

# Positive

SEPTEMBER-OCTOBER 2002

# LIVING

## CLINICAL TRIALS 101



## Making an informed decision

INSIDE:

Reflecting on the Barcelona conference

David M. Gold, J.D.: On the trail of an HIV vaccine

Building better bone

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BARCELONA 2002

# RENEWAL of COMMITMENT

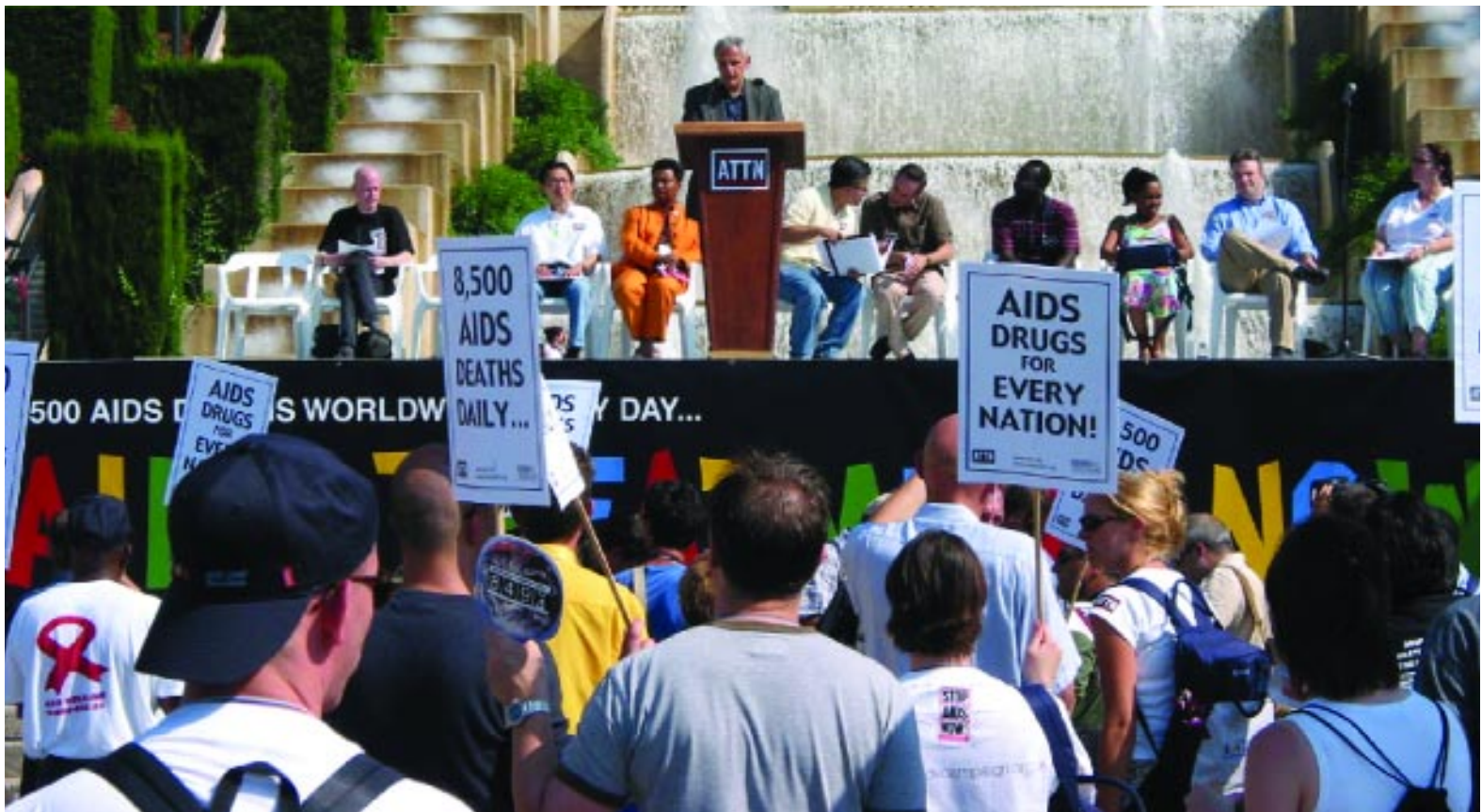
By LEE E. KLOSINSKI, Ph.D.

International AIDS Conferences serve as benchmarks for measuring changes in the disease.

The 1996 Vancouver conference is remembered for immortalizing the positive impact of combination therapy and initiating the hope of viral eradication. The conference in 2000 convened in Durban, South Africa. Media coverage impressed the world with images of the ruthless and unrelenting trek of HIV through the developing world, and communities of color in the United States.

At 21 years, the HIV/AIDS epidemic entered its adulthood in Barcelona. The Barcelona conference will be remembered for several issues consistent with a maturing epidemic.

A peaceful March for Life and rally preceded the opening of the International Conference on AIDS in Barcelona, Spain.





Coffin manufacturer in Masaka, Uganda (photo provided by AIDS Therapeutic Treatment Now).



The diversity of the conference delegates and representation of non-governmental organizations spoke to the expanding impact of the disease. Three Africans attended the first International AIDS Conference in Atlanta in 1985. At Barcelona half the delegates were from the developing world. Emerging epicenters like Poland, Russia, Brazil, India and China had strong

representation.

As the scope of the problem has changed, so too has an appreciation of its drivers.

A new realization that acquired immune deficiency syndrome is not related simply to infection with HIV clearly emerged, too. AIDS is a collection of old, familiar diseases that take advantage of the opportunities created by HIV, poverty, poor nutrition,

unclean water, child and domestic abuse, imbalances of social capital, homophobia, depression and substance abuse. The HIV epidemic is syndemic with these other social ills.

### THE ROLE OF PREVENTION

The role of medicine in prevention also grew.

Prevention of HIV transmission from mother to child

through the use of antiretroviral drugs is successful, safe and increasingly simple and inexpensive. Decreasing perinatal transmission is the greatest prevention success story in the developed world and offers remarkable opportunity to the developing world.

Developing countries like Uganda and Thailand made science-based prevention policy issues. By addressing HIV





Knowledge and Commitment for Action was the theme of the XIV International Conference on AIDS.

transmission issues honestly and accurately, they reported remarkable accomplishments in their ability to lower transmission rates.

In only months, definitive news about the usefulness of the concept and efficacy of a vaccine based upon the body's capacity to develop effective immunity through the production of antibodies to one of the outer proteins of HIV will be announced.

If clinical trials demonstrate at least 30-percent effectiveness in providing immunity, this vaccine may be licensed and a process to improve its rate of success will be initiated. If the vaccine proves ineffective, resources will be freed up to pursue other approaches.

Either way, vaccine research is approaching a significant crossroads.

Unfortunately, a junction like this will not be encountered again soon. Information about the next candidate vaccine does not become available

until 2008.

Since HIV transmission is intimately related to multiple social conditions, advances in preventing perinatal transmission and vaccine research that medicalize prevention may curiously impede a "cure" for HIV disease. Antiviral therapy and vaccines may function as quick fixes not responsive to larger, more structural and systemic factors driving the disease and promoting human suffering. Without addressing the upstream issues, the effectiveness of medicalized prevention may be limited. Social scientists as well as clinicians and researchers need to work together.

#### **RALLYING FOR TREATMENT**

The opening ceremonies of the conference were preceded by "AIDS Therapeutic Treatment Now," a rally and march demanding expanded access to HIV treatment organized by AIDS Healthcare Foundation and three other

groups, and co-sponsored by AIDS Project Los Angeles and more than 500 other organizations. If the question "Should we extend treatment?" was raised in the Durban conference, then Barcelona will be remembered for asking "How will we do it?"

The development of generic versions of anti-HIV drugs in certain developing world countries will be part of the solution. The Global Fund to Fight AIDS, Tuberculosis and Malaria, established by the 2001 United Nations General Assembly Special Session on HIV/AIDS, may supply some of the leadership.

The establishment of this fund signaled the realization that health should be a priority for governments, and that HIV/AIDS is a global problem, closely connected to endemic diseases and requiring the financial support of richer nations. A protest against the size of the United States' contribution to the Fund, held

during a speech by U.S. Health and Human Services Secretary Tommy Thompson, hijacked much of the news about the Fund's potential.

The Global Fund's impact is not clear simply because its initial grants are on the verge of distribution. The hope is that the Global Fund will function as the mechanism to balance the needs of the national and regional level with the community level and develop sustained and effective medical and social responses.

Whether governments have the will to embrace "Knowledge and Commitment for Action," the theme of the Barcelona conference, remains to be seen. +



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## Study explores massage therapy benefits

Cedars-Sinai Medical Center Department of Psychiatry is conducting a research study on the treatment of depression in people with AIDS with massage therapy.

To qualify, participants must have an

AIDS diagnosis and currently be depressed and qualify through clinical ratings

Participants must be at least 16 years old. All participants will be eligible to

receive 10 vouchers for free massages in their home after study participation is complete.

For further information, please call

## Care-giving to adult men with HIV studied

HIV-positive men age 18 or older who receive regular help from a woman who is their mother, wife, or female partner age 35 or older are sought for a study on care-

giving at UCLA.

If both of you qualify you could get up to \$60 for each person for two completed study interviews.

Regular help can be assistance provided with various daily living activities and health needs.

To find out if you both qualify for the



# Bush Administration turning up the heat

By PHIL CURTIS

AIDS activists are concerned about the government's handling of a recent request for a general audit of 16 prominent AIDS organizations in the U.S.

The July 17 request from a dozen Republican legislators in the House of Representatives, came just five days after demonstrators shouted down a speech by U.S. Health and Human Services (HHS) Secretary Tommy Thompson at the XIV International AIDS Conference in Barcelona, Spain.

The request, initiated by Rep. Mark Souder (R-Ind.), calls on HHS to provide "the total amount of U.S. federal assistance" that went to the Conference. The request also asks "How many individuals – from both the government and non-government organizations – attended the conference with some form of federal assistance? Please provide a complete list of these individuals and their affiliations."

The demonstrators were protesting insufficient U.S. funding for AIDS domestically and globally. Many demonstrators had signed a flier announcing the demonstration, and some later met with Secretary Thompson to discuss their differences. Some also signed a letter to Thompson after the Conference outlining their differences and thanking him for their discussions in Barcelona.

Among the groups who signed on to the flier were the Gay Men's Health Crisis

(GMHC), the AIDS Vaccine Advocacy Coalition, Project Inform, Treatment Action Group and AIDS Project Los Angeles.



"Groups that do advocacy and get public money are always concerned that there's an awkwardness in that situation," said Terje Anderson, Executive Director of the National Association of People with AIDS (NAPWA). "But I can't think of another time there's been talk of retaliation."

"The question we have to ask is what is the intent of this?" asked Robert Dabney, communications director for the National Minority AIDS Council, which the Health Resources and Services Administration of HHS has asked to document spending at the Barcelona Conference. "Our fear is that audits will have a chilling effect on these organizations."

Mark Harrington of Treatment Action Group said "all organizations are threatened" by the gathering of names and numbers, regardless of what is done with the infor-

mation. "Anybody who hears what happened is going to think twice about signing another flier or planning another demonstration," he added.

*By shouting down a speech by U.S. Secretary of Health and Human Services Tommy Thompson, the demonstrators were protesting insufficient U.S. funding for AIDS in domestically and globally.*

HHS officials described the request for information as routine and said they are obliged to respond. HHS Deputy Secretary Claude A. Allen said the department is working overtime to produce the information.

"It doesn't behoove us to want to engage in a witch hunt," Allen said. "This is not Secretary Thompson's style. We work with both our supporters and our detractors. We know that when you're engaged in highly significant issues that affect life and death, you're going to have differences of opinion."

Rep. Souder also initiated another recent congressional request for an audit of Stop AIDS Project in San Francisco. Souder and other legislators alleged that HIV/AIDS prevention education at Stop AIDS violated federal funding rules by promoting sex in some of their workshops. The

audit is currently under way.

Souder's letter regarding the Barcelona demonstrations stated that the U.S. is spending \$1 billion on international HIV/AIDS and that in light of these figures the legislators were "very disappointed by the rude reception Thompson received."

The legislators also objected to what they said was a lack of religious groups at the conference – they claimed the Vatican had been "uninvited," which a Spanish co-chair of the conference vigorously denied – and said taxpayers dollars should not be used to support such "religious intolerance."

The HHS letter was signed by Reps. John T. Doolittle of California, Robert B. Aderholt of Alabama, Jim DeMint and Sue Wilkins Myrick of South Carolina, Joseph R. Pitts of Pennsylvania, John B. Shadegg of Arizona, Jim Ryun of Kansas, Todd Tiahrt of Kansas, John Sullivan of Oklahoma, Sam Johnson of Texas and Jo Ann Davis of Virginia. All of the legislators are Republicans.

As of publication, none of the organizations mentioned above had been audited or contacted about a potential audit. APLA will continue to monitor the situation as it unfolds. +



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# Conference coverage on the Internet

Abundant information about the XIV International AIDS Conference in Barcelona, Spain, can be found on the Internet.

