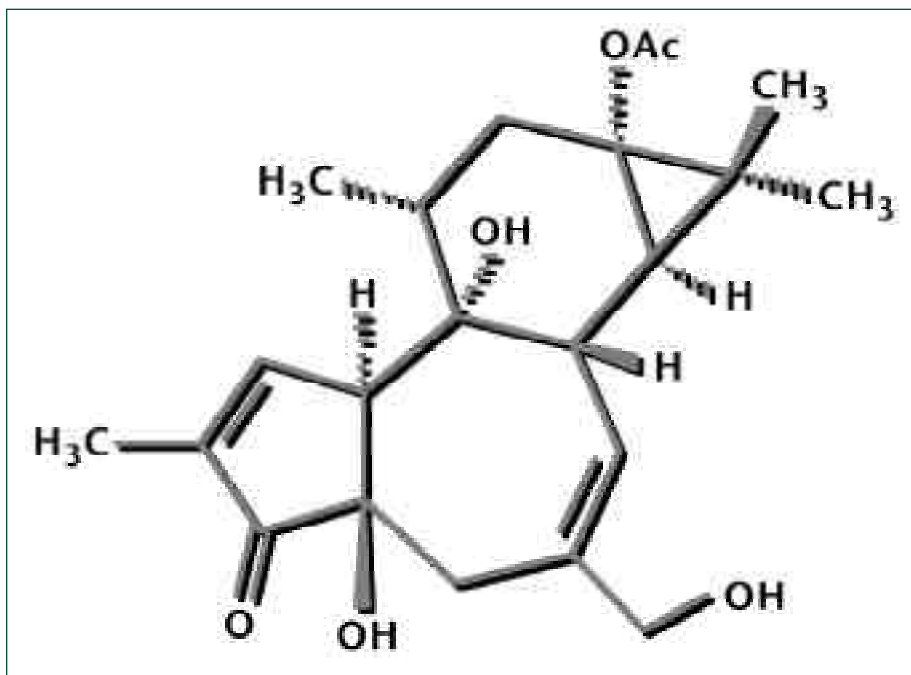
Since then, ARA has initiated a number of top research collaborations to determine if prostratin might work in people, including studies with Dr. Jerome A. Zack (UCLA Center for AIDS Research), Dr. Eric de Clercq (Rega Institute in Belgium) Dr. Ivan Hirsch (The French National Institute of Health and Medical Research), and Dr Jose Alcamí (Spanish Institute of Health).

Already, we have convincingly shown in test-tube studies that

...we've learned that prostratin can activate the dormant virus...

prostratin, when present at the time of introduction of HIV, prevents the virus from infecting cells. Prostratin acts like an entry inhibitor—which is exciting because it attacks the virus at a different stage than the other three classes of FDA-approved anti-HIV drugs.

Our next round of studies should provide important data to help us determine if prostratin should and can safely proceed to human clinical trials as a way of eliminating the reservoir of latent HIV in infected individuals.



Prostratin: one of the most potent anti-tumor promoters

It also appears to work on a cellular target rather than a viral target. If confirmed in ongoing experiments, this will be important and may mean that it's more difficult for HIV to mutate around a cellular target and gain resistance.

More importantly, we've learned that prostratin can activate dormant virus from a number of different types of cells where HIV reservoirs lurks in the human body. Continuing studies with Dr. Zack will look at the specific ways that prostratin activates HIV within these reservoirs.

The uniformly exciting findings from these studies are moving ARA closer to determine if prostratin's unique properties in cell cultures can be used to treat HIV in humans.

Moving prostratin forward

There is a lot of work still needed

We can't reasonably expect that HIV+ people can take these drugs for a lifetime, and yet the lifelong persistence of HIV reservoirs appears to make this necessary.

before prostratin can be tested in humans. We've formulated an aggressive scientific plan to move prostratin forward to clinical trials. Our next round of studies should provide important data to help us determine if prostratin should and can safely proceed to human clinical trials

continued on next page

Prostratin

cover story continued

as a way of eliminating the reservoir of latent HIV in infected individuals. ARA and UCLA will further study the effects of prostratin on various T-cell populations in animals to create a better picture of prostratin's antiviral properties. Several additional potential reservoirs of latent virus have been discovered, and ARA will look at them to study their importance.

