

# **Resolute!**

*Dedicated to Surviving HIV/AIDS*

*A Publication of the PWA Coalition Colorado • Spring 2004*

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## *The 11th Conference on Retroviruses and Opportunistic Infections Update*

**Letters  
from Africa:  
Partners in AIDS  
Services send  
home stories of  
hope and  
compassion.**

**Abbott  
Labs Hikes  
Price of Ritonavir  
400%!  
But Where Should we  
be Directing our  
Outrage?**



A Publication of  
The People With AIDS Coalition Colorado

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CIRCULATION: 4,000      ISSN: 1072-1606      2004, Resolute!, Inc

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PWA  
COALITION COLORADO  
EMPOWERING PEOPLE LIVING WITH HIV AND AIDS THROUGH  
EDUCATION AND ADVOCACY.

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It is well documented that people who receive care from HIV specialists live longer and healthier lives. The PWA Coalition Colorado recommends that all people living with HIV/AIDS seek medical care from health care providers who focus on HIV care and who are competent, licensed, and fully HIV/AIDS-informed.

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This issue of *Resolute!* was funded through a variety of sources. We would like to gratefully acknowledge the following contributors for their support.

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From the Editor

## It's Bigger than HIV Folks

By Shelley Cohen McKittrick

Whether it's Abbott Labs and their obscene Norvir® (ritonavir) price increase, or the upcoming presidential election, or Matt Kailey's article on gender in this issue of *Resolute!*, the fact is, it's not just about HIV. In general, this periodical focuses on accurate HIV treatment education. But we are all citizens of the US and the World. We don't live in an insulated, isolated world of only HIV - Thank God! And therefore we need, sometimes, to contextualize events happening in our community; to look at the bigger picture. I'd like to look at the Abbott issue from that broader perspective.

The problem:

- ⇒ Abbott Laboratories increases the price of Norvir® 400%, holds Kaletra® price steady.
- ⇒ Community accuses Abbott of:
  - A:** Trying to control the PI market by making Kaletra® the most cost-effective boosted PI, leading to increased prescribing of *their* drug over other boosted PI regimens;
  - B:** Discourage further development of protease inhibitors (like tipranavir) that are necessary, but dependent on ritonavir boosting;
- ⇒ HIV physicians and activists call for a boycott of Abbott and pricing roll-back;
- ⇒ This does not happen, but Abbott agrees to:
  - A:** Freeze the price of the current formulation of ritonavir (that requires refrigeration and causes icky gastro-intestinal side-effects) for Medicaid and ADAPs forever. (*Gee whiz, we're so grateful that poor people will always have access to the older version of a medication after a better one comes out.*)
  - B:** Start making available bottles of 30, 100mg capsules, so that a month's supply is less expensive per bottle (not per pill).
  - C:** Offer the current ritonavir 100 mg caps to clinical development trials for the former per-pill price of \$1.71.

⇒ Oh - and they opened up their patient assistance program to anyone who needs it, regardless of income.

Now, in my opinion, when a pharmaceutical company like Abbott Labs carries out a ridiculous act like a 400% price increase on a drug that's been on the market for nearly 8 years, we need to jump out of our HIV box and look at the core problem. We have a corporate, profit-mongering pharmaceutical industry in this nation of ours. We have, effectively no pricing controls and incredibly generous patent laws. There is no mechanism for accountability when it comes to calculating the cost of research and development (the age old excuse for the outrageous pricing of medications). It is nearly as ridiculous for us to focus all of our anger at Abbott Labs as it is for our society to focus its efforts to fight "the war on drugs" by putting addicts in jail. It's not about Abbott and it's not about addicts; it's about our society's priorities and how we legislate those priorities.

Is the most effective mechanism for change, AIDS activists acting up at an individual corporate atrocity? Or, by now, shouldn't we have joined forces with the rest of the health-advocating communities to change the system; to elect individuals who would truly fight for real health care and real campaign finance reform; to elect individuals who would fight to stop the lobbying that runs this country; to elect individuals who would actually act on behalf of *the people*, not *the corporations* our government protects?

Abbott's actions are reprehensible. Shame on them. Individual corporations *should* be held accountable for their actions. But we need much bigger reform than action against one company can bring. We need a truly regulated pharmaceutical industry. And perhaps, we should be worrying about which *companies* our elected leaders are sleeping with, rather than which White House aides.

## PWACC Salutes Top Fund Raisers for 2003

The PWA Coalition Colorado would like to thank the following individuals whose donations and fundraising in 2003 helped us continue serving the Colorado HIV Community.

⌘ Dr. Ben Young for his generous donation of \$8,000 in speaking honorariums.

⌘ Vince Kassube, who selflessly turned his thirtieth birthday on August 24th into a fundraiser for our Colorado AIDS Walk Team, soliciting not only his friends and family but also everyone who lived in his apartment building. Vince's efforts raised \$3,438 and made him our top AIDS Walk participant.

⌘ Frankie Siebert, who tirelessly raised AIDS Walk donations for not only PWACC's team but also Project Angel Heart and Colorado AIDS Project. Frankie's efforts resulted in \$1,310 in donations for PWACC.

⌘ Barbara Gabriel, Jay Woodward, KC Loomis and James Connor, who each raised over \$500 for our AIDS Walk Team.

⌘ Charlotte Schaffner for her annual donation of \$500 in memory of her son Bill.

⌘ Thomas Hurley, who personally raised enough funds from friends to enable us to hold our Annual Summer Barbeque for the Community.

⌘ Emily Haack, Natalie Green and Amy McCord who each raised over \$300 for our AIDS Walk Team.

⌘ Dr. Ken Greenberg for his donation of \$1,500.

⌘ Jeffrey Hopper for his monthly support through the year.

⌘ Michael Beatty for making PWACC the beneficiary of Weekend In Oz.

⌘ Sarah Wolfgram and Ron De Herrera for organizing PWACC's first Art Auction.



*Frankie and Vince, at Vince's Birthday Party*

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*I presented the following keynote address, which has been edited for this publication, at the Pikes Peak Gay and Lesbian Community Center Awards Dinner on February 7, 2004. It addresses the idea of community -- something we all need now in the face of current political efforts to tear us apart. Now, more than ever, we all need to stand strong -- together. The complete address can be found at my Web site, [www.mattkailey.com](http://www.mattkailey.com).*

# ***It's All About Gender - Discrimination***

**Keynote Speech -- Pikes Peak G&L Community Center**

**By Matt Kailey**

We're here tonight to celebrate the achievements of our community. We talk about, celebrate, fight for and fight about our community a lot. But, in reality, do we know what "our community" is?

Some call it the "gay and lesbian community." Others say the "GLBT community." And still others, after taking a deep breath, say the "GLBTQQI community -- gay, lesbian, bisexual, transgender, queer, questioning and intersex--GLBTQQI." That's a lot of letters and there are still more that we probably can and will add. In fact, we can keep adding on letters forever, just to show that we're inclusive, but unless we are ready to make a solid commitment to the word "community," that's all we will have -- a string of letters. No matter where any of us are with relationship to that commitment, we each need to constantly examine and reexamine what "community" means to us.

When I started my transition and began working as an activist in the GLBT community, I met a great many wonderful, open and accepting people. I met people from organizations that had formed as GLBT organizations, without any debate as to whether or not the T belonged there. I met others who began as GLB organizations and later added T to their names when they realized the commonalties -- the community -- that we all shared. But I also met some who were fighting tooth and nail to keep the T as far away from their GLB as possible.

It was a struggle to figure out where I fit in my new community -- especially because I discovered that my new identity was, in fact, often in conflict with itself underneath the banner of GLBT. The "problem," you see, was my attraction to men, something that is perfectly acceptable when you are a heterosexual female. But because of this attraction, when I transitioned from female to male, within a matter of months, I went from being what society saw as a straight female to being what society saw as a gay male.

I went from straight to gay. I changed my sexual orientation, something that has never been successfully accomplished by anyone in Exodus, International. But when I thought about it, I realized that I hadn't changed my sexual orientation at all -- I only changed my label. My attraction, which was to men, remained the same. What I did change was my gender. And that's when I realized then that sexual

orientation has very little to do with the gender you're attracted to and everything to do with the gender that you are. The label that you receive from our culture -- straight, gay, lesbian, bisexual -- based on who you love has to do with your gender.

So based on my gender, I was suddenly gay. But as I went merrily along my way, trying to assimilate into my new community and my new gay identity, two phobias reared up in front of me -- transphobia and homophobia. I had expected to experience these things from outside my new community, but I never expected that they would come from within it.

Transphobia. When I tried to claim my new status as a transperson under what I thought was a GLBT umbrella, I discovered that trans people are the stuff of some GLB nightmares. You're trans? You don't belong here. You're different; you're strange; you're not one of us. You're weird. You're sick. Please stay away from us; you'll only bring us down. We've worked so hard to get where we are, to prove we're just like "them," and if "they" think you're one of "us,"

you'll destroy everything we've worked for. This wasn't coming from straight people, folks. It was coming from some members of what I thought was "my" community. What did that mean? Was the T on the end of GLBT some kind of trick? Was I really not wanted here?

Maybe I could find solace with "my own kind." But when I turned to some members of "my own kind," I got hit with something else. Homophobia. You're gay? You don't belong here. You're different; you're strange; you're not one of us. You're weird. You're sick. Please stay away from us; you'll only bring us down. We've worked so hard to get where we are, to prove we're just like "them," and if "they" think you're one of "us," you'll destroy everything we've worked for. We're not gay. We don't want T on the end of GLB. We don't want to be there at all.

Well, by that time there was no turning back, so I realized that I had some serious thinking to do. And that's when I came back to gender. Both sides were wrong. Yes, the T does belong on the end of GLB, no matter who wants it there or who doesn't. It belongs there because it's all about gender.



*Continued on page 27*



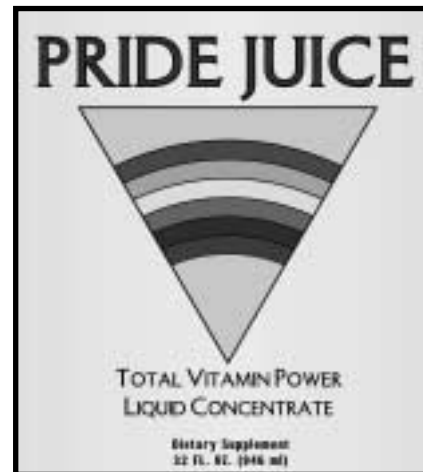
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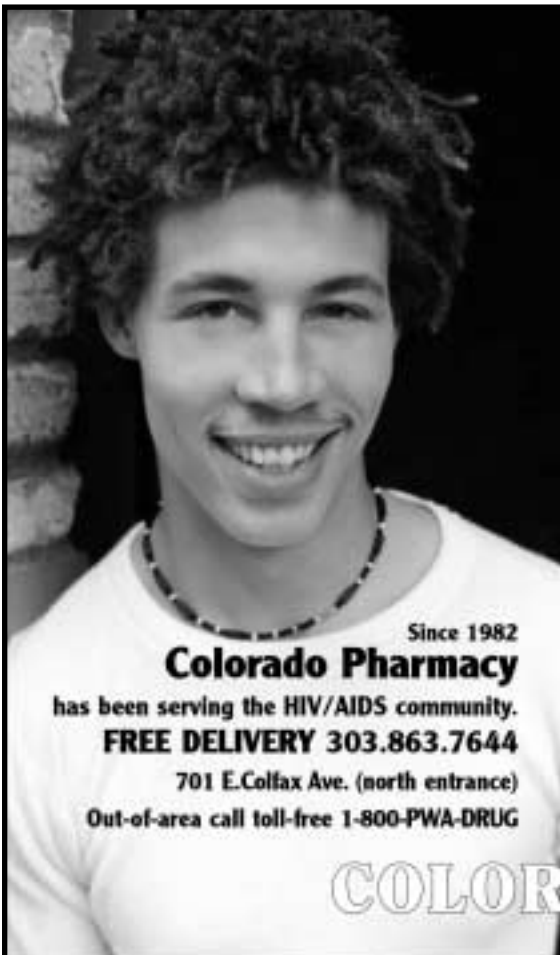
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No one would disagree that living with HIV/AIDS is tough. Constantly and consistently taking medications, trips to the pharmacy, endless doctor appointments and the lab work that comes with them can all add up to feeling like the virus has taken control of your life. Now imagine for a moment that you have another virus in your body, one that is trying to destroy your liver. Hepatitis C (HCV) does just that, it attacks the liver of the person it is living in. Unfortunately, HIV/HCV co-infection is a reality for many of us. Estimates range anywhere from 15% to 40% of people infected with HIV are also infected with hepatitis C.

Much in the same way HIV tries to destroy a person's immune system; HCV relentlessly attacks the liver causing damage such as fibrosis, cirrhosis, liver cancer and eventually liver failure. Hepatitis C alone can cause a person to need a liver transplant, and when coupled with HIV in the body it progresses much faster. End stage liver disease (ESLD) is one of the leading causes of death for people living with HIV.

Hepatitis C is spread by blood. Transmission risks include IV drug use, tattoos, body piercing, blood transfusions prior to 1992 and transfusions of clotting factor prior to 1987 to treat hemophilia. Less common means of transmission include sex, and "household transmission"; including sharing razors, toothbrushes, nail clippers and files. As you can see, HCV has

many of the same transmission risk factors as HIV does. Because of these similarities in transmission, it is strongly recommended that everyone who has been diagnosed with HIV be tested for HCV and everyone who has HCV be tested for HIV as well.

One of the unique characteristics of the liver is that it has no sensory to feel pain; so many people will live decades before having any symptoms of hepatitis C. Once symptoms do occur, they are often vague and most physicians will mis-diagnose the chronic fatigue, nausea, and abdominal pain as the flu. But a simple blood test is all that is

needed to find out if you have hepatitis C. Ask your doctor if you have been tested for HCV, if not, get tested. The medications used to treat HCV can cause side effects, but they can also save your life.

May is Hepatitis C Awareness Month in Colorado. To learn more about HIV/HCV co-infection please join us at the Galaxy Grill for a PWA Coalition Colorado/Hep C Connection collaborative Community Dinner and Education Forum on May 24th from 6:00 - 9:00 pm. You can also contact me at Hep C Connection at 720-917-3970 or 800-390-1202 with any questions regarding HIV/HCV co-infection.

*Daniel Reilly is the Co-infection Program Manager at The Hep C Connection,*

## HIV/HCV Co-infection Concerns

By Daniel Reilly

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The Beacon Clinic has some great changes for 2004 -- a new doctor, a new location and a Ryan White Title III federal grant! All of these changes equate to better, more comprehensive care for Boulder and Broomfield counties and much of northern Colorado.

Dr. Heather Pujet has come to us from Massachusetts General Hospital in Boston. We are thrilled to have her. She loves working with HIV/AIDS patients and her knowledge is remarkable. Dr. Pujet is also bilingual in Spanish. Since her father is Peruvian, she has spent portions of her life living in South America. Patients who have seen Dr. Pujet have given her rave reviews. We know she is going to be a great asset to the clinic.

On a bittersweet note, Dr. Charles Steinberg has left the clinic in order to teach HIV/AIDS medicine to doctors in Uganda. He had been trying to leave for awhile, but had been delayed due to the instability of that region of Africa. We are sad to see him go, but very proud of the work he is doing. Dr. Pujet has taken his place.

As some of you may know, Boulder Community Hospital has been extremely generous in supporting the Beacon Clinic. We would not be here without them. Now Boulder Community Hospital has become the recipient of a Ryan

White Title III grant. The federal government will be giving us \$1 million over the next three and a half years! This grant means many things. First, the hospital will be supported in its dedication to serving uninsured HIV/AIDS patients. Second, we will now be able to help provide care for Weld and Larimer counties, as well as Boulder, Broomfield, Gilpin and Clear Creek counties. We will be using a collaborative care model,

which means we will work closely with other providers, such as community health centers, mental health facilities and dental care providers. We will also have a much stronger collaboration with BCAP and

NCAP. Overall, this will give us the chance to provide even more comprehensive care to our patients.