Here are some of the many sites providing Conference coverage:

- [www.aids2002.com](http://www.aids2002.com)
- [www.thebody.com/confs/aids2002/aids2002.htm](http://www.thebody.com/confs/aids2002/aids2002.htm)
- [www.natap.org/2002/barcelona/ndxbarcelona.htm](http://www.natap.org/2002/barcelona/ndxbarcelona.htm)
- [www.hopkinsaids.edu/publications/report/nov02\\_2.html](http://www.hopkinsaids.edu/publications/report/nov02_2.html)
- [www.gmhc/issues/julaug02/barcelona.html](http://www.gmhc/issues/julaug02/barcelona.html)
- [www.thebody.com](http://www.thebody.com)
- <http://hivinsite.ucsf.edu/InSite>
- [www.ithoughtaboutyou.com](http://www.ithoughtaboutyou.com)

## Limited T-20 compassionate use program launches in October

Individuals with HIV who are in need of a salvage therapy and who meet certain criteria may be able to access T-20, also known as Fuzeon, through a compassionate use program expected to begin in October.

T-20, a member of a new class of drugs called fusion inhibitors, is admin-

istered by injection twice a day. FDA approval of the drug is expected soon.

Only 600 slots in the program are available. Individuals enrolling in the program must be 6 years old or older, have a viral load greater than 10,000 copies and a CD4 count of less than 100 cells/mm<sup>3</sup> while on highly active

antiretroviral therapy. Individuals must also "be limited by the currently commercial available antiretroviral agents as per the judgment of the investigator," according to a letter announcing the program.

Individuals interested in the program should consult their physicians. +



# ON THE TRAIL OF A VACCINE

*an interview with David M. Gold, J.D.*

With HIV infection continuing to spread, an AIDS vaccine is the world's best hope for controlling the epidemic.

The recent XIV International AIDS Conference in Barcelona, Spain, provided an opportunity for researchers and observers to mark progress in vaccine development.

At the center of this quest is The International AIDS Vaccine Initiative (IAVI), an organization dedicated to speeding development of an AIDS vaccine. Based in New York City with an office in Europe, IAVI representatives at the recent conference included David M. Gold, J.D., IAVI's Vice President for Policy and Public Sector Support.

Besides Mr. Gold's work for IAVI, his portfolio includes advocacy work for the Washington, D.C.-based AIDS Vaccine Advocacy Coalition, and education at Gay Men's Health Crisis. He has also served on research advisory panels for UNAIDS and the U.S. NIAID, among other organizations.

During the conference, Mr. Gold took time to be interviewed for POSITIVE LIVING by AIDS Project Los Angeles' Associate Director of Education David Pieribone.

**Q** In the past, vaccine research seemed to be a priority for the government, such as the polio vaccine. Why is HIV vaccine research so different?

**A** I'm not sure it's not a priority. It's becoming more of a priority at the National Institutes of Health (NIH) in the U.S. and for other governments. But it's still not a huge priority. If you look at the \$420 million spent on developing an AIDS vaccine in both the public and private sectors, it is still relatively small given the horrific impact of this epidemic. That may sound large to some people but—and living in Los Angeles, you can appreciate this—Hollywood spends that much on producing two major movies a year. So, if you just follow the money, you can see where we as a global society, place our priorities.

**Q** Scientists and researchers have been working on a HIV vaccine for a long time. What are some of the major scientific roadblocks?

**A** Number one—the most important—we still don't know exactly what kind of immune response a vaccine should generate that could be protective. There's strong evidence for a cellular response. CD8 and CD4 helper cell responses seem to be very important in both monkey and human studies. And there's clearly some evidence that antibodies can be protective. Now we're seeing evidence supporting these ideas, but we're not sure.

**Q** Most vaccines in the past have focused on the antibody response, right?

**A** That's correct. Take, for example, the Polio and Hepatitis B vaccines.



# *Even with a vaccine that needs just one dose, it's important country with great amount of wealth, such as the United*

They generate a certain level of antibodies that are protective. But HIV is different. As you know, the so-called HIV test [the ELISA test] is an antibody test, so we know people with HIV are generating antibodies. But these levels of antibodies are not protecting them from disease and infection. We know some of the vaccines that are currently in clinical trials, including the VaxGen product, generate a low-to-moderate level of antibodies. However, in lab tests, these antibodies don't seem to neutralize human strains of HIV. In monkey studies that have been done more recently, it's been shown that monoclonal antibodies generated high enough levels of antibodies to protect monkeys against SIV (a cousin of HIV). The problem is, none of the vaccines tested so far seem to generate anything near the level of antibodies that the monoclonals do. So, I think it's fair to say that if you can generate the highest levels of antibodies, you can probably be protective.

**Q** What are some of the promising vaccine candidates that are being studied now?

**A** Well, there's VaxGen's AIDS<sub>VAX</sub>®, which is a GP120 protein vaccine. GP120 is from the outer surface of HIV, its envelope. This vaccine is in Phase III trials in North America and in Thailand. The population being studied in North America is men who have sex with men (MSM); in Thailand it is injection drug users (IDUs). The North American study will be completed at the end of 2002 and we should have some results at the beginning of 2003. The Thai trial should have some results the following year.

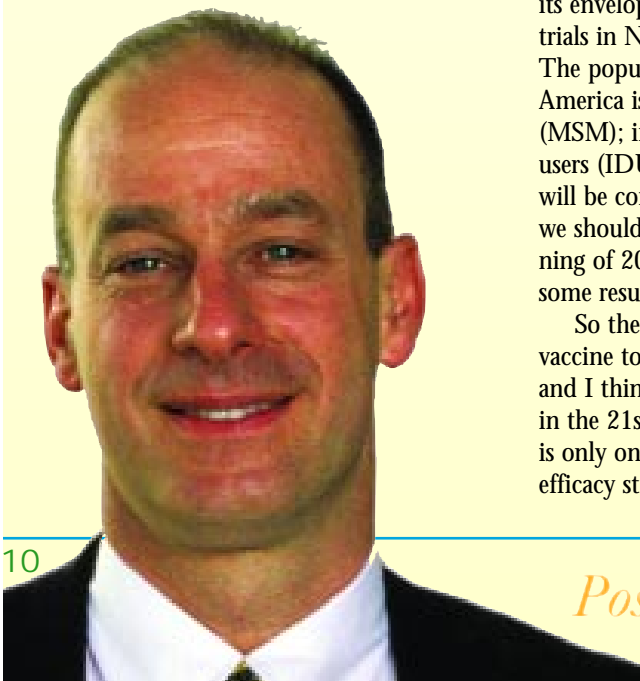
So the VaxGen product is the only vaccine to go into a Phase III trial so far and I think that's a problem. We are now in the 21st year of the epidemic and there is only one vaccine that has ended up in efficacy studies. Beyond that, the product

that most people are excited about is the Merck combination vaccine, a DNA vaccine combined with an adenovirus vector that uses pieces of the HIV genes inserted into the vector. In monkeys, it seems to be quite protective against a certain challenge strain—a combination of HIV and SIV, known as a SHIV virus. The vaccine combination is now in human trials and, they are also testing it as a therapeutic vaccine for individuals already infected with HIV. Another product people are focusing on is IAVI's own product: a combination of a DNA vaccine and a viral vector known as MVA (modified vaccinia Ankara) which is a weakened strain of the small pox virus. This vaccine is in Phase I and II trials in the UK and Kenya. The interesting thing about this vaccine is that it is based on a strain of HIV that is common in Kenya known as clade A. Most of the other HIV vaccines that have been tested are based on clade B, which is the strain common in North America and Europe. IAVI's goal is to put the combination into Phase III trials by the end of the 2004. That is a very fast track development plan.

Beyond these, there are a bunch of other DNA plus viral vector combinations being tested by different groups. There's a canary pox vector combined with gp120 that is about to start Phase III trials in Thailand. The canary pox vector has been tested for a while; we know what it does and it seems very safe. So those are probably the four products that are most advanced.

All these vaccines, with the exception of the VaxGen gp120, are focused on generating a cellular response. But antibodies will clearly be needed to provide complete protection. At the International Conference on AIDS in Barcelona, IAVI announced the creation of a consortium of researchers that will focus on developing vaccines that generate strong and broadly neutralizing antibodies. The con-

David M. Gold, J.D.





## *to see if it can be effectively delivered. Even in an industrialized States, it is not easy to get a vaccine out to adults.*

sortium is being led by Dennis Burton of the Scripps Institute, who is one of the top antibody researchers in the world. Other participants include the Dana Farber Cancer Institute, Cornell Institute in New York and the NIH, which is offering advice and assistance. So the goal of this initiative is to bring these researchers together to focus on developing vaccine that produces potent antibodies.

**Q** What exactly is the prime boost strategy and does this mean that you will need more than one dose of a vaccine for it to be effective?

**A** Well, the prime boost is when you use one type of vaccine to prime the immune system, and another vaccine to boost it. In the HIV arena, it's been tested primarily with a DNA prime to start with and then a viral vector boost. But in the Thai trial, it's a canary pox prime and a gp120 boost.

Your second question about how many doses will be needed is an important one. The VaxGen trial, for instance, includes six or seven doses and that's clearly not an easy thing to do. The Hepatitis B vaccine, which is safe and approved, needs three immunizations and they found that getting people to come back for the third dose was not easy. Records need to be kept, and it points to an even bigger problem of how to develop vaccines that are practical to deliver in resource-poor countries. One of IAVI's prime focuses is the development of a vaccine that is safe and effective and can be delivered in a resource-poor setting.

One oral vaccine that we are developing is based on a salmonella bacterial vector. This should be a more practical way of delivering vaccines in poor countries so you don't have to use needles and it also may be relatively inexpensive to produce. We also hope that the vaccine will generate more potent immunity in the mucosal

system.

IAVI has another vaccine in development that is an adeno-associated virus. In monkeys, this vector seems to generate a more persistent immune response with one immunization. But even with a vaccine that needs just one dose, it's important to see if it can be effectively delivered. Even in an industrialized country with great amount of wealth, such as the United States, it is not easy to get a vaccine out to adults.

The Hepatitis B vaccine is a good example. It's been available in the U.S. for some 20 years but we still see that in groups that are at high risk for Hepatitis B infection, such as men that have sex with men, less than 50 percent of the population is immunized. Imagine the complications of getting a vaccine out in a poor country. The challenge is trying to keep track of who's going to get the fourth shot and who's getting their third, which won't be easy.

So clearly we have to look at how we develop products that are practical to be delivered. Interesting enough, this is where I feel there's an overlap between treatment and prevention, because as we build up the infrastructure to deliver treatment, if we do it right, it's going to be the infrastructure we use to deliver the AIDS vaccine. Instead of looking at it like conflicts between treating people in developing countries and developing prevention technologies to prevent them from getting infected, we should look at the tremendous areas of commonality.

Another commonality is in therapeutic vaccines. As I mentioned before, Merck's vaccine is already in trials in people with HIV. Glaxo is going to do the same thing with their AIDS vaccine candidate. And the IAVI DNA/MVA combination that is being developed by Dr. Andrew McMichael at Oxford University is scheduled to move into trials in HIV-positive

people shortly. These will not be IAVI-sponsored trials. Our mission is very clear; it is to develop a preventative HIV vaccine for the world. But what Dr. McMichael is doing is taking the vaccine that we have paid to develop and conducting his own trials of the vaccine as a therapy. We are thrilled that it's being done and we think it points to the importance of investing in good product development and immunology research, and when that happens everyone benefits.

**Q** OK, we talked about vaccines in the U.S. and Africa. Will a vaccine that is effective in the United States be effective in Africa and other parts of the world?

**A** As you know, there are a number of different subtypes or clades of HIV around the world. HIV has a great deal of genetic variability; will a vaccine that is developed for one population be effective in another population? We don't know. And that's why we have to conduct clinical trials.

As I have mentioned, IAVI is developing an AIDS vaccine based on a strain of HIV that is circulating in Africa and Asia. We've flipped around the model, in the past, most of the other products being developed were based on strains prevalent in U.S. and Europe. Now the question is, is that relevant? We don't know. Merck has some data showing that the cellular immune responses their vaccines generate can neutralize virus from other strains, but it's not conclusive and until we do the studies where we take a vaccine developed from one strain and test it both in areas where the circulating virus is the same and different, we will never know. It will take political and scientific leadership to make sure we can test vaccines in human trials as soon as possible.

**Q** Most vaccines are not 100-percent effective. What kind of effec-



## The vaccine may net out without a real public health gain

tiveness do you need to bring an epidemic like HIV to a halt?

**A** Again, we don't know for sure. The VaxGen trial, for instance, is designed to detect protection above 30 percent. And the way they define protection is sterilizing immunity, meaning that people either get infected or they don't. Vaccines that stimulate a cellular immune response are more likely, based on the monkey studies, to prepare the immune system for exposure/infection of HIV. So if it doesn't stop infection, these vaccines may still be protecting the monkeys against disease. So the vaccinated monkeys and the unvaccinated monkeys will both get infected. But the unvaccinated monkeys will get sick and die from monkey AIDS while the vaccinated monkeys will have undetectable viral loads and normal CD4 counts.

But again, that's the monkey model, and again, most of these monkeys are challenged with an infectious dose of about 50 times of what we normally would take to infect. The reason for that is efficiency of cost. You cannot do good studies if your control monkeys do not get infected or sick. So, they need a high threshold and a very efficient infection. We don't know how similar that is to human infection. But we do know that, compared to these monkey studies, it is more difficult for people to become infected with HIV. I'm not advocating for people not to protect themselves, but clearly there is a different rate of risk from transmission of HIV in an actual human, sexual transmission and a monkey vaccine study where you want the monkeys to become infected. So whether the cellular immune vaccines provide so-called sterilizing immunity in some people, we won't know until we do the studies.