This fall, ARA will meet with FDA officials to determine the required studies necessary for a Phase I study (including additional toxicology studies). A test must be developed to measure plasma levels of prostratin, and finally, if all goes well, limited Phase I trials will begin, possibly involving testing of HIV tissue levels in gut-associated lymphoid tissue in collaboration with Dr. Peter Anton of UCLA (also a member of ARA's Medical Executive Committee).

The bottom line

There's no cure for HIV infection. Current treatments slow the HIV virus, but are too costly and toxic, won't work indefinitely, and don't completely eradicate HIV from infected people. We can't reasonably expect that HIV+ people can take these drugs for a lifetime, and yet the lifelong persistence of HIV reservoirs appears to make this necessary.

The search for a cure for HIV infection must go beyond treatments that merely slow the virus down. Targeting HIV where it hides is crucial to improving the lives of HIV+ people everywhere and possibly ending this pandemic. We hope that prostratin may be a key tool in the arsenal against HIV and its hiding places, and we're funneling critical resources into moving the compound as swiftly and safely forward as possible. ***But we can't do this without your support.***

Moving promising drugs forward from "test-tube" studies to human clinical trials requires hundreds of thousands of dollars. Your continued generosity helps fund important and very exciting research like prostratin, and helps pave the way for the total elimination of HIV from the human body. With your help, we are making a difference.

For more information on our current prostratin fundraising, please see the box at left.

PROSTRATIN FUNDING

Key funders step to the front of exciting transitional work on prostratin

Viral eradication won't occur without strategies to target the places that HIV hides—and we have great hopes that prostratin may be a major step on the path to eradication.

Our enthusiasm about prostratin's treatment potential and our encouraging findings have been recognized by some of our long-term donors and attracted new funders as well. The funding needs for the first year of prostratin research are estimated to be at \$400,000.

We have received significant lead grants from **The Gere Foundation, The McDonald Family Foundation** and two **anonymous gifts** totalling \$172,000 to help us move ahead with this promising compound. The support of all our donors sends an important message that an outright cure must remain a primary goal of HIV research.

Many thanks.



Marching

Vaccine study participants celebrate Pride

AIDS ReSearch Alliance's participants in the **AIDSVAX™ B/B** clinical trial joined staff members on June 17th to march in the **Christopher Street West** annual Gay Pride Parade.

ARA enrolled its first volunteer in this first-ever vaccine clinical trial in August, 1998, and it has been ongoing since that time. Study analysis of the trial's results is expected in June of 2002. (Media interest in the trial continues to be strong, with the **Jim Lehrer News Hour** covering it in a recent television story.)

Organized by **Michelle Simek**, ARA's Outreach Coordinator, these marchers represent the first ARA contingent in the Los Angeles Gay Pride Parade since 1992. Volunteers from the study were proud and excited to participate; for some, this was their first experience marching in Christopher Street West. Our participation in the event served to raise



PHOTO BY KAREN J. WELLENKAMP

CSW/VaxGen MARCHERS (from left to right): **Michelle Simek/ARA**, **Gregory Hamman**, **Ramon Capiral**, **Brian Reidlinger**, **R.A. Kerr**, **Adam Martinez**, **William Webster**, **Bob Reyes**, **Roland Lopez**. Not pictured: **Irl Barefield/ARA**, **Claude Bergeron**, **Robert Nash**, **Karen J. Wellenkamp/ARA**.

awareness of this historic vaccine study. Marchers wore T-shirts and tank tops provided by VaxGen, sponsors of the **AIDSVAX™ B/B** trial.

Our grateful thanks go to all who marched with us, and to those that helped out at our information booth at the CSW Festival. Special thanks to **Adam Martinez**, who provided his beautiful red Mustang for our use in the march.



Logo for West Hollywood's club "Rage", host to ARA's vaccine study participant thank-you party in April.

AIDS ReSearch Alliance held a thank-party for our participants in the VaxGen-sponsored **AIDSVAX™ B/B** clinical trial on April 29th at **Rage**, a popular West Hollywood club on Santa Monica Boulevard. Rage's manager **Michel LeChasseur** donated their VIP room for the event and the use of all lighting and sound equipment. **VaxGen, Inc.** assisted AIDS ReSearch Alliance and "party planner" **Michelle Simek** in event coordination by partially underwriting party expenses.