In order to accomplish all of these changes, Boulder Community Hospital has found us a new office space. **We are now located at 1136 Alpine, Suite 205, just across the street from our current office.** Our new office space is big enough to house our expanded staff and even gives us room to grow.

Lastly, we realize we have been going through some growing pains over the last year. We want to thank all of our patients for bearing with us.

*If you have any questions about the Beacon Clinic, please feel free to call us at 303-938-3167.*

## Great News for the Beacon Clinic and Northern Colorado!



### Here, you're always family.

Everyone knows PFLAG is a great place for parents, but did you know it's also a welcoming place for members of the GLBT community? Actually, it always has been. And we'd like you to join us.

At PFLAG, we're all family. Gay. Straight. Parents. Children. Young. Not so young. Whatever. It's a place where everyone can share the warmth and support that comes from getting together with and being part of a family—a big, loving extended family.

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## Help Save the Lives of Others

### Donate Your Unused Meds

Are there opened (or unopened) bottles of HIV medications, antibiotics and other meds that you no longer need just taking up space in your medicine cabinet? The PWA Coalition Colorado wants your leftover meds. We collect for a number of national and international agencies and clinics that assist people around the world to access these life saving regimens. These programs depend on donations of medications that others no longer need to help those who do. Bring them by our office, mail them to us (we'll reimburse your postage if necessary) or call us if you're in the Denver Metropolitan Area and we'll pick them up. You can make the difference between life and death for PWA's around the world. Please help!

Questions? Give us a call at 303-329-9379.  
Places we've sent meds in the last few months: Zambia,  
Ghana, The Ukraine and South Africa

# Glossary of Treatment and Research Abbreviations and Terms

## Antiretroviral Meds

### Nucleoside Reverse Transcriptase Inhibitors, Nucleoside Analogues, NRTIs, Nukes

**AZT, ZDV** = zidovudine, Retrovir®

**ddI** = didanosine, Videx®

**ddC** = zalcitabine, HIVID®

**d4T** = stavudine, Zerit®

**3TC** = lamivudine, Epivir®

**ABC** = abacavir, Ziagen®

**FTC** = emtricitabine, Emtriva®

### Nucleotide Reverse Transcriptase Inhibitor, Nukes

**TDF** = tenofovir, Viread®

### Combination Nukes

**AZT + 3TC, CBV** = Combivir®

**AZT + 3TC + ABC, TZV** = Trizivir®

### Non-Nucleoside Reverse Transcriptase Inhibitors, NNRTIs, Non-Nukes

**NVP** = nevirapine, Viramune®

**DLV** = delavirdine, Rescriptor®

**EFV** = efavirenz, Sustiva®

### Protease Inhibitors, PIs

**ATV** = atazanavir, Reyataz®

**SQV (HGC)**, saquinavir hard gel capsule, Invirase®

**SQV (SGC)** = saquinavir soft gel cap, Fortovase®

**IDV** = indinavir, Crixivan®

**RTV** = ritonavir, Norvir®

**NFV** = nelfinavir, Viracept®

**APV** = amprenavir, Agenerase®

**APV** = fosamprenavir, Lexiva®

**LPV/r, KLT** = lopinavir/ritonavir, Kaletra®

### Fusion Inhibitors

**T-20** = enfuvirtide, Fuzeon®

## Terminology

**Anecdotal** = individual stories that accumulate into a body of "knowing" with no clinical science behind it.

**Antiretroviral** = drugs that fight retroviruses. HIV is a retrovirus.

**Double-Blinded, placebo controlled** = clinical trial design in which neither the researchers nor the study participants know which arm of the trial they are randomized to, or which drugs they are taking. This is the most scientifically rigorous and reliable model of evaluating whatever the study is looking to find.

**Efficacy** = the effectiveness of a particular drug or regimen. "How well it works."

**Open Label** = clinical trial design in which both the researchers and study participants know what arm of a trial individuals are randomized to.

**Retrovirus** = a class of enveloped viruses (including HIV and hepatitis C) start out as RNA and use the reverse transcriptase enzyme to translate their RNA into DNA.

**Undetectable** = desirable results of a viral load test. It means that the virus could not be detected using the assay that particular lab uses at the level that labs can count to. In other words <20 or <50 or < 400... This is a moving target. As the science and laboratory capabilities improve, undetectable is a lower and lower number. See BLQ below.

## Abbreviations

**AE** = Adverse Event

**BLQ** = below the level of quantification. Essentially means undetectable, but if you study the definition of undetectable, you will see that this is a more accurate way of defining a viral load result.

**n** = number of people participating in a study, or a given arm of the study

**pts** = patients

**tx** = treatment

**QD** = Once a day/ every 24 hours

**BID** = Twice a day/ every 12 hours

**TID** = Three times a day/ every 8 hours

**QID** = Four times a day/ every 6 hours

**prn** = as needed

**ITT** = intent-to-treat, missing = failure. Counts as "failures" any study participant who stopped meds, changed meds, or left the trial. This is the most rigorous evaluation of a clinical trial.

**OT** = only those still on their original regimen at the end of trial

**TC** = Total Cholesterol

**LDL -c** = low density cholesterol (the bad stuff)

**HDL-c** = High Density cholesterol (the good stuff)

## Pharmaceutical Companies

Abbott Laboratories, *RTV, KLT (LPV/r)*

Agouron Pharmaceuticals, *NFV*

Boehringer Ingelheim Pharmaceuticals, *BI, NVP*

Bristol Myers Squibb, *BMS Virology, ddI, d4T, EFV, ATV*

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# CROI 2004

By Shelley Cohen McKittrick

*This year's 11th Conference on Retroviruses and Opportunistic Infections (CROI), held in San Francisco in February, continued to provide us with new information on how to best combine - or perhaps more often, not combine - antiretroviral combinations; new agents in development; important information on older meds, especially as they are applied in the developing world settings and; complications of long-term HAART (highly active antiretroviral therapy). We will hit the highlights of these topics as well as some important socio-political-economic issues in both this country and across the world.*

## Triple Nukes - Dead in the Water!

This is not headline stuff anymore, but there was further data presented through the Tonus study, Landman, et al, that supported last summer's surprise findings regarding the triple nuke combo tenofovir, abacavir, 3TC. This study again showed an extremely high percentage of virologic failure (12/36, 33%). Eleven of the 12 had virologic failure with the K65R and the 184V mutations, 1/12 only had the 184V. Then there was the Jemsek, et al, data that showed miserable results with tenofovir, ddI and 3TC. Same story, different channel; 20/22 participants experienced virologic failure. 91%. No one reached <50 copies. Ouch! 10/20 (50%) had the K65R and 184V mutations, 10 had the 184 alone. In both studies, those with viral loads >100,000 at baseline had the worst outcomes. The table below compares data from these two trials presented at CROI as well as the ESS3009 from last summer.

	<50 VL	K65R +M184V	M184V Only
Jemsek, et al ddI/TDF/3TC (n=24 )	0/22	10/20	10/22
Tonus Study ABC/TDF/3TC (N=38)	24/36 (67%)	11/12	1/12
ESS3009 ABC/TDF/3TC (n=345)	100/345 (29%)	64%	36%

Now, it's not fair to compare these results to the ACTG 5095 results comparing Trizivir® (AZT, ABC, 3TC), Combivir® / efavirenz (Sustiva) and Trizivir® /efavirenz. In that study, Trizivir® did poorly compared to the two efavirenz-containing arms, but not to the same degree as the results shown above. In that study, 74% of TZV alone arm reached a viral load of <200, compared to 89% in the 2 efavirenz arms. The Trizivir® arm was stopped because of the statistically significant difference between the efavirenz containing arms and the Trizivir® arm. Time to virologic failure was also shorter in the Trizivir® arm. If you are on Trizivir® alone, and your viral load is undetectable, these results do not mean you should change your regimen. But rather, monitor your viral load closely.

All of these data *do* mean that we have ample clinical trial evidence that triple nuke therapy is not a good idea; and that some combinations are disastrous. There are ongoing clinical trials evaluating whether starting therapy with a more intense, potent regimen, then backing off to Trizivir® might be a valid therapeutic approach. Do we know that answer yet? **NO**. Should you and you Doctor be playing around with such an approach before the clinical trial data is in? We don't think so. There are so many viable, tolerable regimens out there these days. It is much wiser to wait for the data, being gathered in a controlled setting, than to be practicing cowboy medicine in this age of choices.

## So, If Triple Nukes are Dead, What About Quad Nukes?

Elion et al. presented data from the COL40263 study that looked at once-daily Trizivir® + tenofovir (Viread®) in antiretroviral naïve individuals. The early results are less than stellar. With 8 week data on 88 participants, 78% of those on treatment had viral load (VL) <400, 67% <50. For those with a baseline VL >100,000, only 60% reached <400. Granted, it's early data, but it doesn't look too promising. These data are no more promising than Trizivir® alone and beg the question why bother with the 4th drug, especially when there seems to be a high level of toxicity-related drop-outs (22%). The most interesting thing to emerge from this study so far is that of 8 virologic non-responders, only 1 person developed the K65R mutation. It appears that AZT prevents the development of the K65R. So what's up with this K65R mutation? Read On.



### What's up with the K65R?

The K65R mutation is new to many of our HIV vocabulary. It is a nucleoside reverse transcriptase-associated mutation selected by the nukes abacavir (ABC, Ziagen®), ddI (didanosine, Videx), d4T (stavudine, Zerit®) and tenofovir (TDF, Viread®). The triple nuke data above speaks to the risk of "popping" the K65R, especially in sub-optimal combos like TDF, ABC and 3TC. There you have 2 drugs that select for the K65R and 3TC which has the signature mutation M184V. So, there's a lot of hype out there about the K65R. Depending on one's pharmaceutical bias, or lack there-of, there has been the wide-spreading of panic, or the down-playing of significance. In an attempt to see through the industry hype, there are some very interesting aspects to this little-known, but growing in prevalence mutation.

There are at least 2 ways in which nucleoside mutations can cause resistance: decrease binding or incorporation and increased excision. When nucleoside analogues work, they are incorporated into the cell blocking reverse-transcriptase

from being able to assist HIV in its replication process. Incorporation is good. It means the drug is getting where it needs to be. Decreased incorporation is bad.

Excision is the process by which the drug(s) in question are removed (excised) from their proper place of work -- booted out. Excision is bad. Decreased excision is good. Whew - this is complicated stuff.

The K65R seems to decrease incorporation of most nukes (this is bad), but also, with some drugs, decrease excision (this is good). For tenofovir, abacavir and ddI decreased incorporation caused by the K65R appears to lead to at least a partial decrease in drug susceptibility. With d4T the resistance jury is still out. Of interest however, with AZT, the K65R, decreases incorporation, but also decreases excision to such a point that it outweighs the negative effect of decreased incorporation. It actually appears to make the K65R mutant virus more susceptible to AZT. It also appears to reverse pre-existing AZT resistance. You could visualize it as:

Tenofovir, ddI and abacavir and the K65R mutation: ↓incorporation + ↑excision = ↓susceptibility (this is not so good).

AZT and the K65R mutation: ↓ incorporation + ↓↓ excision = ↑susceptibility (this is good!).

D4T and the K65R mutation: ↓ incorporation + ↓excision = ?? the jury is out.

Got that? We'll look more at incorporation and excision in a future issue of Resolute! It's fascinating though, don't you think?

### Getting to Know the K103N and NNRTIs

There were several presentations that addressed non-nucleoside reverse transcriptase inhibitors (NNRTIs) and their signature mutation, the K103N. There are currently 3 FDA approved NNRTIs: efavirenz (Sustiva®), nevirapine (Viramune®), and delavirdine (Rescriptor®). The most commonly used are efavirenz and nevirapine, two drugs that have low pill counts, are very strong and have long half lives, making them easy to take and easy to combine with NRTIs. In the past couple of years, nevirapine has also been used in the developing world to prevent MTCT (mother-to-child-transmission), with just one pill to mom during labor, and one to the baby after delivery. The results have been similar to the long-standing short course AZT therapy used during labor and delivery. With all of this in mind, let's look at the data presented at CROI concerning these drugs and the K103N mutation.

#### The K103 Sticks Around and Does Not Effect Replicative Capacity

Little et al. presented data after following 10 individuals for 3 years who were infected with NNRTI-resistant HIV. These individuals had HIV virus that replicated very well (84% of wild type) and there was a very slow and incomplete reversion of their virus to wild type. What does this mean? This data in conjunction with the data from Palmer et al., which showed the persistence of NNRTI mutations even when the drugs have been removed, gives strong evidence that NNRTI resistance is long lasting and does not effect replicative capacity. (Unlike some other mutations, associated with NRTIs and PIs, that reduce HIV's ability to replicate.)

What's the real world, take home message? Efavirenz and nevirapine are highly effective antiretroviral medications

that, when used in combination with other medication and when very well (high level of adherence) can lead to very long-lasting combos. However, when NNRTI resistance occurs, it sticks around and does not effect the "fitness" of the K103N mutant virus.

#### Single Dose Nevirapine Leads to Development of the K103N Mutation

Martinson, et al. presented data that showed the emergence of the K103N and other NNRTI-associated mutations with just one dose of nevirapine. 623 HIV infected mothers received nevirapine (NVP) before delivery; their infants were given NVP within 72 hours after delivery. 456 women and children were followed for 7 weeks after delivery. Almost 40% of the women were found to have NVP resistance. The transmission rate to infants was 8.6%. 42.4% of the HIV-infected infants also had NVP resistance. There was

increased risk for NVP resistance developing with higher viral load and lower CD4 count. Muro et al. supported these finding by giving 200 HIV negative women single dose NVP and then tracking how long the drug stayed measurable in their blood. The median half life measured was 56.7 hours (with the range being 25.6 - 164 hours!). The time to "undetectability" (when no drug could be measured) ranged from 11 days to > 22 days. The implication of this study supports the emergence of resistance from single dose nevirapine because it hangs around in the blood so long.

The obvious question is, should we be giving single dose NVP to pregnant women in the developing world? Not if we want to be able to use those drugs later. Considering that the World Health Organization's combo pill made from generic drugs contains nevirapine, the answer is a resounding NO. Could we, however, give 2 other antiretroviral meds for a couple of weeks following delivery to "cover the nevirapine tail"? Perhaps. It will need to be studied.

#### **Adding Nevirapine to Short-Course AZT During Labor and Delivery, Lowers MTCT Rates.**

In another study, by Lallemand et al., short course AZT monotherapy to mother and child was compared to AZT + NVP. The study was double blinded. Placebo controlled. There was a placebo arm in which no NVP was given. This arm was stopped because there was such significant difference this arm and the NVP-containing arms. The results were impressive. The transmission rate dropped from approximately 6.3% (in the stopped placebo arm) to 2% and 2.8% in the continuing arms. This brings the perinatal transmission rate down to close to that of what women on HAART therapy are experiencing in the US. Once again, transmission was associated with higher viral loads and lower T-cell counts.

#### **Race, Side Effects and Efavirenz Clearance**

In a sub-study of ACTG 5095, Ribaud et al. looked at correlating efavirenz (EFV) concentrations with race, discontinuation, CNS toxicity, and viral load response. 190 subjects were available for analysis: 19% women, 32% AA, 15% Hispanic. What did they find? Race, it turns out, was strongly associated with EFV clearance. African Americans and Hispanics cleared EFV slower than whites. In fact, white

folks cleared EFV from their system 32% faster. There appeared to be no association between how fast EFV cleared and hepatitis C coinfection (good news). There was an increase in discontinuation of EFV with slower clearance. In other words, the longer the drug hung around in people, the more likely they were to quit taking it. However, this study showed no association between slower clearance rates and increased central nervous system (CNS) side effects. (Say What? This doesn't make sense to this treatment advocate - it makes me wonder how they defined CNS side effects and why these folks discontinued the drug?). There was no association between EFV clearance and how well it suppressed HIV (that's good news).