And, what's your definition of effectiveness? Is it 50 percent of the people don't get infected? Is it all of the people

who get vaccinated get infected but none of them get disease for 15 years? In some developing countries, there's massive HIV infection. So if 30 percent of the adult population become protected against HIV, it could be a very important step forward. So, even when you define effectiveness it's difficult because effectiveness could also be preventing disease for 10 to 12 years, but not infection. And if we treat people who become infected, most of them won't progress for a long time anyways. So how do you detect differences in progression in a vaccine trial? Can you go by the difference in "viral set point" if a vaccinated person has a very low viral set point while an unvaccinated person has a typical set point? Is that enough for licensing a vaccine? How long do we have to wait out before we decide whether we want to get that vaccine out to a population? Is there a different risk-benefit analysis in Botswana compared to Belgium?

But if we get a partially effected vaccine out to people, some may very likely increase their risk behaviors, thinking the vaccine is fully protective. So you may have a moderate level of protection and people engaging in more high-risk behavior. So the vaccine may net out without a real public health gain, or in fact create more infections. These questions are just not easy.

**Q** Some people I've talked to are worried that an HIV vaccine could infect you with HIV, or cause symptoms of HIV disease. What can you tell us about that?

**A** None of the vaccines in development at this point have a risk of infecting the trial participant with HIV. The current vaccines in clinical trials contain genetic pieces of the HIV, which have been tested thoroughly in animals and humans. The only vaccine that has a risk

is the live attenuated vaccine that has been studied in monkeys, and that is not currently in active development, and my guess is that would only be considered for human trials in 10 to 15 years, if everything else fails. The whole-killed vaccine also could possibly pose a theoretical risk, but again human trials are not likely. Both of these vaccine approaches have been used widely for vaccines against other diseases, but no one is talking seriously about moving any of those types of products to humans at this time.

**Q** If we had a vaccine that was effective, or partially effective, do you think it would be mandatory in the United States?

**A** My guess is that it would not. At the first stage, it would be given to adults and adolescents at high-risk of HIV. Eventually, after a long and a very clear safety profile, it would be considered for child immunization programs. So I think there's almost no chance it's going immediately to so-called mandatory infant immunization programs.

**Q** You talked a little bit about vaccines for people who are already infected with HIV. Do you think we are close to a vaccine that will help people get their immune systems to fight HIV without the need for medications?

**A** Again, we don't know. And again the only way we are really going to find out is doing studies so it's good to hear that these studies are getting done. The goal with therapeutic immunization would be to immunize people while they're on HAART. Hopefully, the vaccine will generate a more potent cellular immune response. A strong, HIV-specific cellular immune response is often found in so-called long-term non-progressors who are not in treatment. Almost all of these individuals have good cellular



*or create more infections. These questions are just not easy.*

immune responses to HIV and seem to control HIV without medication. But paradoxically, when you treat people with HIV, the cellular immune responses go down because the amount of virus that causes the immune responses often goes down to undetectable levels. The goal of a therapeutic vaccine would be to generate a cellular immune response while the virus is undetectable, then take people off therapy, and see whether the vaccine can, in a way, teach the immune system to control the virus without antiretroviral drugs. The attractive thing about this concept is that you can test this relatively rapidly. You can take people off therapy, and you should know within 12 months, whether there is significant difference in controlling the virus, for those who were on the vaccine during HAART and maybe continued getting the vaccine versus those who are unvaccinated and went off therapy.

**Q** If someone were interested in joining a vaccine trial, what kind of advice would you give to him or her?

**A** The NIH has an information number for those who are interested in vaccine trials. And I also encourage people to look at [www.iavi.org](http://www.iavi.org). We have a database of vaccine trials. amfAR's website: [www.amfar.org](http://www.amfar.org) also has a clinical trials database. For those who are interested in the overall issue of vaccines, I would suggest to look at our website, we have an excellent newsletter on AIDS vaccines, *The IAVI Report*, and a wealth of other information on efforts to develop a vaccine. +



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# FOR YOUR **BENE**

HIV and the current economic climate make this a difficult situation to manage. In this section, we offer you ideas and tips with opportunities to stretch your dollars.

By RICE RUSSELL

# working

IT ALL OUT

As access to effective HIV treatment improves, so do workplace opportunities for people living with HIV.

Even in strong economic times, looking for work can be tough. In today's bumpy economy, your best bet is to seek out as much support as possible for your job hunt. And if going back to school is part of your plan to get to that next job, vocational counseling and a working understanding of student financial aid are imperative.

AIDS Project Los Angeles' Benefits and Work Services Program, in collaboration with the California Employment Development Department (EDD), offers customized employment services to people living with HIV in the Los Angeles area. On-site job services at APLA include:

- Weekly job seeker orientation
- Résumé and cover letter assistance
- Cal Jobs registration and on-line résumé (State Job Bank)
- Job leads and referrals by on-site EDD job developer

To access these services, sign up for the weekly Job Seeker Orientation held each Monday (except holidays) from 10 a.m. to noon at APLA's David Geffen Center. For reservations, call Rice Russell at (213) 201-1616.

During the orientation, job seekers will get the opportunity to calculate their target income, discuss their most suitable job, and take a job skills analysis. After the orientation, one-on-one appointments are set up with our EDD Job Developer, America Solis. America works exclusively with people with HIV. In the last year, she has placed an average of four clients a month in jobs in Los Angeles. Working with a job development professional from an outside agency ensures HIV confidentiality with employers.

See Page 34



Illustration by MICHAEL STORC

# FIT

By making your financial  
goals a priority, we help you get familiar  
with the system and make ends meet

# STRETCHING YOUR BUDGET WITH

**W**ith the high cost of living in Los Angeles County, it's no wonder so many people on a disability income struggle to make ends meet.

Usually, financial survival hinges on one's ability to piece together various resources and benefits that will allow you to meet your basic needs. This "resource patchwork quilt" usually consists of resources such as disability income, housing assistance grants, health care assistance programs, drug assistance programs, bus passes and food bank assistance.

One lesser-known "patch" that might be added to your resource quilt is the Food Stamp program: one of the more underutilized public benefits available to individuals with limited resources.

## WHAT ARE FOOD STAMPS?

Food Stamps are "coupons" with a dollar value that can be exchanged for food.

The Food Stamp program is designed to allow people with limited resources to

increase their nutrition and free up cash resources to be used for other necessities such as rent and utilities.

They can be redeemed at a local grocery. In Los Angeles County, approximately 8,000 sites accept them.

## WHO IS ELIGIBLE?

Food Stamp eligibility is fairly straightforward.

If you are less than 60 years old, you must be able to demonstrate that your total assets are below \$2,000 (\$3,000 if you are over age 60). Common items that count as assets are cash, savings, stocks, bonds and retirement accounts. Exemptions from the \$2,000 limit include the property you live in and a burial plot.

You are also allowed to own one vehicle. The vehicle cannot be worth more than \$4,650. Exceptions to this rule are made, if you live in your car, use the vehicle as part of your work (such as a garden-er) or if you or someone in your household is disabled. In such cases, your vehicle can be worth any amount.

Income is also considered when determining Food Stamp eligibility. In 2002, an individual living in a single household

must have a monthly income below \$931 to qualify for assistance. The maximum Food Stamp benefit for a single individual in L.A. County is \$135 per month. The amount of Food Stamps you receive will be based on several factors, including what type of income you receive, how much you pay in rent and utilities, and how much you pay in out-of-pocket medical expenses.

## OTHER ELIGIBILITY FACTORS

Immigration status also impacts Food Stamp eligibility.

You must be either a U.S. citizen or a Legal Permanent Resident to qualify. If you are not a citizen or Legal Permanent Resident but have children who are, your children may be eligible to receive Food Stamp assistance.

Supplemental Security Income (SSI) recipients are not eligible to receive Food Stamps. This is because California has calculated a food allowance into your monthly SSI check. Also, individuals who have a drug-related felony conviction after Jan. 1, 1997 are permanently ineligible for Food Stamps (this regulation is being reviewed and may change in the future).





# food stamps

You may also be permanently ineligible for Food Stamps if you have been caught selling Food Stamps worth \$500 or more.

## HOW DO FOOD STAMPS WORK?

Once you are found eligible to receive Food Stamps, you will be issued a white card, which is called a Permanent Issuance or PIC card.

You will also be assigned a Food Stamp outlet location near your home. Each month you can present your PIC card at your Food Stamp outlet in order to pick up your monthly Food Stamps. It is important to remember that your Food Stamps are similar to cash and cannot be replaced if lost or stolen.

Food Stamps cannot be used to purchase non-food items, such as cleaning and paper products, pet food, diapers, alcohol or tobacco.

Food Stamps are also accepted at certified farmer's markets and can be used to purchase seeds or plants to grow your own food.

## HOW TO APPLY

To apply for Food Stamps, you must apply in-person through the local

Department of Social Services (DPSS) office.

It is important to note that not all DPSS offices process Food Stamp applications. A Benefits counselor at AIDS Project Los Angeles can identify the office nearest to your home.

A DPSS eligibility worker will work with you to complete several forms in order to assess your eligibility. You will need to provide identification, proof of your income and assets, rent receipts, vehicle registration and out-of-pocket medical expense receipts. If you don't have all of your documents at the time you apply, you will be allowed 10 days to provide the necessary documents.

If you are experiencing HIV symptoms that make it difficult to work, it is important that you notify your eligibility worker so that your case will be processed as an "unemployable disabled" applicant. This will allow you to avoid having to participate in the employment programs that apply to non-disabled applicants.

## MEDICAL FACTORS

To verify that your HIV condition prevents you from working, you will be

examined every six months by a county health care worker through the WATTS Mobile Clinic. Be prepared to show the clinic worker a note or diagnosis form from your doctor verifying your HIV status, as well as a list of any medications, treatments, complications or side effects you are experiencing.

Once your application is processed, you will receive a letter confirming your eligibility and explaining how much Food Stamp income you are eligible for. Food Stamps applications should be processed within 30 days.

In cases of emergency, Food Stamps can be issued within three days. To qualify for emergency Food Stamps, you must prove that you are at risk of losing housing or utility service, or have less than \$150 in gross income per month.

The Food Stamp program is something that might help you to stretch your monthly income. If you think that you may be eligible, contact an APLA Benefits Counselor at (213) 201-1472. +

Visit [www.apla.org](http://www.apla.org) for a list of farmers' markets in the Los Angeles area



Julie Cross manages AIDS Project Los Angeles' Benefits and Works Services Program. She can be reached by calling (213) 201-1475, or by e-mail at [jcross@apla.org](mailto:jcross@apla.org)

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# FARMERS MARKETS IN

CHINATOWN (Los Angeles) Farmers' Market  
727 North Hill, between Alpine & Ord  
Parking lot adjacent to United Commercial Bank  
Market Manager: Lan Gieng  
Thursdays 4 to 8 PM

LA CIENEGA Farmers' Market  
Corner of La Cienega and 18th Street  
Thursdays 3 to 7 PM  
Market Manager: Cynthia Ojeda

CALABASAS Farmers' Market  
23504 Calabasas Rd., at El Canon Ave.  
Saturdays 8 AM to Noon  
Market Manager: Linda Evron

LOS ANGELES Adams & Vermont Farmers' Market  
1432 W. Adams Blvd., near Vermont  
(St Agnes Catholic Church parking lot)  
Wednesdays Sep - May : 2 - 5 PM; Jun-Aug:2 - 6 PM  
Market Manager: Roy & Ida Edwards

CLAREMONT Farmers' Market  
235 Yale Ave. at Bonita Ave.  
Sundays 8 AM to Noon

MONROVIA Farmers' Market & Family Festival  
Myrtle Ave., between Olive & Colorado  
Fridays Jan-Feb: 4 - 8 PM; Mar-Dec: 5-9PM  
Market Manager: Lloyd Fujiwara

COVINA Farmers' Market & Family Night  
Citrus Avenue in front of the Civic Center  
Fridays 4 PM to 9 PM April 5 thru mid Dec  
Market Manager: Harry Brown-Hiegel

OXNARD Farmers' Market  
Plaza Park, corner of Fifth & "C" Streets  
Thursdays 9:30 AM to 1 PM  
Market Manager: Desire Ventura

GARDENA Farmers' Market  
13000 Van Ness Ave. South of El Segundo Blvd.  
(Holly Park Church parking lot)  
Saturdays 6:30 AM to Noon  
Market Manager: Roy & Ida Edwards

POMONA Valley Farmers' Market  
N.W. corner of Garey & Pearl  
One block north of Holt  
Saturdays 7:30 - 11:30 AM  
Market Manager: Harry Brown-Hiegel



# LOS ANGELES

REDONDO BEACH Farmers' Market  
 Redondo Pier, End of Torrance Blvd  
 In front of Veteran's Park  
 Thursdays 8 AM - 1 PM  
 Market Manager: Jerrie Watkins

SANTA MONICA Phone: 310-458-8712  
 E-mail: Farmers-Market@ci.santa-monica.ca.us  
 Wednesday Santa Monica Farmers' Market (1):  
 Intersection of Arizona Ave. & 2nd St.  
 Wednesday 9 AM - 2 PM  
 Market Manager: Laura Avery

SANTA MONICA (2):  
 Saturday Santa Monica Farmers' Market  
 Intersection of Arizona Ave. & 2nd St.  
 Saturdays 8:30 AM - 1 PM  
 Market Manager: Mort Bernstein

SANTA MONICA (3):  
 Pico Santa Monica Farmers' Market  
 Corner of Cloverfield & Pico  
 Saturdays 8 AM - 1 PM  
 Market Manager: Ted Galvan

SILVERLAKE Farmers' Market at Sunset Junction  
 3700 Sunset Blvd.  
 Between Edgecliff & Maltman Avenues  
 Saturdays 8 AM - Noon  
 Market Manger, Edwin Gomez

STUDIO CITY Farmers' Market  
 Ventura Place, between Ventura & Laurel Canyon  
 Sundays, 8 AM - 1 PM  
 Market Manager: Polly Ward

WEST HOLLYWOOD Farmers' Market  
 Plummer Park  
 1200 N. Vista St. at Fountain Ave.  
 Mondays 9 AM - 2 PM  
 Market Manager: Shirley Berry

WESTWOOD Village Farmers' Market  
 On Weyburn Ave at Westwood Blvd.  
 Between Westwood Blvd. and Tiverton  
 Thursdays 2 - 7 PM  
 Market Manager: Aaron Shapiro

By LESLIE KLINE-CAPELLE

# GETTING YOUR



## Most applicants are interested in two Social Security benefit programs: Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI).