Over 100 vaccine study volunteers and ARA staff members attended the party, dancing and enjoying the delicious hot and cold hors d'oeuvres pro-

Party

ARA celebrates vaccine study participants

vided by **Rage**, who also catered the party. Party-goers happily participated in a raffle and took home T-shirts and tank tops provided by VaxGen.

Our deep appreciation goes to all of the participants in the vaccine study, which has been ongoing since 1998 (*see above*). Our grateful thanks also to the generous donors of the exciting raffle prizes: **William Karpiak/Ramada Inn** for a 2-night hotel stay; **Paul Rogers/The Face Place** for a relaxing facial; **Debbie King/Starbucks** for coffee gift bags; **Kelly Sumners/Wolfgang Puck Café** for dining gift certificates; **Bob Laemmle/Laemmle Theatres** for movie passes; and **E. Wiley Bartine III/Bloomingdale's** for store gift certificates. Finally, our thanks go to ARA volunteer **Paul Kaplan** for helping us secure these gifts, and to vaccine trial participant and local DJ **Bryan Baptiste** for facilitating Rage's generous donation.

Director of Scientific Communications joins ARA staff

Marjan started her tenure recently at AIDS ReSearch Alliance by attending, with ARA's Director of Clinical Research Dr. Stephen J. Brown, the March *Keystone Symposia of AIDS Pathogenesis* in Colorado. (Her report on upcoming vaccine developments will be published in the Fall issue of *Searchlight*.) Her job duties as ARA's Director of Scientific Communications include assisting in the development and design of clinical trials and serving as *Searchlight's* new editor.

Marjan brings a strong scientific background to ARA and contributes her expertise in basic science, biology and chemistry to our pre-clinical and clinical research development. She explains "I have a deep interest in the field of epidemiology and infectious disease. More specifically, I am interested in studying the emergence of new pathogens such as HIV, and how to minimize their impact on public health and safety. I firmly believe that AIDS ReSearch Alliance's mission to accelerate the development of effective treatments for HIV will make a considerable impact on all aspects of public health related to HIV."

She grew up in Tehran, Iran, moving to Switzerland with her family at age 17. She earned her Bachelor of Science, Biochemistry and Chemistry at the Swiss **University of Neuchâtel** and continued her studies with scientist **Dr. Werner Schlegel**, a specialist in intracellular signalings and endocrinology, at the **University of Geneva**, receiving her Ph.D. in Biochemistry in 1996.

Marjan moved to San Diego and completed her first post-doctoral fellowship at the **University of California** at San Diego, resulting in the publication in *Science Magazine* of "Recovery of replication competent HIV from patients despite suppression of plasma viremia for two years" by J.K. Wong, Marjan Hezareh, H.F. Günthard, D.V. Havlir, C.C. Ignacio, C.A. Spina and D.D. Richman. She next served as a Research Associate at the **Scripps Research Institute** in La Jolla, California, where she co-authored "The effector function activities of a panel of mutants of a broadly neutralizing anti-HIV antibody", which is presently in submis-



*Marjan Hezareh
Director,
Scientific Communications*

sion. Her work has also been published in the *European Journal of Biochemistry*, the *Journal of Neuroendocrinology*, the *Journal of Virology*, the *American Journal of Physiology* and *Endocrine Reviews*.

"Marjan brings critical expertise to ARA as our organization begins to expand its capacity to move promising new drugs from the laboratory into human clinical trials. Because ARA targets drug candidates where there is little or no monetary incentive for pharmaceutical industry involvement, her skills as a basic research scientist with experience in the clinic will further enhance our ability in this area," noted ARA's Executive Director, Irl Barefield. "We are thrilled that Marjan is joining our biomedical research team."





AIDS RESEARCH ALLIANCE

STAFF

Executive Director

IRL S. BAREFIELD

Director of Clinical Research

STEPHEN J. BROWN, M.D.

Medical Director

GEORGE C. FAREED, M.D.