In another study, Haas et al. tried to get at why EFV concentrations are higher in some folks, there was an association with the presence of a polymorphism called the CYP2B6 G516T (it's a particular manifestation of a liver enzyme). This polymorphism is more frequent in the African American population, and may explain why EFV concentrations are higher, and clearance slower in African Americans. In this study, presence of the CYP2B6 G516T was associated with increased CNS side effects. There were no apparent differences in virologic or immunological response.

These findings are significant and must be followed up with further analysis. They speak to several issues on the minds of those living with HIV and those treating HIV infected individuals. One is, people are not paper cut-out dolls. We come in differing sizes, genetic make-up, hormonal influences and who knows what else. We cannot go into the future treating every PLWH/A like they will react the same to these meds. We need therapeutic monitoring of the drugs that we can monitor easily NOW. In this world of inequalities, it is especially important that racial differences be followed up and understood. The barriers to treating disenfranchised communities are too large to have only a little information on medication differences. This is fascinating information and if appropriately followed, could lead to reducing the side effects of efavirenz in some individuals, while maintaining its potency. That would be great!

#### **Lopinavir/r (Kaletra®) QD Another Once-a-Day Option?**

Gathe, et al, presented 48 week data from a open label study that compares lopinavir/r (Kaletra®) once-daily (QD) to lopinavir/r twice-daily (BID). Participants in both arms also took FTC (Emtricitabine/Emtriva®) and tenofovir (Viread®). The virologic results are impressive. The QD arm performed as well as the BID arm, with the only statistical difference being the amount of diarrhea experienced in the QD arm. The results are below.

	QD	BID
ITT Viral Load <50	70%	64%
OT Viral Load <50	90%	85%
T-Cell Increase	185	188
Discontinuations	19%	25%
Adverse Events	12%	5%
Diarrhea	16%	5%

### The New Drug Pipeline is Not Dead: Long Live the Antiretroviral Pipeline!

Our CROI coverage has really concentrated on the here and now. Just like you, our readers, we are very interested in the drugs coming down the pike. The closer to approval, the more effect it has on our daily lives, but the more novel the targets, the more hope there is for the future. Rather than go into the details of all of the new drugs in development, I'd like to just report this:

We currently have 20 licensed antiretroviral medications. At a recent CROI update, Steve Johnson, MD, eloquently summarized what characteristics new medications being developed should have: more potency, fewer pills, fewer side effects, less drug-drug interactions, effective against resistant virus, and useful in pregnancy. At this year's CROI there were reports on: 10 entry inhibitors; 3 NRTIs; at least 6 NNRTIs; 1 PI; and 1 maturation inhibitor. That's 21 new agents that were presented. There are far more in development. What does this tell us? The pipeline is alive and well. Some of the new drugs are aimed at new targets. In the next issue of Resolute we'll look at these new targets, including: CCR5, CXCR4, budding, attachment, integrase...

Within the next year, we'll most likely see: tipranavir, a new protease inhibitor; abacavir-3TC combined formulation; tenofovir-FTC combined formulation and new formulations of d4T, nelfinavir, saquinavir, and lopinavir-ritonavir.



# CROI 2004

## International Report

By Al McKittrick

### The Key Note Speech Ambassador Stephen Lewis, United Nations Special Envoy on HIV/AIDS in Africa

United Nations Special Envoy on HIV/AIDS in Africa, Stephen H. Lewis, presented an intelligent and passionate assessment of the AIDS pandemic in Africa and what is required to effect real change. The 3x5 Initiative is an ambitious program developed and cosponsored by the World Health Organization (WHO) in conjunction with UN AIDS. The program goal is to get 3 million people on treatment by 2005; hence 3x5. Up until now, people have not gotten tested because, "a prognosis of death without hope is hardly an inducement to seek the prognosis." Now with this initiative, "we give people hope through treatment and with well designed programs they will [testing] in ever greater numbers." WHO's aim is to fill the antiretroviral treatment gap emergency. "The initiative cannot be allowed to fail or we will have given the pandemic a license of unbridled human dissemination, greater even than that which presently exists." For the 3X5 Initiative to work, Lewis laid out the following programmatic needs:

- ⌘ WHO needs an additional \$200 Million in 2004 and again in 2005 to accomplish 3x5.
- ⌘ We must use triple dose once a day generic ART. The Clinton Foundation got the price to \$132/person per year

with an Indian manufacturer. Canada is amending PhRMA patent legislation and he urged other Western Countries to do the same.

- ⌘ "Involvement of Community is [essential]. The key elements of the community are the people living with HIV/AIDS, who are the real experts and must be acknowledged as such. They should be consulted on every aspect of the treatment process and they should be seen as helping to mobilize the community to work in an equal partnership with the medical facility dispensing the treatment. Wherever this formula has been genuinely applied, testing increases exponentially, stigma and discrimination drop significantly and adherence rates are generally higher than they are in this city of San Francisco."
- ⌘ You cannot achieve equity in 3 x 5 without opening the doors to women. "It is a matter of bewildering shame that even an insatiable pandemic, malevolently targeting women has failed to demonstrate once and for all the size of the gender gap and the deadly risk we face in failing to close it."

In addition to 3x5, Ambassador Lewis, outlined the following world wide needs:

- ⌘ Global Fund on AIDS, Tuberculosis and Malaria must be embraced by the World.
- ⌘ The Developed World should spend 7/10ths of 1% (.007) of their GNP (gross national product) on AIDS.

⌘ We must bring Microbicide Gels to Market - "People are dying in [horrific] numbers and the majority of those people are women." In a recent poll, only 7% of married women in 14 African countries reported condom use with their regular partner (husband). There is a growing body of evidence to show that a significant number of infected women in Africa have been infected by their husbands. "The power imbalance in marriage is too great to permit or to request the regular use of condoms. A way must be found to allow the woman to protect herself independent of male hegemony."

⌘ "We must get a vaccine."

Ambassador Lewis concluded his powerful Key Note speech with the observation that there are two things about AIDS in Africa that drive him crazy. First, the ferocious assault of the virus on women: "We are paying a dreadful and inconsolable price for the refusal of the international community to embrace gender equality. And in so many parts

of the world, gender inequality and AIDS is a preordained equation of death." Second, orphans: "The orphan crisis is a crisis without parallel. Somewhere, somehow, someday the world has to understand what AIDS hath wrought. That understanding is not yet in evidence. An apocalypse has unfolded and it has to be stopped in its tracks before it engulfs us all. If morality is found wanting in the actions of governments let it be rediscovered in the advocacy of individuals."

*Editorial note: President Bush's "abstinence until marriage" program (that he is imposing on Africa while holding out his conditional money) is ludicrous in light of Ambassador Lewis' telling of the increased risk for HIV infection that married women are at, compared to their single counterparts. In general, married women lose power in Africa. The notion of marriage = monogamy is a mainstream American notion, not an African one. If you want to study cultural incompetence, study the Bush White House.*

### Treating the Workers in South Africa

Gavin Churchyard from the Multinational Mining Company, Anglo American, reported on the success of their pilot program to treat employees in Welkorn, South Africa with ART (anti-retroviral therapy). Over 24% of the company's work force in South Africa is HIV+ and have no other access to medications. The pilot program enrolled 3,237 workers in the HIV program. Of those, 2,127 were started on preventative therapy such as Bactrim and TB medication; 1,222 workers were eligible for ART and 90% chose to start the regimens. The average length of therapy was 129 days. 92% reported never missing a dose. The median CD4 count was 145 at the beginning of the program and after six months of therapy, it had jumped to 409; after six months of treatment, over 60% of those still participating in the program were undetectable (<50 copies/ml). Unfortunately, 97% of the participants in the trial were male and no treatment was offered to their partners or spouses. Although Anglo American has 77 sites in two countries where voluntary testing and counseling are available, the demand for these services has been less than expected. The pilot program, however, did prove that effective treatment could be offered through clinics in resource-limited industrial settings. An interesting side note was that of the 85 men selected for treatment that declined the offer, 13% of them stated denial of diagnosis as reason for refusing treatment.

### Uganda - Takin' it to the People

Of the few treatment facilities in Africa, most are based in cities, but much of the population lives in rural settings. The TASO (The AIDS Support Organization) program from Kampala, Uganda demonstrated how to establish services for these folks. Alex Coutinho spoke of the 85% of Uganda's population that live in rural settings and how TASO is planning to get ART to such populations. The challenges are

daunting: minimal existing health infrastructure and personnel with very limited access to lab testing; dispersed population with very little access to transportation; extreme poverty with minimal access to electricity, sanitation and clean water; and potential difficulty with adherence and therefore the potential for the development of antiretroviral resistance. But TASO has been serving people with HIV for seventeen years and it is only now that they are faced with introducing ART into their program that serves 30,000 people living with HIV. Their emphasis is on a family based approach, which has proven to be more successful and comprehensive than an individual approach. The family based approach holds the opportunity to broaden other aspects of HIV care, including voluntary testing and counseling, adherence support and discordance counseling. 30% of TASO's clients have partners who are HIV negative. Coutinho added that because transportation is such a barrier, "It is better to take care to people, than to ask people to come to care." Voluntary counseling and testing is done in cars that travel to rural villages. Distribution and monitoring of clients is done through weekly visits by field officers on motorbikes. The field officers provide pill distribution, adherence support, and questionnaires to elicit drug failure or toxicity and basic sample and data collection of blood smears, sputum, and stool samples, along with weekly weigh-ins. Coutinho also feels that civil society, not governments or the private sector, are better equipped to scaling up HIV treatment and that access to care has to include all elements of care, not just antiretrovirals. He echoed other speakers in emphasizing the need to keep parents alive so that their children do not become orphans. "So let us not forget, in all that we do, that we need to keep people alive not just for their own sake but for the sake of their children too."

**The Final Two  
Community Dinner and Education Forums  
For the 2003-2004 Season**

**Monday, April 26  
6PM-9PM**

**" Why They Call Him, The Leader of the Pack!"  
Who? The CD4 Cell!!**

COME LEARN THE INS AND OUTS OF THE CD4 CELL,  
WHAT IT DOES, HOW IT CONDUCTS THE IMMUNE SYSTEM  
AND THE ROLE OF NEW AND OLD DRUG TARGETS.

**With Liz Connick, MD, Immunologist,  
University of Colorado ACTU and Infectious Disease  
Group Practice.**

**Monday, May 20  
6PM-9PM**

**May is Hepatitis C Awareness Month!  
Come learn the latest about  
HIV and Hepatitis C Coinfection  
With David Wyles, MD, Infectious Disease Fellow,  
University of Colorado Health Sciences Center  
*Cosponsored by the Coinfection Advisory Group,  
The Hep C Connection and PWACC***

FORUMS TAKE PLACE AT THE SUGAR LOUNGE, ONE DOOR EAST OF THE RHINO ROOM  
(FORMERLY CALLED THE GALAXY GRILL) AT 1700 VINE STREET  
DINNER AND EDUCATION FORUMS ARE FREE OF CHARGE

EVERYONE IS WELCOME

RESERVATIONS ARE REQUIRED  
CALL 303-329-9379 TO RSVP



*Hep C Connection*





### **Community Effort Saves Right to Participate In Ryan White Care Act Priorities Process**

*By Al McKittrick*

In December, the Denver HIV Resources Planning Council received notice from HRSA that community involvement in the annual Priorities process would no longer be allowed. This directive resulted from a misunderstanding by HRSA of the community's role in the process. HRSA assumed that the voting by the community in the process constituted a usurping of the Council's responsibilities to determine the priorities and resource allocations for the Denver EMA. What HRSA failed to understand was that the community's involvement served only as a recommendation to the Council. Each year, in the Council's next meeting after the Priorities process, the Council would approve or disapprove the recommendations before sending them on to the Mayor for final approval. Ten years of tradition in community involvement was at risk.

In an effort spearhead by Council member Victor Smith, The PWA Coalition Colorado, Project Angel Heart and Arthur Powers, an appeal to the Council to reject HRSA's directive was drafted. Over twenty-five organizations and individuals (including some dissenting council members) signed on to the appeal. The letter was presented to the Council at their January meeting and with the assistance of Lisa Flores from the Mayor's Office, a compromise was mediated to form an ad hoc committee of council members and community members to change the wording of the Council's description of the process. The committee met a week later and agreed on word changes that satisfied HRSA's concerns and allowed the community to retain its involvement in the Priorities process. Kudos to all who acted up.

What was disheartening to many community members was that the effort had to be mounted at all. Before the appeal was organized, Council leadership, some members of the Council and the Director of the Mayor's Office of HIV Resources seemed prepared to sacrifice the community's voice in the process rather than ruffle any feathers at HRSA in what turned out

to be a matter of semantics. Their reluctance to act did nothing but shore up the concern that the HIV Resources Planning Council cannot always be entrusted to act in the Denver HIV Community's best interests.

### **Gilead Seeks FDA Approval for New Fixed Dose Co-Formulation of Tenofovir (Viread®) and FTC (Emtriva®)**

Gilead Sciences, Inc announced its New Drug Application for a co-formulated medication that includes 300 mg tenofovir and 200 mg FTC. Both drugs are currently dosed once a day.



The co-formulation, if approved, will be one pill, once a day and will be used as the nucleoside analogue back-bone of a HAART regimen. This co-formulated medication will join the ranks of Combivir® (AZT/3TC) and Trizivir® (AZT/3TC/ABC), other co-formulated nuke back bones. GlaxoSmithKline is also working toward the co-formulation of abacavir and 3TC as a once a day nuke back bone.

### **Roche gains FDA Approval for Boosted Saquinavir HGC (Invirase®)**

Although most HIV treating physicians have been boosting almost all protease inhibitors with ritonavir for quite some time, the research necessary for FDA approval and for treatment guideline inclusion are just starting to happen. In January, 2004, the FDA approved the 1,000 mg saquinavir (INVIRASE®) boosted with 100 mg ritonavir in combination regimens for the treatment of HIV. Take note, this is the original hard gel cap (HGC) formulation of saquinavir. Not Fortovase. If you are still taking

Fortovase® with Norvir®, talk to your doc. It turns out that Invirase works better as a boosted medication than Fortovase.

"INVIRASE with ritonavir is an attractive option for the treatment of HIV because it is designed to provide consistently therapeutic levels of saquinavir with twice-daily dosing," said Dr. Frank Palella, Assistant Professor of Medicine, Feinberg School of Medicine, Northwestern University, Chicago. "With saquinavir, physicians and patients have the benefit of eight years of clinical experience on which to base treatment decisions. [The FDA approval] confirms that only low, 100 mg doses of ritonavir are needed to achieve effective levels of saquinavir when given with 1000 mg INVIRASE."

Invirase® capsules do not require refrigeration and are smaller in size than Fortovase® capsules. Roche is developing a 500 mg formulation of Invirase®, designed to be used in the new boosted dosing regimen that will cut the daily pill count in half. A filing for the 500 mg formulation is projected for submission to the FDA for review in 2004.

With this FDA approval, there are now 4 boosted PI dosings that are FDA approved: lopinavir/r (Kaletra), fosamprenavir/r (Lexiva®), atazanavir/r (Reyataz®), and now saquinavir HGC/r (Invirase®).

PR Newswire, January 6, 2004

### **Hepatitis C Positive? Not Sure How Your Liver's Doing? Don't Want to Have a Liver Biopsy? LabCorp Launches FibroSURE™, a Noninvasive Blood Test to Provide Alternative to Liver Biopsy**

LabCorp® announced the availability of HCV FibroSURE™, a noninvasive blood test for assessing liver status in people living with hepatitis C virus (HCV). Developed by leading hepatologists at the Pitie-Salpetriere Hospital and BioPredictive in France, HCV FibroSURE™ is only available in the United States through LabCorp.