For both programs, applicants must prove that they have a disability which affects every aspect of daily life and which will not improve within 12 months. For SSDI, applicants must have worked at least 10 years, paying those FICA taxes out of their paychecks. For SSI, applicants must prove they are “low-income,” which means there are no assets (such as a 401(k), an IRA, rental property, more than one car, jewelry and life insurance). There are many SSI eligibility rules based on income and assets. There are lots of exceptions to these rules. To ensure that prospective applicants are financially eligible as well as medically eligible, they are urged to speak with a counselor in AIDS Project Los Angeles’ Benefits Department or at AIDS Service Center before filing for SSI.

Some applicants will qualify only for one of these programs. Other applicants will qualify for both.

### THE SSI/SSDI APPEAL

If an applicant for Social Security benefits already has received a denial at the Reconsideration level (or if the applicant is part of the “Hearing Process Improvement” changes and the initial claim denial notice advises the applicant to file a Request for Hearing form), then the next step is to request a hearing in front of an ALJ.

Applicants have the right to legal rep-

resentation during any stage of the Social Security benefits appeal process, but it is at the ALJ level that an attorney, or other representative can be the most critical element to winning an appeal. Keep in mind that while applicants can have a representative at the hearing who is not an attorney, they even can designate more than one representative (which normally might be the applicant’s care-giver and an attorney).

### WATCH THAT CLOCK!

Applicants usually have only 65 calendar days to request the hearing (this includes an additional five days for mailing). The time is counted from the date stamped on the Notice of Decision the Applicant will have received in the mail from Social Security. If applicants try to file the forms after 65 days have passed, the Social Security office frequently will refuse to accept the forms, advising applicants that they must file a new application instead.

In rare cases, applicants will be allowed to complete a waiver, or a letter of “good cause” which explains why the appeal forms are late and which asks that Social Security accept the forms even though the 65 days have lapsed.

Applicants are urged to file all paperwork in person at the Social Security office. By law, applicants may file the appeal forms at any Social Security office – there is no requirement that applicants file forms at the particular Social Security office where the file has been assigned. By filing the forms in person, applicants will receive a date-stamped receipt. This receipt is important because the Social Security Administration does lose paperwork. If applicants mail the appeal forms, and they are lost, they may be unable to prove that the forms were filed on time, and may be forced to start all over again,

by filing a new application for benefits. By filing the appeal forms in person, applicants will get the date-stamped receipt – and if the forms later are lost, applicants have proof that the appeal was filed on time.

### HOW DO YOU REQUEST A HEARING?

To request a hearing, applicants must complete the Request For Hearing By ALJ (Form HA-501-U5) and Claimant’s Statement When Request For Hearing Is Filed And The Issue Is Disability (Form HA-4486). Both of these forms are available at your local Social Security office, from AIDS Project Los Angeles’ Benefits Department, from the AIDS Service Center, or from HALSA.

### WHY REQUEST THE HEARING?

Frequently, applicants will choose to file a new application at the local Social Security office, rather than request a hearing in front of the ALJ. The purpose of requesting the hearing is to ask the ALJ to review the current application, to review the medical records and to listen to the applicant explain why she or he believes that she or he is disabled. The ALJ will consider all of the documents and verbal testimony and then decide not only if the applicant is disabled (under Social Security regulations) but also the date this disability became “permanent” (this is called the “onset date”).

By asking for the hearing, applicants are asking the ALJ to agree that they were permanently disabled as of the onset date.



Leslie Kline-Capelle is the Public Benefits Staff Attorney at the HIV & AIDS Legal Services Alliance. HALSA can be reached by calling (213) 201-1640.



The onset date often is the same as the application date, but if the ALJ agrees that the onset date pre-dates the application, SSDI applicants may be entitled to additional SSDI benefits which actually are retroactive to the onset date (for as much as one year prior to the application date).

By filing a new application, applicants close the previous claim, and any possible benefits which might be awarded may be for a much shorter retroactive period. By filing a new application, applicants may lose possible retroactive benefits.

### **HURRY UP, THEN WAIT**

Applicants who are HIV-positive or have AIDS are classified as TERI cases. These applicants suffer from a Terminal Illness and Social Security is required to process their application faster.

Applicants who have health insurance through the COBRA regulations also are required to have their application processed more rapidly. Because so many applicants request hearings, the Social Security's Office of Hearings and Appeals may take as long as a year to schedule a hearing. Use this waiting period to gather the medical records and to ensure that your file is complete and up to date.

Call the Office of Hearings and Appeals, make an appointment to review your file, and copy everything in it (this will save you and your representative a lot of time). Be sure that Social Security has your current mailing address.

### **GET THOSE MEDICAL RECORDS!**

Applicants have the right to submit new evidence (which usually consists of more recent medical records). Some ALJs want to receive the records at least 10 days before the appeal hearing, but some ALJs will accept the records on the day of the hearing itself. According to Social Security, the major reason for denying an applicant's case is that there are insufficient medical records in the file to prove the applicant is disabled. Asking doctors for copies of the most recent records, including laboratory reports and psychological reports, remains crucial.

Applicants should review these records themselves. Is the provider writing down

everything? Are all of the symptoms listed? Are the notes legible? Are the recent lab reports coming in? Is the doctor describing the applicant as "not compliant with the medications" when the applicant takes all of those meds religiously?

In order to clarify any errors in the records, or simply to provide an update of the applicant's medical condition, a letter from the treating doctor is sometimes necessary.

Keep in mind that applicants may not be permitted to get copies of their psychological or psychiatric records. Instead, applicants may need an authorized representative or Social Security to request those records from the therapist. For assistance in getting such psychological or psychiatric records, applicants should contact AIDS Project Los Angeles' Benefits Department or AIDS Service Center, for assistance.

Applicants then should make an appointment at Social Security's Office of Hearings and Appeals to copy the file. (Most OHA offices require applicants to call ahead for an appointment.) Are all of the recent medical records in the file? Take notes on which records are missing. Make arrangements either to have the supplemental copies sent straight to Social Security by the doctor/psychologist/psychiatrist, or to take the copies personally to make sure they are filed properly.

### **SOCIAL SECURITY DOCTORS**

Frequently, Social Security will send applicants a notice to be examined by one of their doctors or psychologists. By law, you can request to substitute your primary treating doctor or psychologist. AIDS Service Center or AIDS Project Los Angeles' Benefits Department staff members can advise applicants on the procedure to switch the appointment with a Social Security medical provider to an appointment with the applicant's personal medical provider.

If applicants plan to be examined by a Social Security doctor, they must keep this appointment and answer any questions truthfully. Even as the Social Security doctor takes notes during the examination, the applicant should take notes as well!

Was the applicant asked to remove any clothing? Were the applicant's height, weight, blood pressure and pulse measured? Were the applicant's reflexes tested? Were any laboratory tests ordered? How long was the doctor in the room with the applicant? What questions, if any, did the doctor ask?

Do not be surprised if a five-minute appointment results in a 10-page evaluation of the disability claim, assessing the applicant as able to work. The ALJ hearing will be the opportunity to tell the ALJ about this examination and why, by comparison, the evaluations and notes from your HIV doctor are a better description of how you feel and how you physically are responding to the medication treatment.

### **EXPERTS AT THE HEARING**

The ALJ assigned to hear the case may request a medical expert or a vocational expert also to appear at the hearing. These experts will listen to the testimony by the applicant and by any witnesses. Usually, they will have reviewed the work history and the medical records in the applicant's Social Security file. They are there to tell the ALJ whether applicants are permanently disabled, or whether there is some other kind of job they could perform.

### **JUDICIAL DISCRETION**

Under the Social Security regulations, the ALJ is allowed a lot of discretion. This means that the ALJ can listen to any testimony and accept virtually any kind of evidence in the consideration of an applicant's case. Often, the ALJ may simply look at the applicant and make a general observation as to whether this person looks sick, even though the law does not allow the ALJ to make a decision regarding the applicant's disability based on the ALJ's own observations. (The ALJ is not a doctor, and does not have the medical training to conduct medical examinations.)

If the medical records are spotty, brief and lack detail, the ALJ may be unable to conclude, under Social Security regulations, that the applicant is disabled. As sick as the applicant will look, by law,

there must be a medical record to document the disability and “back up” any ALJ conclusion that the applicant indeed is disabled.

### **SUBSTANCE ABUSE AND THE DISABILITY DECISION**

In 1996, Congress changed the Social Security laws. There used to be hundreds of thousands of men and women receiving SSI or SSDI because their substance abuse addiction made it impossible for them to work, so they were considered medically disabled. In 1996, however, with the changes in the law, receiving SSI or SSDI is no longer possible if applicants are using any controlled substances.

The law allows the Social Security Administration to consider the effort to get, prepare or ingest the controlled substance as a sort of work activity. Since applicants cannot be approved for SSI or SSDI if they are working, this interpretation gives the ALJ a legal rationale for denying a claim for benefits.

If the applicant is no longer using controlled substances, it will be necessary to prove that she or he has completed a drug rehabilitation program, remains clean and sober, and has submitted to drug screens –which were negative.

If the applicant relapses in substance abuse, the ALJ will have to consider whether the applicant still would be disabled, even if there had been no relapse – whether the substance abuse is “a contributing factor material to the determination of disability.” This “material factor” assessment also is done where the applicant still is using a controlled substance and can be the basis for denying an SSI / SSDI appeal, even if the effort to get, prepare and ingest the substances is not “substantial.” The HIV/AIDS Legal Services Alliance (HALSA) does see cases where the applicant has a severe disability, as the result of HIV/AIDS, but the substance abuse relapse is the basis for the ALJ

denial of SSI / SSDI benefits.

### **NOTICE OF DECISION**

After the ALJ hears the case, preparing the written Notice of Decision can take weeks. Three outcomes are possible: Partially Favorable (the applicant is disabled, but the onset date is later than the



date claimed), Fully Favorable (the applicant is disabled, and the disability began as of the applicant's onset date), or Unfavorable (the applicant is not disabled).

The reversal rate at this hearing level is over 60 percent for all appeals, and even higher for HIV/AIDS appeals. No one can make any guarantees about the likelihood of success for any applicant's case. It is better to assume you will have to argue the smallest detail, and be sure that all symptoms which are affecting your ability to lead a normal life are documented by your doctor and listed in the medical records.

### **OK, I'M DISABLED. WHERE'S MY CHECK?**

The ALJ decides only whether applicants are disabled, and the onset date of that disability. Once this decision has been

made, if part or all of the claim is for SSI, applicants will get a notice to go back to the local Social Security office for an appointment, in order to confirm any financial eligibility requirements (since SSI is the program which also is based on financial need). Applicants will be asked how they were living during this one- to two-year waiting period. Applicants will need to bring rent receipts and other proof of expenses and proof of any income, loans or gifts.

Regardless of whether the claim is for SSI, SSDI, or both, if the applicant has been receiving General Relief, Social Security will have a computer record and this money will be repaid directly to the County out of the applicant's retroactive benefits. The applicant's benefits will not be paid until GR has been repaid. There also will be deductions or offsets for any SDI or Workers' Compensation benefits which the applicant received. If the applicant is eligible for a Long Term Disability or other private insurance benefit, the applicant may be ineligible for SSI, and the SSDI benefits may be reduced for as long as those private benefits are received.

If an applicant retains a private attorney for representation during the appeal procedure, the attorney's fee of 25 percent (with a maximum fee allowance of \$5,000) is deducted automatically from the applicant's retroactive SSDI benefits as well. Right now, attorneys' fees are not deducted automatically from retroactive SSI benefits, but this may change.

In the SSI case, the first Social Security on-going benefits check normally is issued the month following the appointment at the local Social Security office. If the claim does not include SSI, the first on-going benefits check normally is issued the month following a Notice of Benefits letter, which will be sent to the applicant from the Baltimore, Md., Social Security office. This letter outlines the benefits to be paid.