Development Director

VINCENT M. CUMMINGS

Manager, Information Systems

JOE BERGSTROM

Clinical Research Assistant

CORRIGAN CASTRO

Clinical Trials Coordinator/Manager

SERGIO CODINA, R.N.

Director/ Scientific Communications

MARJAN HEZAREH

Information Systems & Website Consultant

DON LEVY

Receptionist/ Administrative Assistant

HELEN MACIAS

Director of Administration

ANTONIO PISIG

Outreach Coordinator/ Clinical Research Assistant

MICHELLE SIMEK

Research & Development Consultant

MICHAEL SLATTERY

Clinical Trials Coordinator

MICHELE VERTUCCI, PA-C

Controller

STU WALTER

Director, Publications

KAREN J. WELLENKAMP

Clinical Trials Coordinator

GEOFF WILSON, PA-C



PHOTO BY ANNE'S BUCASABIAN

Antonio Pisig
Director of Administration

ARA Welcomes Antonio Pisig

AIDS ReSearch Alliance welcomes Antonio Pisig to the staff as Director of Administration. Antonio has had experience working in the HIV/AIDS field since he left **Washington University** in St. Louis, where he graduated *cum laude* with a degree in Spanish Language and Literature. After living and studying in Madrid, Spain, Antonio moved to Washington D.C. where he worked as the Program Director of the **Indochinese Community Center's HIV Education and Prevention Program**. Funded by the *Centers for Disease Control* and local County grants, this program provided educational outreach, referral, and condom distribution to gay/bisexual Asian and Pacific Islander (API) men, as well as refugees and recent immigrants from Vietnam, Laos, and Cambodia.

In 1993, Antonio moved to San Francisco where he accepted the position of Program Director at **Asian AIDS Project (AAP)**, a local community-based organization that provided outreach and education to APIs in the Bay Area. Antonio helped to create and oversee AAP's innovative

programs that reached API populations at high risk for HIV infection. This included a theater program and bar outreach to gay/bisexual API men, as well as one-on-one outreach to incarcerated youth, transgendered sex workers, and women who worked in massage parlors—hard-to-reach groups in which AAP staff was able to develop trust by hiring staff from within those populations.

After leaving AAP, Antonio went to work for his parents in Ventura. He managed their business, providing medical exams for life and health insurers, modernizing the office and doubling the business. Antonio was also able to spend more time with his family, one of his goals when he decided to work for his parents.

"I look forward to working closely with the staff of ARA. Coming to work for ARA brings me full circle back into the HIV/AIDS arena." Antonio believes that there is still a lot to be done in fighting this epidemic, and hopes to contribute in the fight against AIDS through his work at ARA. "I knew of Antonio's important contributions in the field of HIV prevention when I was working as a lawyer in San Francisco", said ARA Executive Director Irl Barefield. "I was delighted when Antonio sought out work at ARA since I had seen first-hand his ability to organize effective programs. We are lucky to have him."





Focus on AIDS 2: George Hurrell, "Portfolio #1", 1930s, donated by Rosalie Wilson.

One picture is worth 1000 words. Let us show you 250.

Focus on AIDS 9 will feature over 250 photographs by the world's hottest artists. This may be your best chance to take home an Ansel Adams, George Hurrell, Richard Avedon, Annie Leibovitz, Helmut Newton, Eduard Steichen, Sebastiao Salgado, Greg Gorman, Steven Meisel, David LaChapelle, Andy Warhol, and many, many others.

Be a part of the spectacular crowd flowing through this amazing week-long event at Barneys New York in Beverly Hills. At the same time, support agencies fighting HIV/AIDS through critical social services and medical research.

Focus on a Cure.



Focus on AIDS 9
Barneys New York
9570 Wilshire Blvd.
Beverly Hills
Friday, November 9th
VIP & Artists' Preview on
Saturday, November 3rd
Tickets: \$65; VIP Packages
start at \$500

*For more information, call
AIDS ReSearch Alliance
at 310/358.2423
or visit us at:
<www.aidsresearch.org>*

FOCUS ON AIDS 9 PHOTOGRAPHY AUCTION BENEFITING AIDS ReSEARCH ALLIANCE,
CARING FOR BABIES WITH AIDS AND THE FOCUS ON AIDS FOUNDATION