HCV FibroSURE™ provides an easily accessible alternative to liver biopsy, the standard of care test to assess liver health in HCV-infected individuals. HCV FibroSURE™ uses a



combination of six serum biochemical markers plus age and gender in a patented algorithm to determine the degree of liver fibrosis and the level of ongoing liver inflammation. The test, which has been clinically available in Europe for the past two years, has been shown in several studies to enable quantitative, reproducible assessment of fibrogenic and necrotic activity in the liver of HCV-infected individuals.

HCV FibroSURE™ is recommended for use to assess liver status following a diagnosis of HCV, as a baseline determination of liver status before initiating HCV therapy, as post-treatment assessment of liver status six months after therapy completion, and for noninvasive assessment of liver status in patients at risk of complications from a liver biopsy. The blood sample for HCV FibroSURE™ can be collected in minutes and results can be returned to the physician within days. The test uses six biochemical markers that are routine and considered standard of care in the United States.

SOURCE: Laboratory Corporation of America Holdings. CONTACT: Pamela Sherry of Laboratory Corporation of America Holdings, 1-336-436-4855, or Shareholder Direct, 1-800-LAB-0401 PR Newswire, March 17, 2004

### **Boehringer Ingelheim Issues New Warnings for Nevirapine (Viramune®) and Hepatotoxicity**

Over time, some rare, but unfortunately severe hepatotoxicity issues have emerged with nevirapine use. Ultimately the scoop is that women with higher T-Cell counts are at increased risk of developing severe hepatotoxic events. The FDA has required Boehringer Ingelheim, the drugs manufacturer to put a black box warning on the drug. The company, in our opinion, has acted very responsibly in highlighting these issues before the required black box issuance. The take away message? Nevirapine is a very good antiretroviral medication that can, in a small number of people cause life-threatening liver toxicity. If you are going to start nevirapine (Viramune®). Be sure and follow the dose escalation model (200 mg once a day for 2 weeks, then 200 mg twice a day from there on out), and be sure to have your liver

enzymes monitored frequently (every two weeks) for the first few months on nevirapine therapy. You may also want to avoid starting abacavir (Ziagen®) and nevirapine at the same time as rash and other symptom of hypersensitivity can overlap and cause confusion!

#### ***Please note the following warning:***

Women with CD4+ counts >250, including pregnant women receiving chronic treatment for HIV infection, are at considerably higher risk of hepatotoxicity. Some events have been fatal. The T-Cell count was analyzed when starting a regimen containing nevirapine.



The greatest risk of severe and potentially fatal hepatic events (often associated with rash) happens in the first 6 weeks of nevirapine treatment. However, the company recommends frequent monitoring for the 1st 18 weeks of therapy.

*For more information go to:*  
[www.fda.gov/medwatch/SAFETY/2004/Viramune\\_PI.pdf](http://www.fda.gov/medwatch/SAFETY/2004/Viramune_PI.pdf)

### **T-1249 Development Put on Hold**

Trimeris, the biotech company developing T-1249, T-20's (Fuzeon®) more potent, but difficult cousin, announced the indefinite pausing of continued development of T-1249. The problem, as was the case with T20, is the drug's difficult formulation. Although T-1249 looks very promising for suppressing HIV replication in drug experienced folks, it is an injectable drug that requires 4 injections/day. This is twice the number of injections of Fuzeon®. The company has not abandoned T-1249. Clinical trials currently under way will continue. But, realistically, unless the company can come up with a formulation that requires

fewer injections per day, the likelihood of seeing T-1249 on pharmacy shelves is small. Trimeris partners with Roche Pharmaceuticals to market T-20 and future entry inhibitors.

### **President Bush, Abandoning World AIDS So Soon?**

Predictably, President Bush has backed away from his unbelievable promise to fully fund the global fight against AIDS. Never mind that the actual dollar amount that he spoke of in his State of the Union Address last year has already been breached -- You remember the quote, "I ask the Congress to commit \$15 billion over the next five years...to turn the tide against AIDS in the most afflicted nations of Africa and the Caribbean. Seldom has history offered a greater opportunity to do so much for so many." -- But if you scan his newly unveiled 5-year plan to fight AIDS, abstinence, or abstinence-until marriage appears 35 times in the report! (See coverage on Ambassador Stephen Lewis in our CROI coverage this issue). At the time of his speech it seemed like some sort of weird fantasy had come true -- compassionate conservatism lives! Right.

Well, shortly thereafter, President Bush submitted a budget line item request for \$2 billion for the year. That \$2 billion, of course, came with restrictions. A certain percentage had to go to "abstinence- until-marriage" programs and money earmarked for drugs would be controlled by Bush's newly appointed Global AIDS Coordinator Randall Tobias, the former CEO of pharmaceutical giant Eli Lilly & Co. Do you think the American government is planning on giving developing nations the money to purchase or produce generic HIV meds? Think again.

This year, according to the Wall Street Journal, "President Bush plans to ask Congress for relatively small funding increases to fight AIDS and poverty in the developing world, stepping back from his highly publicized pledge to spend huge sums to help fight them."

It makes me nauseous.

**PLEASE DON'T FORGET TO VOTE.**

*Want to know more about President Bush's un-kept promises? Go to <http://daily.misleader.org>*

### **Colorado State Legislature Steps Up to the Plate to Save AIDS Drug Assistance Program (ADAP). Funding Legislation goes to Governor Owen's Desk!**

Hold on to your hats and get ready for some good news! By the time you read this, House Bill #1421, that appropriates monies from Colorado's Tobacco settlement totalling 88 million dollars, should be signed into law. The Bill will fund many a wanting program, including Colorado's strapped State ADAP to the tune of over 3 million dollars in the 1st year, with annual increases built in, not to exceed \$5 million a year. This comes on the heels of the legislature restoring State funding to ADAP in the amount of \$204,375.

As the Denver Post reported on Sunday, April 4, "*Colorado is home to less than 1 percent of the nation's 385,000 people living with AIDS. But somehow...accounts for roughly one-third of those on [ADAP]waiting lists.*" The ADAP waiting list currently sits at 280 people. The tobacco settlement funding will alleviate this crisis.

Who do we have to thank for this truly righteous legislation? The idea was Representative Tom Plant's of western Boulder County. The Bill was cosponsored by Representative John Witwer, from Evergreen, and Senator Ron Teck, from Grand Junction, along with Reps Plant and Young and Senators Owen and Reeves. Thanks to you all! And here's to Governor Owen's doing the right thing! Sign away Governor.

### **Tibotec Pharmaceuticals Gives Microbicide Compound To International Partnership for Microbicides to Develop**

The International Partnership for Microbicides (IPM) announced on March 29 that it had reached an unprecedented agreement with Tibotec Pharmaceuticals, Ltd to take over the development of Tibotec's promising compound TMC120 to make a safe and efficacious Microbicide to help women protect themselves from HIV infection. TMC120 is a NNRTI (non-nuke) based gel, which is currently in Phase I Clinical Trials. IPM will assume responsibility for development of the compound as well as looking to develop other formulations of TMC120, both

alone and in combination with other ingredients.

Under the agreement Tibotec, a subsidiary of Johnson and Johnson, will still bear the cost of the compound through Phase II testing and will remain active as a scientific partner with IPM.

The agreement is unprecedented because it is the first time in the microbicide field that a major pharmaceutical has collaborated with a public-private partnership like IPM.

IPM is a non-profit organization that works with the public and private sectors to accelerate the development of microbicides. It was established in 2002

and is funded by five European countries; Denmark, Ireland, the Netherlands, Norway and the United Kingdom as well as the Bill and Melinda Gates Foundation, the Rockefeller Foundation, UNFPA and the World Bank.

Peter Piot of UNAIDS hailed the agreement as "a major milestone in global efforts to develop a Microbicide for all women around the world and is a model of the innovative collaboration that is crucial to reversing the AIDS epidemic."

Over half of all HIV infections globally occur among women. They often are powerless in relationships to abstain from sex or to insist on condom use. According to a recent Rockefeller Foundation report, a Microbicide that is even partially effective against HIV could prevent 2.5 million HIV infections over three years.

### **Looking Good Tenofovir Data at 144 Weeks**

Gilead releases 144-week data from its double-blind, phase III Study 903 that compared tenofovir (Viread®),

3TC, efavirenz to d4T (Zerit®), 3TC, efavirenz. Virologically, in an intent-to-treat analysis, 73% of the tenofovir arm and 69% of the d4T arm continued to have viral loads <50 copies/ml. These are impressive data, 3-years out. There was significantly less lipotrophy in the tenofovir arm (3% vs. 19%); and far less triglyceride increase in the tenofovir arm (1mg/dL vs. 134 mg/dL). There were no study discontinuations due to renal toxicities and <1% of patients in each arm had notable increase in serum creatinine levels. However, there has been tenofovir-associated renal toxicity (some quite severe) documented for individuals who started tenofovir with a history of kidney disease. These study results not only speak to the efficacy of tenofovir, but also to the long-lasting efficacy of non-nuke based regimens. It's always nice to have long-term data!

### **New Drug-to Drug Warnings with Atazanavir (Reyataz®)**

In March, 2004, the FDA released new drug interaction warnings that have led to changing the atazanavir package insert. If you're taking atazanavir (ATV), or go onto it in the future, please be aware that there are many drug-to-drug interactions that can either reduce the level of ATV in your blood, or, increase the levels of other drugs, or both. We're not going to get into the nitty gritty here. But be aware that:

1. Tenofovir (TDF/Viread®) decreases the level of ATV, and ATV increases the level of TDF, which could lead to increase renal toxicities. If you take these drugs together you need to boost the ATV with 100 mg ritonavir (RTV) and watch your kidneys;
2. Efavirenz (Sustiva®) reduces atazanavir levels and requires boosting ATV with RTV 100 mg;
3. Antacids and acid blockers (like Prilosec, Prevacid, Nexium...) reduce atazanavir levels and should be avoided;
4. Viagra, Cialis and Levitra levels may be increased by ATV, leading to increased side-effects associated with these drugs -- this can be dangerous!;
5. You should eat with your atazanavir.

Biggest take away message: Always talk with your Doc about any medications you're taking (whether they are prescribed by her/him or not!).



### **OUCH! RYAN WHITE FUNDS IN DENVER TAKE A HIT**

If you're Ryan White (RW) and math savvy, you can look at the numbers below and say wow - we took an overall hit of 10%, but our supplemental award took a 20% hit! Then you can ask yourself why? This is the part of our RW funding that is competitive -- based on the grant that is written by the Mayor's Office of HIV Resources, which is based on the performance of services in the Denver Eligible Metropolitan Area. Nationally, we're in the company of St Louis, MO, San Francisco, CA and Newark, NJ, who also took >20% supplemental hits. Ultimately, the outcome is that services are cut, while need is growing. Can we blame the current Congress for their dismal appropriations to fund the RW CARE Act? Yes. But is that the end of the story? We don't think so. We should look to the Mayor's Office for answers.

	Title I Formula	Title I Supplemental	MAI	TOTAL AWARD
<b>FY 2003</b>	<b>\$2,517,729</b>	<b>\$2,304,860</b>	<b>\$213,223</b>	<b>\$5,035,812</b>
<b>FY 2004</b>	<b>\$2,440,665 (-3.1%)</b>	<b>\$1,843,081 (-20%)</b>	<b>245,361 (+15.1%)</b>	<b>\$4,529,107</b>
Title II				+ \$429,219
MOHR Administration (5% MAI & Title I; 10% Title II)				(-\$269,377)
Planning Council Administration				(-\$151,785)
Quality Management				(-\$100,000)
Title II Insurance Continuation				(-\$110,240)
<b>ADJUSTED SERVICE DOLLARS</b>				<b>\$4,326,924</b>
<hr/>				
<b>TITLE I SERVICE AWARDS</b>				
<b>ADAP</b>		<b>\$527,285</b>		
CDPH&E	\$527,285			
<b>CASE MANAGEMENT</b>		<b>\$418,799</b>		
Adoption Exchange	\$22,196			
Colorado AIDS Project	\$253,290			
Empowerment	\$78,818			
POCCAA	\$39,367			
Servicios de la Raza	\$25,128			
<b>CLIENT ADVOCACY</b>		<b>\$62,636</b>		
PWA Coalition Colorado	\$50,108			
Women's Lighthouse Project	\$12,527			
<b>DENTAL CARE</b>		<b>\$384,411</b>		
Denver Health	\$152,765			
Howard Dental	\$231,646			
<b>EMERGENCY FINANCIAL ASSISTANCE</b>		<b>\$81,877</b>		
Colorado AIDS Project	\$81,877			
<b>FOOD BANK/HOME DELIVERED MEALS</b>		<b>\$108,077</b>		
Colorado AIDS Project	\$40,334			
POCCAA	\$5,134			
Project Angel Heart	\$62,609			
<b>HOME HEALTH CARE</b>		<b>\$117,493</b>		
Jewish Family Services	\$25,543			
Visiting Nurse Association	\$91,950			
<b>HOSPICE</b>		<b>4,913</b>		
Visiting Nurse Association	\$4,913			
<b>HOUSING ASSISTANCE</b>		<b>\$157,203</b>		
Colorado AIDS Project	\$157,203			
<b>INSURANCE CONTINUATION</b>		<b>\$152,406</b>		
Colorado AIDS Project	\$152,406			
<b>LOCAL DRUG REIMBURSEMENT</b>				<b>\$431,080</b>
Children's Hospital	\$49,747			
Denver Health	\$245,759			
University Hospital	\$135,575			
<b>MENTAL HEALTH</b>				<b>\$225,161</b>
Colorado AIDS Project	\$42,758			
Denver Health	\$41,835			
MHCD	\$80,450			
University Hospital	\$60,118			
<b>PRIMARY CARE</b>				<b>\$1,325,173</b>
Children's Hospital	\$50,092			
Denver Health	\$880,710			
University Hospital	\$394,372			
<b>SUBSTANCE ABUSE</b>				<b>\$159,659</b>
ARTS/UCHSC	\$67,408			
Colorado AIDS Project	\$44,657			
Denver Health	\$47,594			
<b>TRANSPORTATION</b>				<b>\$47,898</b>
Colorado AIDS Project	\$31,340			
Denver Health	\$10,892			
Empowerment	\$3,032			
POCCAA	\$2,634			
<hr/>				
<b>MINORITY AIDS INITIATIVE (MAI) FUNDS AND SERVICES</b>				
<b>Client Advocacy</b>				<b>\$71,093</b>
Servicios de La Raza	\$35,547			
Sisters of Color				
United for Education	\$35,547			
<b>Mental Health</b>				<b>\$71,093</b>
Sisters of Color				
United for Education	\$7,1093			
<b>Substance Abuse</b>				<b>\$90,906</b>
Denver Area				
Youth Services	\$90,906			
<b>TOTAL MAI</b>				<b>\$233,093</b>

# New HIV Protease Inhibitors-New Options in the PI Class for Treatment-naïve Persons

*Benjamin Young, MD PhD*

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## INTRODUCTION

The past decade has seen gigantic changes in the options for the treatment of HIV. The use of antiretroviral medications has dramatically changed the quality and quantity of life for persons living with HIV infection. The first potent antiretroviral medication combinations (termed highly active antiretroviral therapy, HAART) usually included protease inhibitors (PIs). PI-based HAART regimens were tough to take, with frequent dosing and lots of pills; frequent side effects and toxicities added more difficulty with adherence. Ultimately, these issues led to short-lived treatment benefit and drug resistance.

Because of these issues, the easier-to-take non-nucleoside reverse transcriptase inhibitor-based regimens became very popular, pushing protease inhibitors to later rounds of HAART treatment.

However, the story isn't over-active research programs have continued to improve PIs, attempting to retain the potency strengths of PIs while addressing the previous limitations.