### **“NOT DISABLED?” WHO'RE YOU KIDDING?**

If the applicant receives an



Unfavorable decision from the ALJ, it is possible to appeal again. Anyone who receives an Unfavorable decision from the ALJ should file a new application for SSI/SSDI immediately. The right of appeal, at this level, does not prevent the applicant from filing the new application.

This time, the file, and any new medical records or other documentation the applicant wants to submit, will be sent to the Appeals Council in Falls Church, Va., or the applicant will have to file a lawsuit in federal court. The reversal rate at this level is less than 10 percent. Remember the part about the ALJ having judicial discretion? They are allowed a lot of leeway in reaching their decision, and for this reason, the Appeals Council rarely issues a reversal. For this reason, the federal court judge will not reverse the ALJ unless there has been some error of law, of legal procedure or some drastic change in the facts.

Cases which must be appealed to the Appeals Council, and which still are denied, can then be appealed again by filing the lawsuit in federal court, or the

applicant can start over and file the new application for benefits.

### WHERE DOES THE LAWYER COME IN?

Applicants often consult with an attorney after receiving a reconsideration denial. If the medical records document severe symptoms of HIV/AIDS, HALSA provides free legal representation to persons with HIV or AIDS at these hearings.

Applicants may wish to hire a private attorney. Most attorneys agree to accept such Social Security appeal cases on a contingency. As mentioned already, the fee for such cases is 25 percent of the retroactive benefits award, with a maximum allowed of \$5,000. For the name of an attorney who represents applicants in such cases, applicants can call the Lawyer's Referral Service at (213) 243-1525, (310) 451-5633 or (310) 553-4022. Applicants also can call the National Organization of Social Security Claimants' Representatives (NOSSCR) at (800) 431-2804 for a referral to a Los Angeles-area attorney.


Applicants can designate a representa-

tive who is not an attorney to assist during this appeal. If applicants have a long-term caregiver, or other trusted person the applicant wishes to appoint as the representative, this also is permitted.

The representative will help applicants gather medical records, review and copy the Social Security file, and often review questions the ALJ or the representative will ask during the hearing. The attorney may also prepare a written analysis of the facts of the applicant's case and the applicable law, to present to the ALJ during the hearing.

If you would like your Social Security case reviewed for possible representation, call AIDS Service Center at (626) 441-8495, AIDS Project Los Angeles' Benefits Department at (213) 201-1472. For an assessment of your disability case, call the HALSA intake line at (213) 21640. ✦

*Funded by the County of Los Angeles,  
Department of Health Services, Office of  
AIDS Programs and Policy*

A woman with dark hair, wearing a vibrant, multi-colored floral patterned shirt, is seated at a white sewing machine. She is looking towards the camera with a slight smile. Her right hand is on the top handle of the machine, and her left hand is near the needle area. The background is a bright yellow wall with a pattern of pink and red flowers. The lighting is warm and focused on the woman and the machine.

**I encourage anyone who is in an illegal enterprise to consider a legal business.**



By LYNN BRIDGES

# MAKING IT IN business

When I was a child in Venice, Calif., I had a best friend whose mother was impeccably dressed every day. I wondered how she could afford to own so many beautiful clothes.

When I learned that she made her clothes herself, I was stunned. Until then, all of the people I knew who made their clothes *looked* like their clothes were homemade.

I began to spend as much time as I could with my friend's mother. I watched her cut and sew, turning fabric into beautiful garments.

The pivotal moment came the day that she allowed me to accompany her to a fabric store. I was mesmerized by all of the beautiful fabrics and trimmings. My imagination went wild and my creative juices overflowed.

I began to sew my mother's clothes, and then I began sewing for her friends, and that led to sewing for other ladies in our church and community.

## AN ENTREPRENEUR AT HEART

As far back as I can remember, I have had an entrepreneurial spirit.

It began with participating in the candy drives at school, which led to selling greeting cards. I used the money I earned for selling greeting cards to purchase my first typewriter.

When I was 20, I accepted that I was transgender. And then I made an unwise decision to get into prostitution, which led to a three-year prison sentence in Nevada in 1996.

## SOME CHANGES IN ORDER

During my incarceration, I decided that I needed to make serious lifestyle changes.

I began to take college courses in busi-

ness management, offered by a program of the prison system and the Community College of Southern Nevada. After a few classes, I realized that business management was my passion. It seemed to come naturally to me.

## BACK TO CALIFORNIA

After my release from prison, I enrolled in courses at the Community College of Southern Nevada. Because I was unable to find courses in fashion at community colleges in Nevada, I decided to return to California and enroll in courses at Los Angeles Trade-Technical College.

Even before returning to California, I became aware of AIDS Project Los Angeles and its employment services for people with HIV. In 1999, Rice Russell of APLA's Work Services program referred me to the Wilshire Worksource Center. There, I saw an advertisement for MicroEnterprise Training offered by the Valley Economic Development Center (VEDC).

I attended the orientation for MicroEnterprise Training and was surprised to learn that that program is part of the Welfare to Work Program, which helps low-income clients move from public assistance to financial independence, through business ownership.

When I studied Small Business Management in college, the curriculum was geared to working for someone else. While dreams of large successful businesses are not discouraged, the MicroEnterprise Training focuses on home-based business ownership.

My business concept is a home-based couture (custom-made apparel) business, which will expand into a boutique. During the training, I obtained not only a

better understanding of my industry but also a clearer picture of managerial procedures needed to run any business. I also utilized the library of the Small Business Development Center and learned numerous ways to market my business.

The center also has a liaison with the Fashion Business Incubator, which is an organization that provides business and educational services to startup apparel manufacturers. I now have the support I need to not only assist me in my entrepreneurial goals but also support me throughout the life of my business.

Thanks to the Valley Economic Development Center, I have a comprehensive plan to make my goal of self-employment a reality. While I am currently doing couture work for friends, in early 2003, I plan to open my business to the public.

## THINK ABOUT TRAINING

Since its inception in 2000, the MicroEnterprise Training Program has trained more than 190 individuals and introduced 50 new businesses to Los Angeles.

I encourage anyone with a business concept—even if you think it is too lofty to achieve—to consider this training. And I encourage anyone who is in an illegal enterprise to consider a legal business. If you have a profitable illegal business, I am certain that you can apply the same practices to a legal business, just as I did. Not only will that eliminate your risk for incarceration, you will drastically improve the quality of your life.

For information on the MicroEnterprise Training Program, call the Valley Economic Development Center at (818) 907-9977 or visit [www.vedc.org](http://www.vedc.org).  
+



# WHEN MEDI-CAL SAYS 'NO' TO SEROSTIM

By LESLIE  
KLINE-CAPELLE

**M**edi-Cal recipients can obtain Serostim, a human-growth hormone which is prescribed to control HIV Wasting Syndrome, as one of the drugs covered by the program.

Because HIV wasting syndrome is not simply a decrease in body weight, but in fact involves the loss of lean body mass (skeletal muscle, organ tissue, blood and blood constituents and even intra- and extra-cellular water), it results in muscle weakness, organ failure and eventual death.

Nutritional intervention (a simple increase in the caloric intake each day) is not effective in the severe Wasting Syndrome cases, because an increase in calories results in an increase in body fat. Use of Serostim results in an increase of the lean body mass, a decrease in body fat and a significant increase in body weight.<sup>2</sup>

## **NORMAL MEDI-CAL PROCEDURE**

When the U.S. Food & Drug Administration approves a drug, it is approved for "label use," or a specific medical purpose. As the drug is prescribed and used, often the medical community and the public discover other effective uses for the drug. The medical community may begin to prescribe the drug for "off-label" uses.

If Medi-Cal has approved coverage of the drug, it approves the drug for label use. If a Medi-Cal recipient needs the drug for an off-label use, the recipient's treating physician have to provide written evidence to Medi-Cal documenting that this "off-label" use of the drug has become a common practice in treatment of the condition. This written evidence also must include literature (such as medical

journal articles) which describes the medical research or testing to support this new use of the drug.

## **SEROSTIM MEDI-CAL PROCEDURE**

All bets are off when it comes to Medi-Cal approval of Serostim.

Serostim costs between \$7,000 and \$8,000 per month per recipient. Body-builders use it to increase lean body mass, and trade of the drug on the black market is thriving. Fraudulent attempts to obtain Serostim by Medi-Cal patients who, medically, do not "need" the drug are rising. As of May, the Department of Health Services has informed all Medi-Cal beneficiaries that Serostim, as well as several other drugs, are not available automatically upon the prescription of the medical doctor.

As of May, treating physicians must complete a Treatment Authorization Request (TAR) before Medi-Cal will pay for a Serostim prescription. The TAR includes a list of the recipient's HAART medications, the recipient's current weight, the recipient's height, and the results of a recent body cell mass test.

If the medical information in the TAR supports the treating physician's prescription of Serostim to control severe HIV wasting, then Medi-Cal should approve the TAR and pay for Serostim – for that month. In the subsequent month, another TAR may be required, with another body cell mass test, to verify that ongoing use of Serostim is medically necessary.

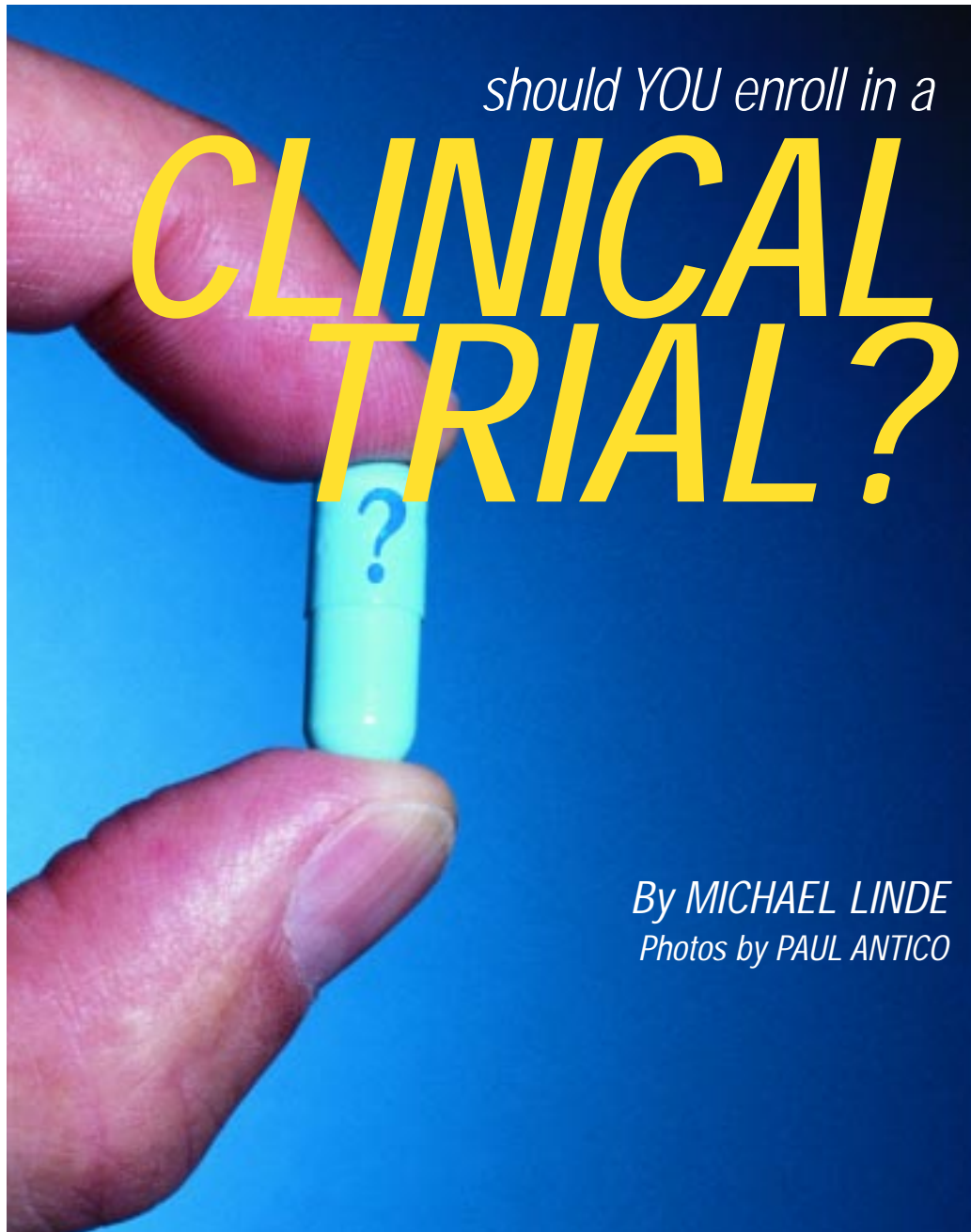
If the treating physician does not submit a new TAR, the recipient probably will be unable to get a Serostim refill at the pharmacy, and the pharmacy may direct the recipient to speak directly with the treating physician.

If the treating physician submits a new TAR, but does not include the height, weight, medications list and body cell mass index, Medi-Cal will "defer" approval of the TAR until this information is received. Unfortunately, the pharmacy may not inform the recipient that the TAR approval is "deferred." The recipient may be told (incorrectly) that the TAR was denied, or the recipient may be told that the TAR was "not approved." The recipient then assumes that the TAR is denied. The recipient may ask the physician to submit another TAR or file an appeal with the California Department of Social Services, requesting a hearing with an Administrative Law Judge.