## BENEFITS OF EARLY PROTEASE INHIBITORS

Two thousand-three marked the sixteenth year of licensed therapies for the treatment of HIV-1 infection. Until 1995, HIV doctors only had nucleoside reverse transcriptase inhibitors (NRTIs, nukes). This mono- and dual-drug era was one of desperate times with high death rates and lots of complications.

In the winter of 1995-96, the introduction of the first HIV protease inhibitors (saquinavir, indinavir and zidovudine) revolutionized the medical care of persons living with HIV infection. The addition of a PI to dual nuke therapy resulted finally in the suppression circulating HIV to undetectable levels.

Several early clinical trials, showed the ability of PI-containing HAART to suppress HIV and increase CD4 cell counts. Subsequently, several studies reported dramatic reduction in the death rate in HIV infected individuals.

## LIMITATIONS OF EARLY PROTEASE INHIBITORS

Not long after we celebrated the successes of PI-based HAART came the realization that not everything was great-issues like high pill burden, need for frequent dosing or short-term side effects. As the life expectancy increased for HIV-infected persons, concerns of long-term toxicities emerged.

Early HIV-1 protease inhibitors treatments involved many pills (sometimes more than 10 a day) and frequent dosing schedules. Saquinavir, indinavir, zidovudine, nelfinavir and lopinavir/ritonavir all needed to be taken with a mind towards diet. Only amprenavir (APV) does not have a food requirement. Dosing of indinavir needed even more behavioral changes, the need to drink lots of water to avoid kidney stones. The recent reformulation of nelfinavir (NFV), from a 250 mg tablet to a 625 mg tablet is a recent effort to lower the pill burden of this PI from 10 a day to 4.

Short-term side effects of PI-based therapy are well known, with frequent gastrointestinal problems, like, nausea and diarrhea. These side effects often resulted in treatment discontinuation. Making matters worse, long-term toxicities (or fear of toxicity) emerged as we treated people longer with PI therapies. One main area of concern was body fat changes, now called, lipodystrophy. While it is increasingly understood that significant risk for lipodystrophy is often raised by non-drug factors, (such as severity of HIV disease or age) many early reports erroneously placed the sole blame for lipodystrophy on the PIs. Nevertheless, many PWAs would choose to avoid HIV therapy altogether, in order to avoid the stigmatizing effects of lipodystrophy.

Elevations in the blood chemicals cholesterol and triglyceride have been in persons taking all early PIs. Ritonavir-boosting generally to make these elevations even greater. The reason this is concerning is that abnormal cholesterol and triglycerides can raise one's risk of heart disease.

Ultimately, these limitations made adherence to tough and negatively affected quality of life. It's is clear that side effect aversion was a significant negative factor in taking pills- a real problem in a world where long-term success requires near-perfect adherence. This issue is so significant that in one study, PWAs were willing to trade years of life and risk death in order to avoid medication side effects.

## CHALLENGES TO PROTEASE INHIBITORS: NON-NUCLEOSIDE RT INHIBITORS

The arrival of non-nucleoside reverse transcriptase inhibitors (NNRTIs, non-nukes) was met with skepticism. Simple and well tolerated drugs couldn't possibly match the potency of PI-based treatment.

Over time, multiple studies showed the superiority of NNRTI-based therapy, compared with PI-based therapy, even among the most ill patients, those with high viral loads or very low CD4 cell counts. Recent improvements in the formulation of the non-nuke efavirenz has yielded a one pill per day drug-an industry benchmark.

## THE RISE OF BOOSTED PIs

HIV PIs are metabolized by similar paths in the liver. The PI ritonavir has the unusual behavior of preventing the metabolism of most current PIs. When dosed together with other PIs, ritonavir increases the drug levels for all of the HIV protease inhibitors, except for nelfinavir. This "boost" decreases the dosing frequency and pill count for saquinavir, indinavir and amprenavir and eliminates the dietary restriction for indinavir.

Pharmacological boosting of lopinavir, results in a clinically relevant product, the co-formulated lopinavir/ritonavir



(LPV/RTV, Kaletra). In key studies, regimens that contained the boosted PI lopinavir/ritonavir were shown to be more potent than those that contained nelfinavir, and improved responses were seen in persons with very high viral loads. Because of these studies LPV/RTV is currently a component of one of the "preferred" initial antiretroviral regimens for initial therapy, a demotion of "unboosted" PIs to the alternate position.

Current boosted PIs are improvements from the early days, but limitations persist. Co-formulated lopinavir/ritonavir and the new 625 mg formulation of nelfinavir are good efforts in lowering the pill burden. Gastrointestinal side effects and elevations in cholesterol remain problems and for some persons, serious intolerance to ritonavir makes boosting an unacceptable option.

### **THERAPEUTIC CHALLENGES AND NEW PROTEASE INHIBITORS**

The treatment of HIV has continued to evolve since 1995, with ever improving prognosis and expanding therapy options. Because of effective HAART, HIV disease need not be fatal, and there inspection of the potency, long-term effectiveness and tolerability of treatments. Non-nuke-based therapies now permit very low pill burden, well tolerated options. Drug resistance is an essential consideration in treatment selection, even for the first treatment regimen in therapy-naïve persons. Pill count, dosing frequency and dietary issues are central to adherence. Clinical trials of new drugs need to assess for potential toxicities, both short- and long-term, that were not appreciated during the discovery programs of earlier PIs.

#### **NEW PROTEASE INHIBITORS**

Three new HIV protease inhibitors are receiving attention because of recent clinical studies; atazanavir (ATV, Reyataz®) and fosamprenavir (APV, Lexiva) are already approved by the US Food and Drug Administration; tipranavir, is now in phase III clinical trials. The improved potency, tolerability, dosing flexibility and resistance properties of the medications has sparked new interest in the role that PIs may play in the treatment of persons living with HIV.

#### **ATAZANAVIR (ATV, Reyataz®)**

Atazanavir was approved by the FDA in July 2003. ATV is the second HIV PI that is approved for once-daily dosing (along with boosted amprenavir). When ATV is dosed with ritonavir, ATV drug levels are increased (called boosted ATV). The usual dose is two 200 mg capsules, once-daily. ATV causes little disturbance in blood lipids and has a promising resistance profile in therapy-naïve persons. ATV should be taken with food.

#### **Studies in treatment-naïve persons**

ATV has been given to treatment-naïve persons in several studies. All involve the use of unboosted ATV; there has been no study of boosted ATV to date.

In early clinical trials (called studies AI424-007, -008), showed that the ATV was about as potent as NFV, with similar proportions of patients achieving undetectable viral loads and similar increases in CD4 cell rise. Elevations in blood levels of bilirubin were frequently observed, particularly among persons who received the highest dose (600 mg qd). In the latest clinical trial, AI424-045, therapy-naïve persons received either unboosted

ATV or efavirenz (Sustiva) with fixed dose ZDV/3TC (Combivir). This study showed that unboosted ATV seems to work as well as efavirenz. This is one of very few clinical trials that has compared a newer PI to efavirenz and suggests similarity between the two classes of drugs for first line therapy.

#### **Studies in Treatment-experienced persons**

The use of ATV in therapy-experienced individuals has been explored in two clinical trials. Study AI424-043 compared unboosted ATV against LPV/RTV and optimized dual nuke background in patients who were experiencing treatment failure. In this study, unboosted ATV was not as potent as lopinavir/ritonavir, and study subjects receiving ATV experienced less reduction in plasma HIV RNA and fewer ATV patients achieved undetectable viral loads.

Study AI424-045 is an ongoing study that compares boosted ATV/RTV (300 mg/100 mg qd) versus lopinavir/ritonavir versus ATV/SQV (saquinavir) in therapy-experienced persons. Patients received tenofovir as part of the randomized treatment (in conjunction with a NRTI). Preliminary 24 week data from this study was recently presented. The proportion of persons with viral load below LOQ (level of quantification or undetectable) was similar in the ATV/RTV and LPV/RTV groups, whereas the ATV/SQV groups tended to have poorer response. The 48 week data from this trial is anxiously awaited. It is tempting, though premature, to speculate that ATV/RTV will have comparable potency and tolerability in treatment-naïve persons.

#### **Side effect profile**

ATV is generally very well tolerated, though has slightly more gastrointestinal side effects than NFV. The drug's once daily, two pill count profile is the lowest pill burden of any currently approved HIV protease inhibitor. A distinguishing characteristic of the protease inhibitor is the lack of effect on blood cholesterol and triglycerides.

The principle and characteristic side effect associated with ATV therapy is elevations in the blood level of bilirubin, a condition called hyperbilirubinemia. Bilirubin is a byproduct of liver metabolism. Hyperbilirubinemia was the most common laboratory abnormality in ATV clinical trials. Clinical cases of jaundice yellowing of the skin have been reported in 11% of all study subjects; 9% reported yellowing of the eyes ("scleral icterus"), though these events rarely resulted in having to stop the medicine. These clinical symptoms are reversible upon treatment discontinuation or interruption.

Mild abnormalities in the electrical patterns in the heart occurred in some patients during clinical studies. These changes were asymptomatic but, because of this cautionary note, ATV should be used with caution in persons with preexisting cardiac conduction abnormality.

#### **Drug-to-drug interactions**

There are a number of significant drug-drug interactions with ATV. ATV should not be taken with commonly used antacids--H2 receptor antagonists and proton pump inhibitors. If taken with tenofovir, ATV needs to be boosted, because tenofovir results in ~ 20% reductions in ATV levels.

**FOSAMPRENAVIR (908, APV, Lexiva®)**

Fosamprenavir, also known as GW-433908 (908) was approved by the FDA in October, 2003. 908 is a chemical relative of the PI, amprenavir. The metabolism of 908 is inhibited by ritonavir, permitting pharmacologic boosting with twice-daily, un-boosted or boosted and once-daily, boosted dosing. Once-daily dosing requires ritonavir-boosting. The unboosted dose is two 700 mg tablets, twice-daily; boosted dosing requires one 700 mg tablet with one 100 mg ritonavir capsules twice-daily or two 700 mg tablets with two 100 mg ritonavir capsules once-daily. A characteristic adverse event is rash. 908 has a favorable lipid profile and promising resistance profile in therapy-naïve persons. There are no dietary restrictions in taking 908.

**Studies in Treatment-naïve Individuals**

Two phase III clinical trials have evaluated 908 in therapy-naïve individuals. The NEAT study compared unboosted 908, dosed twice daily to nelfinavir; the SOLO trial compared boosted, once-daily 908/RTV to nelfinavir.

In the NEAT study, subjects either received 908 twice daily or nelfinavir. While CD4 cell count rises were similar in both groups, a greater percentage of 908 subjects achieved undetectable viral loads especially those with high baseline viral loads, suggesting superior potency of 908.

The SOLO trial evaluated boosted, once-daily 908/RTV versus nelfinavir. In this study, similar percentages of subjects achieved undetectable viral loads at 48 weeks. In an exploratory analysis, a greater percentage of persons with very high baseline HIV viral loads (>500,000 copies/mL) or very low CD4 counts (<50 cells/mm<sup>3</sup>) achieved undetectable viral loads when they received 908 than NFV. More NFV subjects discontinued therapy because of virologic failure; more 908 subjects discontinued because of non-virologic reasons.

**Studies in Treatment-experienced Persons**

The efficacy of boosted 908 was assessed in the CONTEXT clinical trial. PI-therapy-experienced patients were randomized to receive once- or twice-daily 908/RTV versus LPV/RTV. Preliminary 48-week data has been released (though not publicly presented). It reports under-performance of the once-daily arm. Very similar proportions of subjects achieved undetectable plasma HIV RNA levels in the twice-daily 908/RTV and LPV/RTV and there were similar increases in CD4 cell counts.

**Side effect profile**

Fosamprenavir is generally very well tolerated. In studies that compared 908 to nelfinavir, there were decreased rates of gastrointestinal side effects. Diarrhea occurred less frequently in persons taking 908 compared to NFV, this was true, even when 908 was boosted with ritonavir.

Like amprenavir, 908 causes rash in a small percentage of patients, ranging from 2- to 7% in recent studies. Small increases in cholesterol were seen in therapy-naïve persons who received 908.

**Drug-to-drug interactions**

Fosamprenavir, like many other PIs is metabolized by cytochrome P450-to this extent the potential for drug-drug

interactions is similar to most other PIs. A recent report showed that 908 should not be taken with LPV/RTV (Kaletra), because of lower drug levels.

**TIPRANAVIR**

Tipranavir (TPV) is currently in phase III clinical trials in HIV-infected individuals. TPV is the first of a new sub-class, the non-peptide inhibitors of HIV-1 protease. The pharmacokinetic properties of TPV require ritonavir boosting. The dose currently under investigation is two, 500 mg pills with 2, 100 mg ritonavir capsules, twice-daily. TPV has typical PI-associated gastrointestinal side effects, but a very encouraging ability to inhibit PI resistant virus.

**CONCLUSION**

The potency and tolerability of atazanavir and 908 add important new options in the care of persons living with HIV. Together with other protease inhibitors in development and rising rates of initial drug resistance, the protease inhibitor class has seen a renewed level of interest for the care of treatment naïve persons.

Lower pill burden and improved tolerability compared with previous unboosted PIs is desirable-the two pill per day atazanavir and the four pill per day 908 have achieved pill counts similar to the original, highly successful formulation of efavirenz. Pill counts also are lower than the industry standard lopinavir/ritonavir. Compared to early unboosted PIs, gastrointestinal tolerability is much improved.

Is PI drug discovery complete with atazanavir and 908? Low though current pill count might be, there still is room for improvement. Limitations of our existing data set remain-evaluation for long-term safety or complications requires long-term monitoring of study subjects and an improved understanding of how HIV disease occurs. Drug-drug interactions remain problematic for most PI medications, particularly for atazanavir. The optimal choice of which medication class or medication combination to use continues to be the subject of debate.

The newer PIs will change the care for persons living with HIV. The improved tolerability and low pill count of new PIs will challenge the place that non-nukes now hold as first-line therapies. For persons who have inherited NNRTI resistance, PIs must be components of first-line combinations. It has been suggested that persons with very advanced disease might be more appropriately treated with PIs, because of their higher genetic barrier to resistance and the general low likelihood of getting high level PI drug resistance. For persons with high risk of heart disease, atazanavir's lipid profile makes this drug an attractive option. Lastly, for the many persons who are currently successfully taking first-line PIs, the newer drugs offer options for treatment simplification with fewer pills and improved tolerability.

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*Charles Steinberg, MD and Torkin Wakefield are well known to many in the Colorado HIV Community and to many others nation-wide. They co-founded AIDS, Medicine and Miracles in 1987. Charles has been the driving force behind a holistic approach to HIV treatment in Boulder, in Colorado, in the US and now in Africa. Torkin is a tireless humanitarian who lends her compassion and skills to "social/spiritual/health" programs. In this issue of Resolute! you read about the changes at the Beacon Clinic. The clinic Charles established.*

*Now, in classic and beautiful Steinberg-Wakefield form, they have taken their compassion, their skills and their hearts to Africa. They sent these letters to me and Al. As we read them we cried. As I edited them, I cried. As you read them in this issue, and in the future, we hope you are moved to help, in whatever way you can. If you have financial resources and would like to make a donation, see the end of these letters for more information. We are all citizens of the World.*

*Shelley Cohen McKittrick*

## **PARTNERS IN AIDS SERVICE LETTERS FROM AFRICA**

**From Torkin Wakefield and Charles Steinberg, MD**

*"When a lion enters the village it is everyone's job to sound the alarm."*

President Museveni , Uganda

**February 2004**

Dear Friends,

Our sojourn to Uganda and the African AIDS epidemic has been revealing, upsetting, inspiring, and confounding. The people we have met have reminded us of why we thought we wanted to come here. Let us introduce you to a few of them.