When a TAR is deferred, and the requested information is not received, the deferment becomes a denial. The recipient will not be able to file an appeal when the TAR is deferred – only when the TAR is denied. The difficulty is that if the denial is based on a failure to receive requested medical information from the treating physician, the recipient may be unable to win an appeal: if the medical information which Medi-Cal has requested is reasonable, if it is not received within the deadline, and if the TAR therefore is denied, then the denial is likely to be considered valid under Medi-Cal law. Under these circumstances, the recipient has no option other than to request that the treating physician submit a new TAR and to ensure that the supplemental information is included as part of that TAR.

While it may seem like a lot of useless paperwork, the recipient may be required to have a TAR submitted (with that supporting medical information) for each

*See Page 34*



*should YOU enroll in a*

# **CLINICAL TRIAL?**

*By MICHAEL LINDE*

*Photos by PAUL ANTICO*

**W**With 16 anti-HIV medications approved by the Food and Drug Administration and more than 15 years of antiretroviral treatment, you might think the medical community has optimized HIV treatment.

This is not the case. While clinical trials have answered many questions about patient treatment, even more remain. When is the best time to start therapy? Which regimens work best for treatment-naïve patients? Which regimens should be saved for salvage options? How can treatment complications be minimized? What are long-term effects of receiving intermittent treatment or stopping treatment altogether?

Clinical trials are studies designed to test treatment safety and efficacy in patients. Researchers rely on volunteer patients to fill these trials. Some studies require only a handful of patients and a short period of time, while others follow hundreds of patients over a number of years.

Some studies look at the effects of new medications, others look at older medications, and still others do not investigate medications at all. A clinical trial might follow patients' diets, or a holistic therapy or a vaccine. Some HIV trials even need non-infected volunteers. In short, for every patient, there is probably a clinical trial being conducted that could use him or her.

Clinical research depends on patients wanting to get involved in the system. However, before a patient rushes to enroll, he or she should know the facts.

## the 4 phases of clinical trials

Phase I clinical trials are the first step in human testing. Prior to Phase I, treatments are tested in the lab and on animals. If a treatment is safe in the lab and in animals, safety testing is conducted with a small number of human volunteers. In Phase I trials, patients are usually given very short doses of the trial treatment to see the effects. Accordingly, patients are heavily monitored. Phase I clinical trials tend to require a large amount of patient interaction, but not for a very long period.

If a treatment is deemed safe, it moves on to Phase II trials. These follow a larger number of patients for a longer period of time. Phase II trials look for treatment efficacy. Does the new treatment work? As the treatment is still relatively new to human patients, Phase II studies also require a large amount of patient time.

### THE BENEFITS

Clinical trials are the primary method for patients to legally receive medications that have not yet been approved by the Food and Drug Administration.

Prior to widespread release, medications must face a series of tests (see sidebar above). For patients who have had difficulty with approved anti-retrovirals, access to these medications may represent an attractive option. This includes patients who have drug-resistant HIV strains and patients who experience adverse events related to anti-HIV treatment.

Clinical trials may offer the best method to get the latest medications, which may be more potent or more tolerable than currently available anti-HIV medications. Patients should always keep in mind that these drugs haven't been tested thoroughly. Risk is always involved when taking untested treatments.

Even when a medication has been approved by the FDA, it may be costly. Clinical trials offer the opportunity for some patients to receive these medications free of charge. Additionally, patients may receive other benefits, such as compensation for time off from work, or for transportation costs.

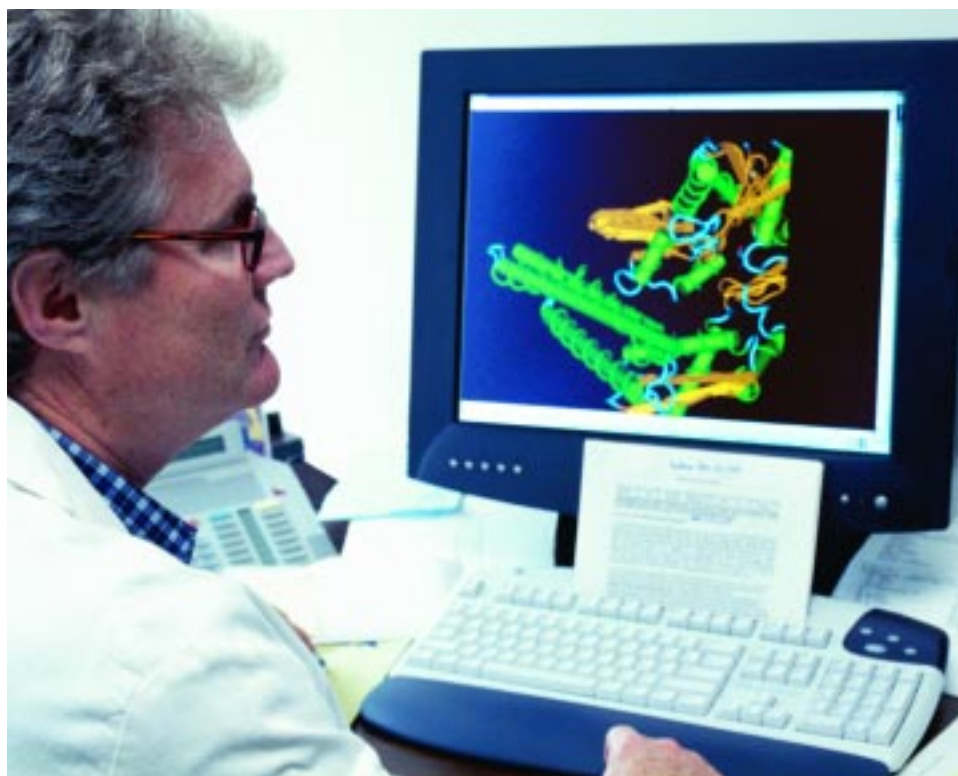
Patients in clinical trials also often receive additional attention from health-care providers. Clinical trials often require more intensive monitoring, which may equate to more frequent appointments, viral genotyping or phenotyping, and monitoring of patient characteristics (such as blood levels of certain chemicals).

Increased monitoring may also mean increased time demands on the patient, however. Furthermore, entering a clinical trial does not guarantee increased attention for the patient. Control arms of

and Education at UCLA.

### THE RISKS

Patients should not lose sight of the fact that clinical trials are investigations.



UCLA's Steven Miles, M.D., examines a representation of resistant HIV protease.

many clinical trial control arms may not offer much benefit to the patient beyond the standard of care or conventional treatment.

"We try not to encourage patients to join [clinical trials] just to try and get better treatment," said Deon Claiborne, outreach coordinator for the Center for Clinical AIDS Research

While there is a risk for any treatment undertaken—whether or not it is FDA-approved—very little may be known about a clinically unproven medication or treatment. Clinical trial outcomes are not assured to be superior to the standard of care.

Clinical trial safeguards protect patients; still, there are risks. On rare

**3** Phase III begins after the treatment is found to be safe and effective for smaller numbers of patients in the first two phases. Phase III trials need to be conducted prior to FDA approval. These trials follow a large number of patients over a long period of time. They do not require as much patient time as phase I and II trials, but the duration of treatment is longer. If the Phase III trial is successful, the FDA may choose to approve the experimental therapy.

**4** After a treatment has been approved by the FDA, the testing does not stop. Phase IV trials are post-marketing trials. They may compare different approved regimens or they may look at side effects of the treatments. They often run for very long periods. Phase IV trials are designed to help optimize already available treatments. As these trials generally look at standard of care treatments, the involvement from the patient is not much different from non-research treatment.

occasions, clinical trials must be closed early due to unforeseen and unacceptable adverse events or poor anti-HIV effect.

Patients in clinical trials may not know what medication they receive. In double-blinded trials, neither patients nor their treating physicians know the medication that the patients receive. This is an attempt to eliminate bias from the study.

In certain circumstances, the blind in a double-blinded trial may be “broken.” This happens rarely, however, and is usually done in response to a serious adverse event.

Not all trials are blinded. Patients will be informed prior to agreeing to enter a trial whether or not it is blinded. If a patient is uncomfortable not knowing which medications are being dispensed, he or she can choose not to enter a trial.

Patients enrolling in clinical trials do not choose the arm they enter. Patients seeking investigational treatment may end up randomized to the control arm, thereby receiving conventional therapy.

One trial conducted at Cedars-Sinai Medical Center is investigating the treatment of depression among AIDS patients through massage therapy. While patients entering the trial may have visions of receiving free massages, the study has three arms—two of which do not involve patient massage. Thus, two-thirds of the patients in the trial will not receive massages (although all patients receive vouchers for massages at the end of the study).

Clinical trials require an investment of

time and commitment. The increased treatment that patients may get as a clinical trial volunteer can be problematic. For one former clinical trial patient, participating in a trial was “inconvenient for work because there were so many clinic visits.”

### PROTECTIONS FROM RISK

“Do no harm to the patient” is one of the primary rules of medicine. Numerous safeguards have been developed to ensure



Suzette Chafey, a nurse practitioner at UCLA, records data from blood specimens.

that clinical trials are safe for patients.

The first measures designed to ensure patient safety come in the trial design.

Clinical trials must be approved by both the FDA and an Institutional Review Board (IRB). These agencies make sure that patients do not undergo unnecessary or unsafe treatment.

HIV clinical trials also have the benefit of the AIDS Clinical Trials Group (ACTG), a large system composed of researchers, industry and patient advocates. The ACTG was created to develop clinical trials that are of importance to both care providers and patients. Thus, the proper design of a useful clinical trial is the first patient safeguard.

Informed consent forms are another safeguard. Once a patient has expressed interest in participating in a clinical trial, he or she is informed of the details of the trial, including the risks involved and what will be expected of the patient. Prior to entering the study, the patient must sign the informed consent forms. Often, patients are encouraged to take the forms home and give the trial serious thought before enrolling. This is a good time for patients to discuss trials with family members, research the treatments being investigated, and generate questions for their treating physician.

Following enrollment, patients are heavily monitored in order to make sure that the treatment is both safe and efficacious. Periodically, a Data Monitoring Committee (DMC) will review the data from the trial to determine if the trial is worth continuing. If one arm is performing poorly compared with another arm, patients in the under-

# There is only one way to find out if a clin

achieving arm are often offered the choice of receiving the more robust therapy.

Patients can leave a trial whenever they want. While it is important for each patient to stay committed to the trials he or she enrolls in, the option to leave is always available. The informed consent form is not a contract and does not bind a patient to participate in the trial.

## WHY VOLUNTEER?

The amount of knowledge gained about HIV over the past 20 years has been nothing short of astounding.

Life expectancies for people with HIV have increased dramatically. The list of antiretrovirals available to patients receiving antiretrovirals has expanded from only zidovudine (AZT) in 1987 to 16 today, with more medications in the pipeline. Without the use of clinical trials and volunteers who enroll in them, these advances could not have been achieved.

Researchers continue to examine the best ways to treat HIV disease. With the continuance of clinical trials, our scientific and medical knowledge advances. This translates into more and better options for patients with HIV, increased management of treatment side effects, and, hopefully, into HIV vaccines both therapeutic and preventative.

One particular problem with HIV clinical trials is that the majority of volunteers have traditionally been white males. *The New England Journal of Medicine* recently reported that minority groups

were less likely to receive experimental procedures for HIV infection. Women also have been traditionally underrepresented.

As the face of HIV changes, the need to study these groups increases. Sex, socio-demographic background, race and other patient characteristics may affect disease course or treatment response. Therefore, getting underrepresented populations involved in clinical research is of utmost importance.



Staff at the Center for Clinical AIDS Research and Education at UCLA work with patients and perform research for clinical trials. From left, Michael Marcial; Ann Johiro, F.N.P.; Judy Carden, R.N.; Steven Miles, M.D.; Margrit Carlson, M.D. and Stevon Washington.

## GETTING INVOLVED

The first thing any patient should do is ask his or her care provider for information.

Some physicians will inform you of prospective clinical trials at the outset of treatment. Dr. Kathleen Squires, Associate

Professor of Medicine at the University of Southern California's Keck School of Medicine and Medical Director at the Rand-Schrader Clinic of the LAC+USC Medical Center, states that she offers clinical trials as a viable treatment option for patients, if they are interested, when treatments are first being discussed.

Not all physicians and clinics participate in clinical trials; not all physicians feel comfortable working in the research setting. Therefore, it may be necessary for interested patients to look at other sources of information. As Dr. Squires states, "patients must be proactive about their treatment."

The AIDS Clinical Trials Information Service ([www.actis.org](http://www.actis.org)) offers a list of clinical trials. The ACTG websites (adults: [www.aactg.s-3.com](http://www.aactg.s-3.com); pediatric: [www.pactg.s-3.org](http://www.pactg.s-3.org)) provide numerous links to sites of interest, both nationally and locally. The HIV InSite ([hivinsite.ucsf.edu](http://hivinsite.ucsf.edu)) has a clinical trial database search. Locally, UCLA ([www.medsch.ucla.edu/aidsinst](http://www.medsch.ucla.edu/aidsinst)) has a list of trials being conducted there.

Another method is through treatment advocates; treatment advocates are valuable resources and will help patients decide whether they want to get involved in clinical studies. There are many advocacy groups that can steer prospective patients to the proper gateway. Clinical

# ical trial is the right decision for you . . .



Steven Miles, M.D., of the UCLA CARE Center.

trials are also sometimes advertised on message boards aimed at people living with HIV.

Even when patients find trials they want to participate in, they must be screened prior to admission. Rejection from one trial, however, does not mean that the patient is not fit for all clinical trials. Many studies are being conducted and all types of patients are needed.

#### WHAT TO ASK

The key to knowing which questions to ask is doing background research on

the trial and medication studied.

One former clinical trial patient advises volunteers to “learn as much as you can about the drugs in the clinical trials on your own. Don’t be afraid to ask questions.” Study operators will be able to answer questions about treatment side effects, the demands the study will make on the patient, and the study design. Patients should find out what will happen to them at the end of the study, such as, if he or she be allowed to continue on the medication.

Patients will want to find out how

often they will have to go to the clinic and for how long. While most studies will pay for the cost of medication, it is important to find out if all medication expenses are covered by the treatment site. Also, patients should inquire about any potential compensation for participating in the study. Some studies will not offer any compensation, but might be able to help with transportation to the clinic.

Other questions include: Does the study require hospitalization at any point? What is the study trying to find out? What sorts of patients are being enrolled?

Most importantly, patients should ask what other options are available. Making an informed choice to join a clinical trial is difficult if other options are unexplored. Patients should ask the same questions about standard treatment options, so they may compare options and make the right decisions.

There is only one way to find out if a clinical trial is the right decision for you: Get informed. The more you find out about what it takes to be involved, the easier it will be to decide on the right course of action. Clinical trials are not for everyone. By informing yourself and talking with your health-care provider and treatment advocate you can determine if you are ready to volunteer. ✚



Michael Linde is a graduate student at the University of Southern California. He previously worked as an HIV writer in New York City and Washington, D.C. He can be reached by e-mail at

linde@usc.edu.

## . . . Get informed.

# Glossary

*of terms commonly used in clinical trials*

## *Adverse Event*

**A side effect that results from the use of a treatment.** Life-threatening side effects are called “serious adverse events.”

## *Arm*

**A branch of the study.** Most studies are divided into groups, or arms, designed to compare one treatment arm with another.

## *Bias*

**A flaw in the study design that could skew the results in favor of a particular conclusion.** Researchers try to eliminate bias in clinical trials to get an impartial and scientific result; however, it is very hard to eliminate all bias from a study.

## *Control*

**The standard that is compared against.** In order to determine if a new treatment is beneficial, it must be compared against a standard. Almost all clinical trials have a control arm.

## *Data Monitoring Committee (DMC)*

**An independent panel that monitors the study results.** The DMC is used to help eliminate study bias. The DMC may also intervene to stop a trial if one arm is found to be unsafe or sub-standard.

## *Double-blind*

**When neither the patient nor the health care providers know which medications are being dispensed to trial participants.** Double-blind studies are used to get impartial results and eliminate study bias.

## *Informed Consent*

**The process of educating a potential clinical trials participant so he or she can make an educated decision as to whether to join a clinical trial.** All patients must be informed of their rights as a participant, the safety hazards they might face, the study aims, and what is to be expected of him or her. Patients must sign an informed consent form to attest that they have received this information.

## *Institutional Review Board (IRB)*

**A panel created to look at and approve or reject clinical trial study proposals.** An IRB is mandated by the FDA and is composed of many different types of people, including researchers, ethicists, lay people, treatment advocates, lawyers, clergy, and others. Clinical trials must be approved by an IRB before they can begin. IRBs are used to help ensure that patients are not exposed to unreasonable or unnecessary risks or unethical treatments.

## *Phase*

**The stage of the trial.** Clinical trials are divided into phases I, II, III and IV. The lower the phase number, the earlier the treatment is in the development pipeline.

## *Placebo*

**An inactive medication given as a control in some clinical trials.**

## *Randomization*

**The process of randomly assigning clinical trial volunteers into separate arms.** This is done to make sure that the arms are evenly balanced by patient characteristics and that bias is not introduced by the assignment of patients.

## *Standard of Care*

**The conventionally given treatment.** It is unethical to knowingly assign patients to treatments that do not meet the standard of care.



# tears

of Mel Becker

Scores of my acquaintances have passed away.

At about 100 deaths, I stopped counting. I think that was when I realized that I was using a “number” and that the only part of that word that was relevant was the first syllable “numb.” Numbers don’t emanate from the heart. The heart doesn’t count numbers.

For me, it started some 20 years ago when I heard that a friend by the name of Chuck was taken to the hospital with an unknown illness. Chuck displayed signs of dementia, among other things, and within a couple of weeks, he died.

We were told that Chuck had contracted this new “gay disease.” Like all of Chuck’s friends, I was confused. And I was puzzled when I was told that it had started showing up in New York City.

What was it? Where did it come from? Could it only strike homosexuals? Naw! Diseases don’t discriminate. Diseases don’t hate because of sexual orientation.

Besides, the purveyors of hate couldn’t be right.

Everyone ignored this new “inconvenience.” We partied, played around and had lots and lots of fun. Whatever it was, it couldn’t happen to me. Besides, like any disease, all we had to do was go to our doctor, get a shot and in a few days be back into the swing of things.

Then this insidious creature started to pop up with more frequency. We started to hear about this person and that person coming down with unusual symptoms and illnesses. New words like *pneumocystis* and *Kaposi’s Sarcoma* began to appear, first in print and, eventually, in our own vocabularies.

We started to get concerned, then worried, when friends became ill with more and more frequency. People began dying and they started to call it a “plague.” More people died and now everyone began to panic. Then, for me, it hit home.

Joey was family. He was my best

friend’s roommate and I saw Joey five times a week.

My friend had everything going for him: a great career, a new home and Joey was special. A fun, wonderful, caring and generous human being. Maybe too much fun. Joey liked to go out every night. Joey liked to party. Joey liked to do drugs. And Joey liked to have fun – a lot of fun.

FUN! A synonym for sex. It was toward the end of the hippie era. A time of sex, sex and more sex. All you had to do was get out of bed in the morning and before you could blink you were back in bed, and not by yourself. You didn’t have to look very far and you could get it practically anywhere, private or public. Sex clubs, bathhouses, bars, parks, just to name a few places. It was there for anyone and everyone.

Joey fell ill. After a few days he was taken to Cedars-Sinai where they performed all kinds of tests. They prodded; they poked; and then they said, “It appears that Joey has this new gay disease. A report of 20 pages or so came down to just two words: Gay disease.

Joey was in the beginning stages. After a while, he went home and led a normal existence, as far as he could under the circumstances. He went back to work and, several months later, his face was horribly disfigured after being injured at his workplace. Joey was hospitalized and, against his will, I visited him several days later.

As I walked into the room, Joey covered his face. I said “Joey, it’s me, cut it out.” Joey lowered his hand and couldn’t look at me. “Hey, you were always ugly,” I said, “you look better now than you ever did.” I got Joey to laugh. In fact, we laughed together for several minutes.

I had to excuse myself and leave the room. The dam inside my heart started to crack. The tears didn’t start with a trickle. No, they did not come one by one. It was a deluge and I could not control myself. When I thought that my heart was dry the tears started again until, finally, I was

able to regain my composure.

Two days later, I visited Joey again. I put on my best face and walked into the room with a big smile. “Hey, you old slut,” I said. Joey let out a short laugh and looked at me with a puzzled look. After a few seconds, he said, “Who are you?”

I thought he was joking. He wasn’t. After what seemed like an eternity, Joey said, “I remember you. You’re the funny one.” I didn’t think it was that funny and my heart started to come apart again. The tears kept flowing.

Joey left the hospital and went home. He was self-sufficient until he had a series of strokes that left him partially paralyzed. However, he was able to take care of himself for over five years when he decided that he had had enough. He was too tired to go on and he gave up. Joey passed away.

That was yesterday. Yesterday took many others, and the tears have never stopped. Some died horribly; some died peacefully. Some even took their own lives. I tried covering my heart with bandages only to find that they were made of gossamer.

I stopped counting long, long ago. The deaths seemed to slow down. However, the tears still kept coming, for the present and for the past.

One year ago, I was taken to the hospital. It had happened to me and I had two weeks to live. With the good grace of God, and the care, and caring, of my doctors and innumerable support people, I am still here. I’m active! I’m kicking! And I’m alive!

It’s funny. My heart did not tear when it came to me. Not one tear! However, in the last two months, I have lost two close friends and my heart started crying again.

The tears flowed and flowed and flowed. +

I stopped counting at 100.

## Work *From Page 15*

### ADDRESSING LEGITIMATE FEARS

Working or considering work can be a unique challenge for those managing HIV disease and the side effects of treatment.

APLA and EDD are committed to meet the full range of employment opportunities of people with HIV/AIDS. That means access to on-site return-to-work benefits and insurance counseling, discussing HIV disclosure and confidentiality, strategies to explain years of unemployment on résumés, and advice on obtaining financial assistance for education and training to get back into the job market.

### SCHOOLING YOUR WAY TO WORK

In today's fast-changing job market, a majority of workers will change careers an average of four times.

Upgrading job skills benefits almost anyone who is out of work and looking for a job. For people who have been out of work for a number of years, getting



## the Breakfast Club

8:30 to 9:30 a.m. each Tuesday  
David Geffen Center

611 S. Kingsley Drive, L.A. 90005  
Networking for HIV-positive job seekers  
(213) 201-1616

good job training is especially important. There are a number of programs to pay for education and job training, both for the disabled and for job seekers in general.

APLA offers a comprehensive workshop series devoted to helping people with HIV gain access to resources to fund education and job training. Voc Rehab and the Work It! Series are generally offered the fourth week of each month at APLA West, 639 N. Fairfax Ave. Voc Rehab features Judith Borstein who has been assisting APLA clients for more than three years. Judith covers eligibility, applications and Department of Rehabilitation services for disabled folks who need training to get back to work. The Work It! Series covers most sources of funding for education and training as well as HIV & Work issues.

For workshop information and reservations call Rice Russell (213) 201-1616.

For someone who has been on disability, going to work can yield many benefits. Besides providing you with additional income, work gets you out of the house among other people, and gives you a feeling of being productive.

Getting familiar with the resources available to you is an important step that you may be glad that you took. +



Rice Russell is a Work services Specialist in AIDS Project Los Angeles' Benefits and Work Services Program. He can be reached by calling (213) 201-1616 or by e-mail at [rrussell@apla.org](mailto:rrussell@apla.org)

## Serostim *From Page 26*

month in which the Serostim is prescribed. Recent fraud cases involving Serostim and its incredible expense make these repeated requests for medical information and a monthly TAR requirement "reasonable" under these circumstances.

### WHAT TO DO ABOUT DENIALS

Treating physicians may prescribe Serostim for an "off-label" problem or for a wasting condition which Medi-Cal decides is not so severe. This is when the recipient must file the appeal and request the hearing. This is when Medi-Cal may have made a mistake.

There is a problem with Medi-Cal's new approval system for Serostim: If the recipient has received Serostim in the past, has responded to the medication – and therefore has experienced an improvement in his or her condition, that recipient may not meet the body cell mass and other wasting guidelines to qualify for ongoing Serostim payments by Medi-Cal. This

suggests that the recipient's condition must re-deteriorate before Medi-Cal, once again, will cover this medication. If this sounds wrong to you, the doctors are not happy, either, since this could create ethical problems for the doctors who are supposed to prevent deterioration of the recipient's condition.

While Medi-Cal is allowed to implement reasonable regulations on its approval of prescribed medications, Medi-Cal is not allowed to substitute its medical judgment for the judgment of the recipient's treating physician. If the recipient's condition satisfies the "label use" for a Serostim prescription, then Medi-Cal must approve it. If the recipient's condition is for an "off-label" use, such as the reduction of lipodystrophy/the buffalo hump, Medi-Cal still should approve it, if supporting literature and other evidence has been submitted which justifies the use of this medication for this additional ailment. If the recipient's condition has responded to prior use of Serostim, but the treating physician believes that ongoing access to Serostim remains medically

necessary, then the recipient has grounds for an appeal, if Medi-Cal denies a subsequent TAR.

If you believe Medi-Cal has denied a Serostim, or any other HIV-related medical prescription, in an improper manner, please call the HALSA intake line: (213) 201-1640 for more information.

If you have general questions about Medi-Cal eligibility, approved drug, and the TAR procedure, contact AIDS Project Los Angeles' Benefits Department at (213) 201-1472 or AIDS Service Center at (626) 441-8495. +

*Funded by the County of Los Angeles,  
Department of Health Services, Office of  
AIDS Programs and Policy*



Leslie Kline-Capelle is the Public Benefits Staff Attorney at the HIV & AIDS Legal Services Alliance. HALSA can be reached by calling (213) 201-1640



## My path to peer advocacy

My name is Kimbery Howard. Before I became a peer advocate at AIDS Project Los Angeles, I was a client.

I was diagnosed with full-blown AIDS on Feb. 13, 1998. After receiving this news, I came straight to APLA to find out what was available to women.

At APLA, I learned what a T-cell count was and how important a low viral load is. I went to the women's luncheons with my mom, and we gained knowledge together. I began to meet other women who were infected and affected by HIV/AIDS. I became active in speaking out on issues regarding HIV/AIDS and I began to volunteer at APLA.

Last February, a position became available at APLA for a peer advocate. The job description was to educate my peers. My definition of this is to help others know what meds are available and what is on the frontier . . . to educate women on what they need to ask of their doctors . . . to make them aware that HIV/AIDS affects them not only physically but men-

tally and spiritually . . . to give them all the options available to help them make informed choices.