Regina is coughing, a deep gurgly cough. She is walking down a dirt path leading us and a volunteer home visitor to her home, a mud brick shed with one small dark room. Inside are two beds, and a make shift table. Against the wall leans a 25 kilo bag of corn-soya flour given to her through a women's group from the UN World Food Program. There is no evidence of any other food. She is a widow and lives here with her two sons, ages 4 and 6. Her husband died two years ago from AIDS and her in-laws removed her and her children from their home. She is already sick with HIV/AIDS and a liability to her relatives. Her sad face breaks into a wan smile as she welcomes us into her home. She does not ask us about when the medicine will arrive. She may not even know that others who live with this disease... have antiretroviral medicines (ARVs). She accepts that she will sicken and die. Many of her friends and relatives have done so and why should her fate be different from theirs? But she does have one burning concern: how will she pay the school fees to keep her



two sons in school. She knows that education is the only way out and that the \$34 per year that it costs to go to school is a barrier so high that her children will be impoverished forever. She tells us that once she dies her children will go to live with JjaJja, grandmother.

The JjaJjas of Africa are some of our new heroes. With an entire generation of working adults dead or dying, almost every family relies on the elderly to provide support, comfort, food, and education for the young ones. The pediatric AIDS clinic, where Torkin spends some of her time, is filled with old grandmothers bringing toddlers to see the doctor. They wait patiently along with a hundred other JjaJjas for the opportunity to get medical help for their grandchildren. In the picture (above), that Charles took, you see a mother with her adult son. He is paralyzed and dying. She has buried three other adult children -- all to AIDS. She has two remaining daughters and is caring for numerous grandchildren.

Maria, aged two sits on my lap attempting to snuggle in as deeply as possible. She is bright eyed and occasionally has the broadest smile that lights up the day. Her eye infection that was festering last week has mostly cleared up. She was abandoned at birth in the bathroom of a local hospital and brought to the Sannu Babies Home for Orphans. We just give ourselves over to be hugging machines once a week trying to pour in love and touch, smiles, and encouragement to a few of the 2 million children that have been orphaned in Uganda by the AIDS epidemic.

When we came to Uganda we anticipated that the ARVs would be rolling out; the buzzwords in the AIDS world were all about "scaling up," "capacity building," "breaking the silence." We were confounded to find almost no organization actually distributing ARVs. Yes, there are lots of pilot projects and Western universities are all eager to do research projects. But very little is available for the uneducated, poverty imprisoned people.

In the Mulago Hospital where Charles is working and training African doctors the clinic is giving out ARVs to approximately 250 individuals. 1,500 others are on the waiting list. Mwanni, a 25 year old widow for 8 years, comes to the clinic on Study Day. She hopes to enroll in the one ARV



trial available, which will give her all her meds, her lab tests and her visits to the clinic at no cost. She had a CD4 cell count of 192 which she paid for on her own and which qualified her for screening into the study. At screening her CD4 is 202, still critically low but 2 points over the 200 cut off required for the study. She is turned away and all we can do is refer her to NACWOLA, the woman's support agency that has enrolled and helped 40,000 women with AIDS in Uganda. They have food, support groups, counseling, and, for some, job training. She is thrilled for the referral since she had never heard of such a place. In the back of my mind I wonder if she is not fortunate to postpone for a while her ARV therapy. Each day we see more mistakes than successes as the local doctors begin up the learning curve. In a few short months we hope they will be doing it better.

Meanwhile the government of Uganda has 38 million dollars of Global Fund AIDS money that is being held in the Finance Ministry. No one seems to know why this money is not being channeled into care with more of a sense of urgency. Activism as we know it in North America is unknown here. Everyone waits patiently, except us. We bitch about it to ourselves and impotently ask our colleagues, Where's the money? Will we learn patience or will we teach activism?

Uganda is a beautiful land filled with natural beauty. We are roused from our sleep at dawn by the earliest calls of birds that serenade our ears, blending with the call to prayer from the nearby mosque. The senses are always stimulated here with sounds of zooming traffic, singing, drumming, babies crying, radios blaring, and street vendors calling out their wares. The sky is a rich blue with five different kinds of eagles and storks flying overhead. Smells of flowers, sweat, garbage and spices waft in the breeze. The people wear colors so beautifully against their ebony skin it is hard not to stare. Braids are intricate swirls with beads and bells woven into women's hair hennaed red at the tips. The old and the new flow together in the streets of Kampala. Business people are on cell phones while peasants plod along with goats. The street stall sells matoke (mashed green bananas) and poshe (steamed corn meal) while the well-to-do can eat Thai, Italian, Ethiopian or French cuisine.

We are "muzungos;" white people who have historically enslaved the Africans, divided and colonized their continent; extracted their wealth. And yet they are still broadly smiling their welcome to us, willing to work with us, to invite us to their celebrations, to treat us with brotherhood. We feel deeply grateful to be here, to receive trust and friendship and have the opportunity to serve and learn. At the end of the day we are filled up and emptied out in a deeply satisfying way.

All of this has led us to our decision to stay here, committing to work for the next year. More on that in the next letter from Africa...lots of love to each of you. Our friends back home mean a lot to us now and we appreciate your love and prayers.

*Charles and Torkin*

### March 2004

Dear Friends,

Charles is teaching twenty African doctors about the complexities of using antiretroviral medicines. Most have never prescribed these drugs but are about to begin. Many have never seen a laptop. At the end of the week they are all researching topics on the internet, and presenting to the class on PowerPoint. Charles stands at the front of the classroom, his lecture on ARVs almost over, engaging the group in an animated discussion about drug interactions. Torkin is working quietly in the back of the room when an anguished scream rips the air and brings us all to silence. Again comes the scream. Torkin is prepared for this moment, having decided last week to go immediately. She runs from the classroom into the adjacent pediatric ward. It is easy to find the young mother in a heap on the floor beside a gurney. The body of her four year old lies lifeless, only partially covered by a thin sheet. Her grief is volatile, enormous, filling the hospital with shrieks of disbelief, anger, and sorrow. Nga chi taro, chi taro, chi taro; So sorry, so sorry, I'm so sorry, Torkin murmurs over and over again, slumped on the floor next to the screaming mother. Other mothers tighten their hold on their own children, knitting their eyebrows. They stay near but look away hoping to ward off such a fate for their own little one. After half an hour, huddled on the floor below the dead child's gurney, the mother exhausts her first wave of grief.

We hear this keening daily. Such is the reality in the pediatric ward at Mulago Hospital, Kampala's teaching hospital. The head nurse tells us there are up to ten deaths a week on her ward. The mother's heart in each of us deeply aches. These deaths are from AIDS, measles, malaria, TB, accidents, and congenital problems, from starvation and poverty and lack of medical care. Many are mysterious without diagnosis. The family must pay 4,000 Ugandan Schillings (2 dollars) to get the body of their child released. Sadly we put this sum in the parent's hands if needed. Hospital wards here are unique. When a patient is admitted members of the family also move in. They provide all the food, care, cleaning, and love. You see them camping on the grass, cooking, reading, carrying on the tasks of life. Below is a photo taken outside the pediatric (peds) ward.

At the Pediatric Infectious Disease clinic Torkin is working on setting up a Teen Club for the 200 HIV+ adolescents that get their care here. Most of these kids are very small having gotten HIV from their mothers at birth. Many are teased at school or rebuffed by their families. Most have lost their mothers. The Teen Club's focus will be to have FUN and make friends. In time, with support, we hope they will begin talking about what it's like living a lifetime with HIV. We have planned a trip to the local amusement park for June and the boys want to start a football (soccer) team. We have high hopes for these youngsters as they are able to get ARVs through a research study being



conducted by Baylor University. Eventually we want to take the most gregarious teens and help them become spokespeople for other teens.

When we arrived in Uganda Charles had a two month contract to work with the Academic Alliance. We had rented our Boulder house out for one year not sure exactly where the

winds of fortune would blow us, but fairly certain that there was work to be done in the AIDS epidemic in Africa. The winds picked us up and swirled us across town from Mulago Hospital to deposit us at Mbuya Reach Out. Reach Out might have been dreamed into existence by us or by many of our friends at Holyoke, Wellspring, or

AIDS, Medicine and Miracles. They believe that medicine without food, food without hope, and hope without medicine is fruitless. To give starving people only ARVs still leaves them in a life-threatening situation.

Reach Out is holistic in its approach; the only such organization we have found in Uganda. It combines HIV/AIDS and TB care with poverty reduction strategies. Started by an Italian priest and a Danish doctor it first served the poor out of the back of a car. Soon it had taken over the church entry hall for its clinical care, and every other inch of space for its pharmacy, lab, charts, administration, and all of its social programs. In two and a half years it has grown to have a wonderful social program that includes UN food distribution of corn/soy flour, micro finance loans, and a school fees program. The tailoring school trains HIV+ clients to sew and the loans program helps them purchase their own sewing machine to start a business. The Reach Out store sells the dresses, tablecloths, aprons, and other items that they make. There is a choir called the Angels of Mbuya singing African healing songs and messages of pride. Young men exercise on the soccer field. And at mid-day, the smell of rice, beans and vegetables pulls staff and clients together for lunch.

The people Reach Out serves are very poor. This week we traveled with the Reach Out Street Theater group to one of our neighborhoods called the Acholi Quarter, named for the tribal people who live here. The Acholi have been displaced from their pastoral homeland during the 17 yearlong civil war going on in Northern Uganda. They have built a mud village

of one-room huts near a quarry. They work with heavy sledges under the hot African sun, crushing large rock into gravel. For this grueling work they get 2,000 Uganda Schillings (one US dollar) a day. Others hire out as day laborers or are scavengers of rubbish heaps. Ferida, a Reach Out patient and a rock crusher, holds Torkin's hand as they



watch the drama group acting out a typical family scene:

The father is drinking, having just arrived home from visiting the prostitute. The small children are crying because they do not have enough to eat. The teenage daughter has snuck off with the boyfriend for a little fun! Ferida whispers in my ear, African men!

They blame the woman for any bad character that their children have. Look at him! He is drunk and in real life he will hit her. From where I sit, the whole family is just responding to the overwhelming pressures to survive. Each is trying to cope with their frustration, poor health, joblessness, and lack of opportunities and education. A lively discussion follows the drama in which the men and women talk about what separates them and how they can work together. Ferida boldly explains: We will never stop AIDS until we women are treated right. The evening ends with a prayer of great gratitude and a room temperature orange Fanta. We feel hopeful. An African saying that the President Museveni of Uganda likes to quote is, "When a lion enters the village it is everyone's job to sound the alarm."

So we hear the Acholi and are sounding the alarm. The poor of the world ask all of us to get involved in an appropriate way, consistent with our life and means. Thank you for your prayers, for your questions. Waybale Nyo (Thank you very much) for listening. We love hearing from you. You can reach us through Resolute! at ResoluteEditor@aol.com.

*Charles and Torkin*

*To donate to the Partners in AIDS Service project, please send all contributions, which are fully tax-deductible, to: All Seasons Chalice, PO Box 2180, Boulder, CO 80306-2180. Make checks payable to: All Seasons Chalice and memo them Partners in AIDS Service Fund*

*Gender - Continued from page 6*

GLBT people all share a common problem -- we are discriminated against because of our gender.

First, we are discriminated against because of our gender expression. Trans people who are born with male bodies but are really female are discriminated against because they express a female gender. Trans people who are born with female bodies but are really male are discriminated against because they express a male gender.

Gay men and lesbian women also experience the same kind of discrimination. If a man is walking down the street alone, no rainbow flags, no T-shirt with a cute saying -- just walking down the street by himself, and some stranger leans out of the car window and yells out "Fag," it's not because this stranger knows the man's sexual orientation -- it's because of the way the man is presenting his gender. It's in the way he's walking or the clothes he's wearing. He's presenting his gender in a way that's inconsistent with what is expected of a straight American male -- and because of this, he's perceived as gay. He might be gay. He might not be. But he's perceived as gay because of his gender expression.

If a gay man or a lesbian interviews for a job and doesn't get that job, he or she might believe it has something to do with sexual orientation. And it might. But if sexual orientation isn't discussed in the interview, and it better not be -- that's illegal -- the only reason it could be a factor is because of gender presentation. If this person is presenting his or her gender in a non-traditional way, the assumption is that he is gay or she is lesbian. The discrimination isn't due to sexual orientation, it's due to perceived sexual orientation based on gender expression.

Even the comment, "Gosh, you don't seem gay," is based on the way a person is expressing his or her gender and the expectations that go with gender expression and sexual orientation. Our society has come to expect that gay men and lesbians will express their gender differently than straight people, and when they don't, it's always a surprise to the straight community. Even that is discrimination.

But this thinking isn't limited to gay men and lesbians. Those of us who are trans are well aware of the stages that we go through, as adults, to try to act like the gender into which we are moving. Many of us go overboard, trying to be as "feminine" or as "masculine" as we can, and the ones who most believe that they are succeeding, the ones who most desire assimilation into the "straight community," are the ones who shy away from any identification with the gay and lesbian community. We suffer from the same stereotypes and the same fears. Those of us who identify as straight once we transition, and that happens to be the majority of transfolk, are so concerned about our own gender presentation and our need to fit into our new male or female roles that we become blinded by our own insecurities and move into our own brand

of homophobia without realizing that the discrimination that many gay and lesbian people face is the same discrimination that we face and are struggling so hard to move away from -- discrimination based on our gender expression.

Another reason that the T belongs with GLB is that we are all discriminated against because of our bodies -- our bodies don't match the traditional expectations of gender in our society. Trans bodies certainly don't match these expectations. A woman with a penis? A man with a vagina? Sorry, no (fill in the blank here -- job, apartment, loan, insurance, benefits, wedding) for you.

But gay and lesbian bodies are "correct," right? They're "normal," right? But they still don't match the gender expectations of our society. Two penises in bed? Sorry. Two vaginas in the shower? Uh uh. Gay men and lesbians are being discriminated against because they turned up with the wrong body parts -- the parts that match those of the person they fell in love with. Remember, it's not the gender you love that's the problem. It's the gender you are.

It's our gender. Our gender denies us the basic civil rights that others enjoy. Our gender causes others to reject us, to hate us, to assault us, to murder us. Our gender causes others to pass laws to deny us even basic human rights. It's our gender that is being used against us.

But those who would keep us down, those who would pass laws to literally make us less than full human beings, don't know something that we do know. It's our gender that links us together and gives us community. It's our gender that makes us strong. It's our gender that keeps us fighting -- our right to be the gender we are, to express that gender however we choose, and to love the people that we love, whatever their gender.

But what about loving? What about those basic civil rights that we are being denied? Everyone knows that there is a Constitutional Amendment afoot to prevent gay men and lesbians from ever marrying -- a Constitutional Amendment that will tell us that we are less than complete and whole human beings. And gay men and lesbians are fighting this hard, as well they should be. With fifty percent of straight marriages failing, somebody has to show them how to do it right.

But with all the arguments, all the protests, all the truly eloquent speeches that are flying around out there, I have not heard one that points out the fact that trans people make a mockery out of the entire marriage amendment, and that no matter which way it goes, there will be gay marriages.

Think about it. The phrase "a union between a man and a woman" is being tossed around like a football out there, but nobody has bothered to define "man" and "woman." And that can and will be their downfall -- as long as we have the foresight to use it to our advantage.

Look at me -- take a good look -- and then think about the answer to this question. Who can I marry? That's the one thing that the backers of the



marriage amendment haven't thought about. Because who I can marry depends on how they define man and woman. And they have failed to do so.

Let's look at the ways they could do it. They could define man and woman by chromosomes -- XY and XX. And if they do that, I can marry a man -- I have an XX chromosome. Now look at me again -- I look like any other man. Picture me in my wedding suit with a snappy boutonniere, my groom by my side. Picture us kissing at the altar. If I marry a man -- instant gay marriage.

Now let's say they decide that "man" and "woman" are defined by genitalia. Here's a little secret I haven't told you yet -- I don't have a penis. I still have a vagina. If "man" and "woman" are defined by genitalia, I can marry a man. One vagina, one penis -- but look at me again. Instant gay marriage.