On the second and fourth Wednesday of each month we have Women's Luncheons. Many of the women who attend these luncheons are the same women who were here in 1998 to welcome me. I feel as though my life has come full circle.

As a client I know I need a lot of information in a basic way, so I try to continue that effort. As a woman, I know that I tend to take care of others before my own needs. So at the luncheons I always try to do something special.

If you're a woman with HIV/AIDS—infected or affected—please know that I am here to talk things over with, provide support and help you find answers to your questions. Please contact me at (213) 201-1677 or drop by the David Geffen Center, 611 S. Kingsley Drive, Los Angeles. ✦

## KidzKorner

By Emily Land

A strong relationship exists between language development and reading ability in the primary grades and beyond.

Books contribute in many ways to children's ability to learn language. To understand what is happening in a story, the child must focus on language more than he or she needs to in real-life context, and this may help to promote

language learning. A history of story-reading experience may also be associated with good language development because a story has the potential to prompt discussion.

Simply talking and hearing lots of talk from adults promotes children's language learning. Talking with children and listening to what they are saying,

then expanding on this in any context, promotes more talk from children.

Adults help to clarify words that children do not understand. Adults can also ask questions about children's comments as they try to verbalize about stories and happenings. Hearing lots of adult talk promotes children's language learning. ✦

# BUILDING BETTER BONE

By MARCY FENTON, M.S., R.D.  
& COURTNEY SANDERS

**B**one is a living and growing tissue that is constantly being built and broken down.

Bones make up the skeleton, which support the structure of the body, protect organs and stores the minerals, calcium and phosphorous. Calcium and phosphorous are released from bone and involved in essential functions, including blood clotting, nerve transmission and the movement of fluid in and out of cells. The body must have enough calcium and phosphorous from the diet to perform these functions, and if it doesn't, bone will be broken down to get it!

Bone grows in length and density during childhood and reaches maximum length during adolescence, 16-20 years. Bone reaches its peak density between the ages 20 to 30. After that age, more bone is broken down than is being built and bone becomes lighter and more brittle.

Building strong bones before the age of 30 is important. After age 30, minimizing bone loss is important.

Two bone disorders have become a new problem for people living with HIV. Osteopenia occurs when there is a loss of bone mass and bone density and osteoporosis

Courtney Sanders, a dietetic intern from West Los Angeles Veterans Administration Medical Center, developed this article during her rotation with AIDS Project Los Angeles' HIV Nutrition Education Program.



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## Keeping your bones healthy

- Eat foods rich in calcium and vitamin D every day
- Talk with your doctor about a supplement if you are not getting enough from food
- Be physically active, especially weight-bearing and resistance exercises
- Do not smoke
- Do not drink alcohol

### Good Sources of Calcium

Calcium sources	Serving Size	Mg of Calcium
Milk (whole, 2%, 1%)	1 cup	300
Yogurt, plain	1 cup	415
Cheese, Swiss	1 oz. or 1 slice	272
Cheese, Mozzarella	1 oz. or 1 slice	185
Broccoli, frozen, cooked	1 cup	94
Kale, frozen, cooked	1 cup	179
Fortified orange juice	1 cup	300
Fortified soy drink	1 cup	180
Canned sardines with bones	3 oz.	325
Cornflakes	1 1/3 cup	237
Tofu (check labels; calcium content varies)	1/2 cup	130-260

### Daily Reference Intake (DRI) for Calcium

Age 9-18, 1300 mg; age 19-50, 1000 mg; age 51 and older, 1200 mg

sis is the diagnosed condition when there is a more severe loss of bone mass and bone density, resulting in weak and brittle bones that are more likely to break. It is unclear if this increase in osteoporosis for people living with HIV is caused by HIV or by the medications used to treat HIV.

Prevent your bones from becoming weak. Be sure to get enough calcium and vitamin D rich foods in your diet every day. Good sources of calcium include dairy products and green, leafy vegetables such as broccoli and kale. Orange juice, soymilk, cereals, breakfast bars and other calcium-fortified products are also good sources of calcium.

Vitamin D allows the calcium you eat from foods and supplements to be absorbed

### Good Sources of Vitamin D

Vitamin D sources	Serving Size	IU of vitamin D
Milk, 1%	1 cup	97.6
Egg yolk	1 large	24
Fish liver oil	1 Tablespoon	1360

### Daily Reference Intake (DRI) for Vitamin D

Age 9-50, 200 IU; age 51-70, 400 IU; age 71-plus, 600 IU

into your bloodstream. It can be found in dairy products, egg yolks, fatty fish, fish liver oil, and breads and cereals fortified with vitamin D.

Vitamin D is also made in the skin from sunlight exposure. Depending upon the time of the year and where you live, about 10 to 15 minutes in the sun two to three times a week with your hands, arms and face exposed helps meet your body's requirements for vitamin D.

Physical activity is another necessary factor in bone health. Just like muscles, bones become stronger the more you use them. Weight-bearing and resistance exercise can help to:

- Achieve peak bone mass in children and adolescents
- Help to maintain or slightly increase bone density in adulthood
- Help to minimize age-related bone loss in older adults

It is important to keep an active lifestyle with a variety of activities to have healthy bones. Weight-bearing activities are those in which bones and muscle work against gravity. Weight-bearing activities include running, dancing, soccer and volleyball. Swimming and bike riding are not weight-bearing activities. For older adults, activities such as intense walking and low-impact aerobics may be just fine. Resistance exercise, such as weightlifting, is another type of activity that strengthens both muscles and bones.

Alcohol and smoking negatively affect bone health. In men and pre-menopausal women, alcohol affects certain hormones that cause calcium to be withdrawn from the bone. Over time, this can lead to a large loss in calcium from the bone.

Alcoholics often have weak bones, tend to lose their balance, have trouble walking and therefore are more likely to fall and break a hip. Smokers, more than non-smokers, have lower bone density and need to be concerned about their bone health. In post-menopausal women, moderate consumption of alcohol may have a positive affect of increasing bone density by increasing the conversion of testosterone into estradiol, a hormone that prevents bone loss. +



Prior to the use of protease inhibitors, one of the greatest fears of a person living with HIV/AIDS was having the “look” of a person with HIV-associated wasting.

Loss of lean body mass and fat causes this skeletal appearance. Even in the era of HAART, HIV-associated wasting still occurs and has a significant effect on quality of life, illness and death.

The fact that wasting is not talked about much, not recognized or even monitored may be due to the focus placed on the body shape or metabolic (elevated blood fats, insulin resistance) changes occurring today. Wasting still occurs and to properly manage it, early detection and frequent monitoring is necessary.

A Bioelectrical Impedance Analysis (BIA) test is one tool to estimate body composition and monitor for wasting.

## BODY COMPOSITION

Part of a person's body weight is comprised of bone, water, muscle, organs, blood and other materials and is referred to as lean body mass or fat-free mass. The rest of a person's body weight is fat.

A specific part of the lean body mass plays a crucial role in fighting infections and the day-to-day chores the body must perform to keep functioning. This part is called body cell mass and includes skeletal muscle, organs, other cells and fluid. A minimal amount of body cell mass must be maintained by the body to support its



BIA tests take less than three minutes to perform and are painless.

day-to-day activities plus fight infection.

Loss of body cell mass is wasting.

Here are some commonly asked questions about HIV-associated wasting:

### Are scales that give body fat percentage useful?

Scale weight alone is not an adequate indicator of internal health. When someone loses, gains or even maintains weight, the composition of that weight needs to be frequently assessed and monitored.

## A tool to fight wasting

### BIOELECTRIC IMPEDANCE ANALYSIS CAN YIELD IMPORTANT INFORMATION

By Janelle L'Heureux, M.S., R.D.

If weight gain or weight loss has occurred, was it in fat or body cell mass? And if weight has remained stable, has the makeup of that weight changed internally?

Frequent monitoring with a BIA test can provide answers to these questions. Other machines on the market may only give weight and fat percentage and not provide the body cell mass component. Not to downplay the need to monitor fat stores and at the same time satisfy everyone's curiosity, the body cell mass is the component associated with wasting and survival.

### How can I keep and increase body cell mass?

Adequate intake of calories from protein, carbohydrates and fats, plus adequate fluid, are part the solution. Viral suppression, exercise, hormonal regulation and absence of opportunistic infections are also needed to maintain and increase body cell mass. If you are experiencing loss of appetite or side effects that interfere with

food intake, speak to your doctor and dietitian for suggestions. Not eating enough leads to weight loss and can further compromise your health.

### Do BIA tests hurt?

No, the test is painless. A person lies on a massage table and electrodes are placed on his or her hands, wrists, feet and ankles. The test requires less than three minutes to perform. No blood is drawn for a BIA test.

### Where can I get a test?

Some doctors are doing BIA tests. That way, your test results get put into your medical chart to help direct the course of your medical care. AIDS Project Los Angeles offers a Preserve Lean Body Mass Class with BIA workshop twice each month. During this workshop, measurements of the waist, mid-arm, chest, plus a tricep skinfold measurement, are taken to track changes associated with body shape. A BIA test should be done more than once to monitor any changes over time. Clients are urged to return and repeat the test every four months.

If you are interested in attending the class and having a BIA test or any other classes, please call Janelle L'Heureux, M.S., R.D., at (213) 201-1556 or Marcy Fenton, M.S., R.D., at (213) 201-1611. +



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# HOUSING ISSUES HOUSING ISSUES

Reports show that approximately 500,000 persons living with HIV nationwide will use HOPWA funds during the course of their illness. Unfortunately, the need is greater than the available funding.

## HOPWA IN LOS ANGELES

At the local level, the HOPWA program is facing dramatic changes:

- The waiver for the HOPWA Short Term Rental, Mortgage and Utility Assistance Program (STAP) has been denied by HUD, and most STAP clients could become ineligible for further assistance this year.
- The HOPWA Coordinator, the City of Los Angeles' second highest-ranking employee dedicated fulltime to HIV issues, has been relieved of her duties.
- Current HOPWA service-providers face funding cuts of up to 35 percent beginning April 1, 2003.

The Los Angeles City Council and the Mayor's office provided up to \$3 million in supplemental funding for the continuation of the HOPWA program during the current fiscal year (FY 2002) which will expire on March 31, 2003. By April 1, 2003 funds will be dramatically decreased.

Last year, the Los Angeles Housing Department (LAHD) applied for a waiver to continue to provide rental assistance to clients through the STAP program every 90 days, which was granted by L.A.'s HUD office. This year, the LAHD applied for a waiver to continue operating the program, but HUD (the Washington, D.C., office) denied the waiver. The LAHD are very supportive of the program and its continuation, and are in negotiations with HUD.

With all these new changes at the local level, thousands of individuals and families living with HIV/AIDS could be at

risk of becoming homeless.

## A CRITICAL NEED

Studies confirm that stable housing is one of the greatest needs of persons living with HIV/AIDS.

Without stable housing, people with HIV/AIDS cannot adhere to complex drug regimens, nutrition and care vital to survival. Stable housing, along with appropriate supportive services responsive

and communities of color. Many HIV-positive people in Los Angeles are coping with two other major issues: homelessness and mental illness. The vast majority of households have been living on incomes of less than \$6,000 per year.

You can voice your opinion on this issue by calling your City Council member. Express your concerns and explain how this program has assisted you, your friends, family, your loved ones and your clients. +

## Programs threatened

### POOR, LOW-INCOME INDIVIDUALS, FAMILIES ARE AT RISK OF HOMELESSNESS

By Marlon Valdivia

to individuals' complex needs, increases the ability of access and compliance with critical life-sustaining HIV/AIDS treatment.

Without stable housing, people with HIV cannot adhere to vital nutrition. Many anti-HIV drugs require specific nutrition guidelines to their absorption into the bloodstream. Other medications need to be taken with specific food products to offset the side effects.

## HOMELESSNESS IN L.A.

In 2000, the HOPWA program in L.A. assisted approximately 10,000 people with HIV; in 2001, HOPWA assisted approximately 13,000 people. Without the sufficient housing subsidies that HOPWA funding supports, poor and low-income persons in every part of Los Angeles County—and their families—are at significant risk of homelessness.

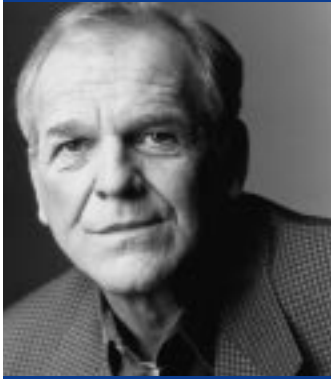
AIDS is a disease that increases the risk of homelessness, disproportionately affecting persons with very low-income



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# I walk because...



John Spencer

**“Being HIV positive doesn’t mean giving up.”**

Rudy Galindo



Whoopi Goldberg

**“It ain’t over.”**



Eric McCormack

**“I’ve lost so many friends too soon.”**

**“A whole new generation is at risk.”**

Vanessa Williams



Madonna

**“AIDS is a disease that still kills people.”**



Eric McCormack

**“Giving up this fight is not an option.”**

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LOS ANGELES  
**OCT 20**

**A ten kilometer fundraising walkathon in West Hollywood**

**Benefiting**



**and other AIDS service organizations across Los Angeles County**

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