And even if those terms are defined by what our personal papers say -- our driver's license or birth certificate, I can marry a woman. I had those things changed. Two vaginas -- instant gay marriage. No matter what they do, and no matter who I fall in love with, if I decide to get married, they'll have an instant gay marriage on their hands.

A few months ago, I e-mailed Marilyn Musgrave with these very situations. I asked her how she would define "man" and "woman." I explained the conflicts that trans -- and intersexed -- people presented to her marriage amendment. Not surprisingly, I never heard back. Yes, she's busy, but I can tell you why I didn't hear back. Because she doesn't know. She

doesn't know the answer to my questions. None of them know how they would define "man" and "woman," and I can tell you that no matter how they define those terms, they will have so many "gay" marriages on their hands that they won't know what to do about it. To gay and lesbian people, I say, we can help you with this. Just let us. We're all in this together.

Which brings me back to community. We are in for some hellish times over the next few years if things continue in the direction they are going. But we are also in for some glorious times. We are in this thing together, all of us, everyone here, and we are all working toward a common goal -- civil rights for all, freedom for all, justice for all. Humanity for all. We cannot afford to be divided. We are all united under a common bond -- discrimination based on some aspect of our gender.

Little chromosomes, invisible to the naked eye, are the only thing they've got in their arsenal to use against us. Those little invisible chromosomes are the things that define our bodies and the gender expectations that go with them. Well, the chromosomes might be invisible, but we aren't. And if they want to use letters against us -- XX and XY -- then we'll haul out all the damn letters we've got -- and we've got a lot of them. Together, we -- GLBTQQI and whoever else wants to come aboard -- together, in community, we can make it work. This is our time. Let's start now.

*Matt Kailey is a author, freelance writer, speaker, and workshop facilitator, focusing on gender and transgender issues. He is also an outstanding thinker! He is a member of the Resolute Editorial Advisory Board. He may be reached through his website at [www.mattkailey.com](http://www.mattkailey.com)*

## CPCRA

### COMMUNITY PROGRAMS FOR CLINICAL RESEARCH ON AIDS

#### Strategies for the Management of Anti-Retroviral Therapy (SMART)

The SMART study is a randomized trial comparing long-term effects of two strategies for use of antiretroviral therapy (ART): **Drug Conservation (DC) Strategy:** Episodic use of ART with the aim of conserving ART options. ART use is guided by CD4+ counts irrespective of viral load levels. **Virologic Suppression (VS) Strategy:** Continuous use of ART to maximally suppress viral load immediately following randomization and throughout follow-up, irrespective of CD4+ counts. Criteria: Greater than 350 CD4, not currently pregnant.

#### Long Term Monitoring(060)

A prospective study of long-term clinical virologic and immunologic outcomes of HIV+ individuals. Open to Treatment Naive individuals only.

Parking, transportation and child care available.

**To enroll or for more information**

Call Julia Weise....303.436.7195

## PEDIATRIC ACTU

### (AIDS CLINICAL TRIALS UNIT)

**ACTG 219C:** Pediatric Late Outcomes Protocol.

**PACTG P1006:** The Effects of Highly Active Antiretroviral Therapy (HAART) on the Recovery of Immune Function in HIV-Infected Children.

**ACTG 1008:** An Observational Study of the Rate of Opportunistic Infection Events in HIV-Infected Children who have Demonstrated Immunologic Reconstitution and who have Discontinued OI Prophylaxis.

**PACTG 1010:** Effect of Antiretroviral Therapy on Body Composition in HIV-Infected Children.

**PACTG P1015:** Intensification of HIV-specific CD4 and CD8 Activity by Cycling Highly Active Antiretroviral Therapy (HAART) in Pediatric/Adolescent Patients with <50 HIV RNA Copies/ml.

**PACTG 1020-A:** Phase I/II Open Label Pharmacokinetic and Safety Study of a Novel Protease Inhibitor (BMS 232632) in Combination Regimens in ART Naive and Experienced HIV-Infected Infants, Children, and Adolescents.

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**PACTG P1021:** An Open-Label Study to Evaluate the Safety, Tolerance, Anti-Viral-Activity and Pharmacokinetics of Emtricitabine in Combination with Efavirenz and Didanosine in a Once Daily Regimen in HIV Infected Antiretroviral Therapy Naive or Very Limited Antiretroviral Exposed Pediatric Subjects.

**PACTG P1025:** Perinatal Core Protocol. An observational study of HIV and pregnancy.

**ACTG A5093:** An Open-Label, Non-Randomized Study of Pharmacokinetic Interactions Between Depo-Medroxyprogesterone Acetate (DMPA, Depo-Provera) and Selected Protease Inhibitor (PI) and Non-nucleoside Reverse Transcriptase Inhibitor (NNRTI) Therapies Among HIV-Infected Women.

*For more information or to enroll call*

Carol Salbendblatt...303.861.6751

#### UNIVERSITY OF COLORADO

#### ADULT AIDS CLINICAL TRIALS UNIT

*Studies Open to Enrollment (March 2004)*

#### NAIVE PATIENTS

**ACTG A5073** - "A Randomized Phase II Open Label Study to Compare Twice Daily Potent Antiretroviral Therapy With Once Daily Potent Antiretroviral Therapy and to Compare Self-Administered Therapy and Therapy Administered Under Direct Observation".

**ACTG A5173** - "A Pilot Study to measure the Clearance of Replication-Competent HIV-1 in Resting Memory CD4+ Cells in HIV Infected Subjects Who Receive T-20 + Oral Combination Antiretroviral Therapy"

#### EXPERIENCED PATIENTS

**ACTG A5115** - "A Phase II Exploratory Study Examining Immunologic and Virologic Indices in Two Age-Differentiated Cohorts of HIV-Infected Subjects to Explore the Basis of Accelerated HIV-Disease Progression Associated with Aging"

**ACTG A5126** - "A Phase II Study of the Predictive Value of Pharmacokinetic-Adjusted Phenotypic Susceptibility (C12h/IC50) on Antiretroviral Response to Ritonavir-Enhanced Protease Inhibitors in Subjects with Failure of Previous Protease Inhibitor-Based Regimens".

**ACTG A5146** - "A Randomized Controlled Trial Evaluating the Impact of Therapeutic Drug Monitoring (TDM) on Virologic Response to a Salvage Regimen in Subjects with a Normalized Inhibitory Quotient (NIQ) Less Than or Equal to One to One or More Protease Inhibitors".

**ACTG A5165** - "A Phase I/II Randomized, Double-Blind, Placebo-Controlled Pilot Study of b-D-2,6-Diaminopurine Dioxolane (DAPD) vs. DAPD plus MMF in Treatment Experienced Patients".

**Tibotec TMC114** - "A Phase II Randomized, Controlled, Partially Blinded, 48-Week Trial to

Investigate Dose-Response of TMC114/RTV in 3-Class-Experienced, Multi PI-Experienced HIV-1 Infected Subjects".

#### OPPORTUNISTIC INFECTIONS/ COMPLICATIONS

**ACTG 736** (cognitive function) - "Cerebrospinal Fluid Human Immunodeficiency Virus-1 (HIV-1) and Cognitive Function in Individuals Receiving Potent Antiretroviral Therapy."

**ACTG A5030** (CMV prophylaxis) - "A Phase III, Prospective, Randomized, Double-Blind Trial of Valganciclovir Pre-Emptive Therapy for Cytomegalovirus (CMV) Viremia as Detected by Plasma CMV DNA PCR Assay".

**ACTG A5079** (reduced testosterone/obesity) - "A Prospective, Multicenter, Randomized, Placebo-Controlled Trial of Physiologic Testosterone Supplementation for Men with Mild to Moderately Reduced Serum Testosterone Levels and Abdominal Obesity".

**ACTG A5090** (cognitive impairment) - "A Phase II, Placebo-Controlled, Double-Blind Study of the Selegiline Transdermal System (STS) in the Treatment of HIV Associated Cognitive Impairment".

**ACTG A5093** (effect of anti-HIV drugs on Depo-Provera) - "An Open-Label, Non-Randomized Study of Pharmacokinetic Interactions between Depomedroxyprogesterone Acetate and Selected Protease Inhibitor (PI) and Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) Therapies among HIV-Infected Women".

**ACTG A5110** (fat wasting) - "A Restrictively Randomized, Open-Label, Controlled, Pilot Study of the Effect of a Thymidine Analogue Substitution or Change to a Nucleoside-Sparing Regimen on Peripheral Fat Wasting".

**ACTG A5127** (hepatitis B/HIV co-infection) - "A Randomized, Phase II, Controlled Trial of the Activity of Adefovir Dipivoxil and Tenofovir Disoproxil Fumarate for the Treatment of Lamivudine - Resistant Hepatitis B Virus (HBV) in Subjects who are Co-infected with HIV".

**ACTG A5163** (Bone Density) - "A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Once-Weekly Alendronate in HIV-Infected Subjects with Decreased Bone Mineral Density Receiving Calcium and Vitamin D."

**ACTG A5164** - (Acute OIs) - "A Phase IV Study of Antiretroviral Therapy for HIV-Infected Adults Presenting with Acute Opportunistic Infections: Immediate versus Delayed Initiation"

**ACTG A5186** (Fish Oil and Fenofibrate on Triglycerides) - "A Phase II Trial of the Effect of Combination Therapy with Fish Oil Supplement and Fenofibrate on Triglyceride (TG) Levels in Subjects on Highly Active Antiretroviral Therapy (HAART) Who Are Not Responding to Either Fish Oil or Fenofibrate Alone."

#### **COMIRB 01-844**

"Concentration-Controlled Antiretroviral Therapy in Patients Experiencing Persistent Viremia".

#### **For additional information contact:**

Graham Ray, RN, MSN (303) 372-5535

Bev Putnam, RN, ANP (303) 372-5537

Cathi Basler, RN, ANP (303) 372-5539

Jim Scott, RN (303) 372-5543

INTERNET INFO: <http://www.uchsc.edu/sm/caactu/>

# HIV/AIDS SERVICES

## Denver Area

### Medical Clinics

#### Apex Family Medicine

Mia Scott, MD, Michael Steward, MD, Peter Prutch, PhD, NP, Paul Mack, PA, Alicia Maltzman, NP  
Ph: 303.321.0222 Fax:  
303.321.6683 210 University Blvd., Ste. #440, Denver CO 80206

#### Children's Hospital HIV Program (CHIP)

303.764.8233  
1056 E 19th Ave., B055, Denver, CO 80218.  
Ryan White funded pediatric, youth and family HIV specialty care. Medicaid/Medicare accepted

#### Colorado Infectious Disease Consultants

Jordan Gulinson, MD, Peter Karakusis, MD, Carolyn Tilquist, MD  
Ph: 303.777.0781 Fax:  
303.777.0786  
950 E. Harvard Ave., Ste. #690 Denver, CO 80210

#### Denver Health & Hospitals ID/AIDS Clinic Open Until 7:00 PM on Wednesdays!

Ph: 303.436.7240 Fax:  
303.436.7244  
605 Bannock St., Denver, CO 80204  
Ryan White funded specialty HIV care for those who live in the City and County of Denver and have no insurance. Medicaid and Medicare also accepted.

#### Denver Infectious Disease Consultants

Rose Medical Center  
Ben Young, MD, PhD, Ken Greenberg, DO, John Hammer, MD  
Ph: 303.393.8050 Fax:  
303.320.1953  
4545 E. 9th Ave., Ste. #120  
Specialty HIV care. Accept most insurance, Medicaid and Medicare.

#### Early Intervention HIV Clinics

Ph: 303.436.4727

Fax: 303.436.4779  
Pager (303) 891-9360  
Cell Line (303) 880-5747  
Traveling HIV Clinic, please call most convenient location. Ryan White funded HIV medical care for uninsured people living in the City and Cty of Denver. Also accept Medicaid and Medicare.

#### Infectious Disease Consultants, P.C.

Rebekah Gass, MD, Raymond Blum, MD  
Ph: 303.831.4774 Fax:  
303.830.7750  
1601 E. 19th Ave., Ste. #3650 Denver, CO 80218

#### Kaiser Permanente Infectious Disease Clinic

Janet Kuhns, MD, Miguel Mogyoros, MD  
Ph: 303.861.3133 Fax:  
303.831.3772  
2045 Franklin St., 4th Floor

#### South Denver Infectious Disease Specialists

Jacqueline Messa, MD, Burton Golub, MD, Susan Dias, MD, Josephine Williams, MD, Sarah Cimafranca, MD,  
303.788.5900  
499 E. Hampden Ave., Ste. #220  
Englewood, CO 80110 Accepts most insurance, Medicaid and Medicare.

#### University Hospital Infectious Disease Group Practice

Ph: 303..315.1540 Fax:  
303.315.1469  
4200 E. 9th Ave., Denver, CO 80262  
Ryan White funded HIV specialty care for those who live outside the City and County of Denver and have no insurance. Also accepts most insurance, Medicaid and Medicare - without residency requirement.

#### Veterans Hospital

303.393.2837  
1055 Claremont, Denver, CO 80204  
Infectious Disease Clinic for Vets with VA medical benefits.

#### Western Infectious Disease Consultants

Marylou Cullinan, MD, Jeff DesJardin, MD, Norman Fujita, MD, Susan Mason, MD.  
Ph: 303.425.9245 Fax:  
303.425.1378  
7760 W. 38th Ave. Ste 290, Wheat Ridge, CO 80033 Accept most insurance, Medicaid and Medicare.

#### Dental Clinics

##### Howard Dental Center

Ph: 303.863.0772. Fax:  
303.832.7823  
1420 Ogden St., Denver, CO 80218

##### Denver Health ID Dental Clinic

**Open Until 7:00 PM on Wednesdays!**  
303.436.7928  
605 Bannock St., Denver, CO 80204

#### HIV Specific Pharmacies

##### State ADAP Pharmacy

**The Apothecary**  
303.499.2879/ 1.866.499.2879  
Fax: 303.499.5308, 350 Broadway, Suite 50, Boulder, CO 80305

##### Children's Hospital Pharmacy

Ph: 303.436.7335

##### Clear Spring Pharmacy

See Add on Back Page!  
Call 303.333.2010  
201 University Boulevard

##### Colorado Pharmacy

See ad on page 7  
Ph: 303.863.7644 Fax:  
303.863.7656  
701 E. Colfax, Denver, CO 80203

##### Denver Health ID Pharmacy

Ph: 303.436.7335 Fax:  
303.436.7663  
605 Bannock

##### University ID Pharmacy

303.315.1455 Fax:  
303.315.1463  
4200 E 9th Ave.

#### Case Management Agencies

##### The Adoption Exchange Families Connecting for Kids

Ph: 303.755.4756 Fax:  
303.755.1339  
Provides assistance with permanency planning and case management for families living with HIV.

**Colorado AIDS Project**

701 E. Colfax, Denver, CO 80203  
 www.coloradoaidsproject.org  
 Client Services 303.837.1501  
 Fax: 303.837-0388

**Empowerment/ Women's AIDS Project**

Ph: 303.320.1989 Fax: 303.320.3987  
 1600 York St., #201, Denver, CO 80206  
 Case management for women living with HIV/AIDS. Services provided include: advocacy and group support, education, GED preparation, employment services, housing programs and emergency financial assistance.

**POCCAA, People of Color Consortium Against AIDS**

Ph: 303.321.7965 Fax: 303.321.6841  
 1652 Franklin St., Denver, CO 80218

**Servicios De La Raza, Inc.**

303.458.5851  
 La Gente-bilingual/bicultural HIV/AIDS case management program.  
 4055 Tejon, Denver, CO 80211

**HIV Testing and Counseling Colorado AIDS Project**

303.837.1501  
 Free Anonymous and Confidential Orasure HIV testing and counseling on the last Thursday of each month from 5:30-8 PM. 701 E. Colfax Ave. Denver, CO 80218.

**Denver Metro Health Clinic**

303.436.7221  
 605 Bannock, Denver, CO  
 Anonymous and Confidential HIV testing as well as a full STD clinic.

**Early Intervention Outreach Testing**

303.851.4098  
 Free Anonymous and Confidential Orasure testing and counseling.

**Empowerment, Women's AIDS Project**

303.320.1989  
 Free Anonymous and Confidential Orasure testing, 3rd Tues of each month from 5 -6:30 pm. 1600 York St., #201, Denver, CO 80206

**The GLBT Center**

**303.733.7743**  
 Free Anonymous and Confidential Orasure testing and counseling. 1st and 2nd Wed. of each month from 6-8 pm. 1050 Broadway, Denver, CO 80203

**It Takes A Village/ Brother Jeff's Health Initiative**

Call 720.297.9349 or 303.367.4747  
 Two Offices: 1532 Galena St Suite 225, Aurora, CO 80010 or 608 26th St., Denver, CO 80205, 303.293.8879  
 Every Tuesday from 10am to 3pm and Every Thursday from 4pm to 6 pm at our offices and other times upon request.

**Jefferson County Department of Health and Environment**

Arvada: 303-275-7501  
 Conifer: 303-239-7078  
 Lakewood: 303-239-7078  
 HIV anonymous and confidential testing, STD testing and treatment, Hepatitis information.

**Mental Health Services**

**Living and Learning with HIV**  
 Mental Health Corporation of Denver 303-504-6501 4141 E. Dickenson Place, Denver, CO 80222. Callers can ask for anyone on the LLH team.

Mental Health Services for people living with HIV/AIDS are also available through:

**CAP**  
 303.837.1501  
**Denver Health**  
 303.436.7240  
**University Hospital**  
 303.315.1540

**New Service Provider for Latinas and other Women of Color! Sisters of Color United for Education**

**Comadres Project**  
 303.863.1446 ext 104  
 1290 King St., Denver, CO 80204  
 Mental Health and Client Advocacy services available.  
 Call Bernadette Berzoza.

**Substance Abuse Treatment "ARTS" Special Services Clinic**

303.355.1014  
 Substance abuse counseling and

primary medical care.  
 2121 E. 18th Ave., Denver, CO 80206

**CADREC**

303.295.2521  
 Substance abuse treatment and prevention for communities of color.  
 3315 Gilpin, Denver, CO 80205

**Project Safe**

303.315.0950, 1.800.429.9240  
 HIV prevention services and treatment entry facilitation for HIV+ drug users.

**Sobriety House/ Stepping Stones**

303.722.5746  
 107 Acoma St. Denver, CO 80223  
 Residential substance abuse treatment. 5-Week intensive inpatient treatment with follow-up half-day programs available. Level II DUI Education and Therapy available. No intake fee. \$20/2-hour session.

**Food Banks/ Home-Delivered Meals**

**CAP Food Bank**  
 303.837.1501. 701 E. Colfax Ave.

**VOA Meals on Wheels**

303.294.0111

**POCCAA Food Bank**

303.321.7965  
 1652 Franklin, Denver, CO 80218

**Project Angel Heart**

303.830.0202  
 Home-delivered meals for people living with HIV/AIDS and other life-limiting conditions. 4190 Garfield St., Unit 5, Denver, CO 80216

**Education and Advocacy**

**The HepC Connection**  
 303.860.0800 1-800-522HEPC  
 1177 Grant Street, Ste 200, Denver, CO 80203. <http://hepc-connection.org>

A unique support system established to assist Hep C-challenged individuals and their families.

**The HEART Institute**

303.329.9379 ext. 106  
 Certification courses in



HIV Treatment Education. Courses are open to HIV service providers, volunteers, PLWH/A and others interested in understanding HIV disease and its treatment.

***New Service Provider for the African American Community!***

**It Takes A Village/Brother Jeff's Community Health Initiative**

Call 720.297.9349 or 303.367.4747  
Two Offices: 1532 Galena St Suite 225, Aurora, CO 80010 or 608 26th St., Denver, CO 80205, 303.293.8879

Peer-based Prevention Case Management, HIV Testing and Counseling and Peer Advocacy and Education by and for the African American community through the **Just Us Project, Phenomenal Women** and other programs.

**PWA Coalition Colorado, Peer Advocacy Project**

Empowering people living with HIV/AIDS through education and advocacy.

303.329.9379

1290 Williams St. Ste.102, Denver CO 80218

Offers bilingual peer advocates to work with PLWH/A experiencing barriers accessing and utilizing medical care. Other services include: Community Dinner and Education Forums, Individualized Treatment Education and Counseling, Resolute! and Denver Buyer's Club and The HEART Institute.

**Servicios De La Raza Bilingual Client Advocacy Services**

Call Maria Lopez 303.458.5851

***New Service Provider for Latinas and other Women of Color!***

**Sisters of Color United for Education**

**Comadres Project**

303.863.1446 ext 104  
1290 King St., Denver, CO 80204  
Mental Health and Client Advocacy services available.  
Call Bernadette Berzoza.

**The Women's Lighthouse Project**

Ph: 720.331.0408,  
Fax: 303.433.3014, 2120 W. 33rd Ave., Denver, CO 80211  
email: womenslighthouse@aol.com

Our Mission: To respect, support and empower women in managing their HIV disease. Education, advocacy and support. Child care, a meal and transportation are always provided. Call Shannon Behning.

**Home Health/Home-Based Services/ Hospice**

**Hospice of Metro Denver**

303.321.2828

**Jewish Family Services**

303.759.4890

Homemaker services free to all People Living with HIV/AIDS in need.

**RAIN Colorado**

Regional AIDS Interfaith Network  
303.355.5665  
1290 Williams St., Denver, CO 80218

**Visiting Nurses Association**

303.698.6405

Home health care for People Living with HIV/AIDS. Call Art Burke.

**Housing**

**Colorado Coalition For The Homeless**

2111 Champa Street  
Denver, CO 80205  
(303) 293-2217

**Continental Divide Management Corporation**

303.393.7368

**Denver Housing Authority**

303.534.0821

**The Hope Program**

303.832.3354

Drop-in Center/Services for the homeless.

**Horizon House**

Housing for People Living with HIV/AIDS  
303.980.9604

**Our House II**

303.742.4729

Assisted living for People Living with HIV/AIDS who qualify for HCBS services.

**Legal Services**

**ACLU Colorado**

303.777.5482  
400 Corona St.; www.aclu-co.org  
American Civil Liberties Union.

**CLIP**

303.282.5602 / 1.877.372.CLIP  
www.clipcolorado.net.  
Contact Michael Brewer.

**The Legal Center**

303.722.0300/ 800.288.1376  
Legal help for HIV/AIDS discrimination. Call Barry or Eric.

**Metro Volunteer Lawyers**

303.837.1313

Nonprofit organization providing free legal services for people with low income.

**Child Care/Family Services**

**Families Connecting for Kids**

**The Adoption Exchange**

303.755.4756, ext. 253, Call MaryBeth.

Services for People Living with HIV/AIDS and are caring for a child.

**VOA Rainbow House**

303.355.9582

Day care for HIV infected and affected children.

**Native American Services**

**Denver Indian Health**

303.781.4050

**Two-Spirit Society**

303.444.9009

Prevention and Intervention Services.

Call David Young.

**Asian-American Services**

**Asian-Pacific Development Center**

Denver: 303.355.0710

Aurora: 303.365.2959

Multiple support services and AIDS education in Asian-pacific ethnic languages.

**Gay and Lesbian Services**

**ATL Foundation**

303-424-1207

P.O. Box 740985, Arvada, CO 80006-0985

The ATL Foundation provides assistance to lesbians in need as a result of ill-health. If you or anyone you know is in need, call or write to us.

**The GLBT Center**

303.733.PRIDE (7743)

234 Broadway, Denver, CO 80203



**EAGR - The Emergency Assistance & Referral Program**

303.860.1779

Emergency financial assistance and referrals to other community resources.

**Rainbow Alley**

303.831.0442

Emergency Pager 303.461.1650

Drop-in center for Gay/Lesbian/Bisexual/Transgender/Queer youth. HIV education and support group.

**Holistic Health****The Denver Buyer's Club**

303.329.9379

1290 Williams St., Ste. 102

Monday - Friday 12 noon to 6 PM

Nutritional supplements at discount prices.

**The Yoga Group**

303.575.1673

Free restorative yoga classes for People Living with HIV/AIDS, three times each week in Denver. No yoga experience necessary. For information on classes, phone us or visit [www.yogagroup.org](http://www.yogagroup.org).**Support Groups****Catholic Support Group-HIV/AIDS Ministry.**

303.715.3287.

Meets the first Monday of each month at 6:30pm at St. Dominic's Parish Hall, 29th and Grove st.

**"Challengers, " Social Support**

303.860.1819

Looking for something fun to do in a healthy alcohol-free environment? Join your peers at a new Friday evening social gathering, with game playing and just plain fun. Come join: Fridays at 7pm at MCC Church of the Rockies. 960 Clarkson.

**Colorado HeteroPoz - Online Support/Networking**

303.359.5685

A group for sharing information and social events for HIV positive heterosexual men and women in Colorado - not just for singles. <http://groups.yahoo.com/group/ColoradoHeteroPoz/>**Grupo Palanca**

303.458.5851

Bilingual/bicultural support for gay and bisexual Latino men living with

or affected by HIV/AIDS. Call Lorenzo Ramirez. Meets alternate Fridays at 7:00pm.

**HIV/HCV Coinfected Support Group**

303.340.4870

About us and by us. Meets at PWACC Group Room. 1290 Williams St. Call Catherine for time and day.

**HIV+ Women's Group**

303.320.1989

Woman-to-woman support. Meets Tuesdays at 1:30pm. Food, transportation and child care available. Call Crystal.

**Jewish Support Group**

303.756.5862

Co-sponsored by the AIDS/HIV Interfaith network. Call Carolyn.

**El Grupo**

303.329.9379 ext. 103

Bilingual support group focusing on treatment, adherence and other educational issues important to group members. Call Rodolfo.

**PFLAG AIDS Family Support Group**

303.333.0286

We meet on the second Monday of every month from 7:30 to 9:00 p.m., at Denver Health Medical Center, in the main building on the second floor. People living with HIV/AIDS, their families, partners, and friends are all welcome.

**Positive Impact Group**

303.436.5972

Meets every other Tuesday from 1:30-3:30pm. Offers food, support, fun events, guest speakers and help with medication adherence. 605 Bannock St., 5th Floor Conference Room #307. Call Debbie Scott-Young

**Positive Support**

303.837.1501

For any HIV+ person with alcohol or drug issues. Meets Wednesdays 5 - 6:30pm. 701 E. Colfax Ave. Call Pam Semmler.

**RISE**

303.832.4188

624 Lafayette. St. Call Marty Flahive

**Straight and Positive**

Thursdays 7:00 p.m. - 8:30 p.m.

For HIV-positive individuals who also identify as straight Capitol Hill Community Center, 1290 Williams St, Denver

**Two-Spirit Society**

303.939.9021

Meets alternate Sundays. Call David Young.

**Young and Positive**

303.837.7358 ext. 2

A support group for young people living with HIV. 1st and 3rd Wednesday of every month at 4:00 pm. Call Myles Mendoza or talk to your case manager.

**Social Services****Adams County Social Services**

303.287.8831

**Arapahoe County**

303.365.5770

**Denver Human Services**

720.944.3666

**Douglas County Human Services**

303.688.4825

**Jefferson County Human Services**

303.271.1388

**Public Health and Safety/Community Planning/Public Policy****Colorado Department of Public Health and Environment**

303.692.2700

Partner notification, prevention case management, Ryan White Title II Consortia, HIV/AIDS prevention and epidemiology.

**Colorado Department of Health Care Policy and Financing**

303.866.3058

State of Colorado Medicaid Program Coordination. Serving all residents of Colorado.

**Coloradans Working Together (CWT)**

303.692.2736 Hotline:

303.692.2717

HIV prevention community planning group. People directly affected by HIV encouraged to participate.



**Jefferson County Department of Health and Environment**

One-on-One HIV Prevention Services  
Please call Amy Robillard at 303-239-7123, or e-mail at arobilla@co.jefferson.co.us.

HIV prevention services and support for those infected with HIV and those concerned about infection. HIV anonymous and confidential testing, STD testing and treatment, Hepatitis information.

Arvada: 303-275-7501  
Conifer: 303-239-7078  
Lakewood: 303-239-7078

**Mayor's Office of HIV Resources**

720.865.5600  
Dept. Environmental Health  
201 W. Colfax Ave suite 1009  
Denver, CO 80202

**PLWH Action Network**

303.722.3083  
Educating the legislature on ADAP and other issues surrounding those living with HIV/AIDS. Call Daniel.

**Ryan White CARE Act HIV Resources Planning Council**

720.855.8641 Call Lisa Lawrence  
4130 S Tejon St.

**Social Security Administration**

800.772.1213

**Tri-County Health Department**

303.363.3071

**Boulder County****Boulder County AIDS Project (BCAP)**

Ph: 303.444.6121 Fax:  
303.444.0260  
2118 14th St., Boulder, CO 80302

**Monday Night men's Discussion Group**

Monday night from 7-8:30 at BCAP Office

For more information contact the group facilitator, Alan Robarge at 303.247.0157 or call Boulder Pride at 303.499.5777

**Experience and Exploration of Healing**

303.444.6121  
A healing circle. Meets alternate Wed. at 7:00pm at First United Methodist Church.

**HIV Testing/Anonymous**

303.413.7500

**Terrie House The Works: AIDS Prevention/Risk Reduction**

303.413.7522  
Free and anonymous needle exchange.  
3305 Broadway, Boulder, CO 80304

**Beacon Clinic**

303.938.3167  
1136 Alpine, Suite 205  
Boulder, CO 80304

**Northern Colorado Northern Colorado AIDS Project Ft. Collins**

970.484.4469/ 800.464.4611  
400 Remington Ave., Suite 100  
Ft. Collins, CO 80524

**Ft. Morgan**

970.867.0300  
909 E. Railroad Ave., Ft. Morgan, CO 80701

**Positive Persons Group**

Ft. Collins  
970.484.4469  
Call for Current Information

**Southern Colorado Southern Colorado AIDS Project Colorado Springs**

719.578.9092  
1301 S. 8th St., Ste. #200,  
Colorado Springs, CO 80906. Email:  
info@s-cap.org. Web site: www.s-cap.org.

**Pueblo**

719.561.2616  
2410 N Grand, Pueblo, CO 81003

**Mom's Groups Colorado Springs**

719.578.9092  
Call Phyllis McNaughton.

**Pueblo**

719.561.2616 Call Phyllis King.

**Western Colorado Four Corners Living with HIV/AIDS**

Durango  
970.247.5702  
For anyone living with or affected by HIV/AIDS. Meets second and fourth Tuesday of every month. Call D.B.

**Western Colorado AIDS Project (West CAP)**

1.800.765.8594  
115 N. 5th St., Ste 210 Grand Junction, CO 81501. Email: Westcap@GJ.net  
www. GJ.net/~wcap/Main.html

Due to funding cuts and difficulty in maintaining the accuracy of other State's information, Resolute! can no longer maintain a multi-state resource guide. Our last resource guide that included Wyoming, Utah, Kansas and Nebraska can be found online at <http://www.thebody.com/pwacc/pwaccix.html>.

Denver Public Health Counseling and Testing Site (CTS) is now offering a rapid OraQuick HIV test to all clients. This process requires a blood sample taken from a finger stick, and results are available 20 minutes after the test is started. There will be no additional cost to clients who choose this option. However, during this preliminary phase, clients must provide a name to receive the rapid test.

All clients who wish to make an appointment with CTS are asked to pay a \$10.00 fee. Those who cannot pay will not be turned away. Appointments can be made by calling (303) 436-7251.

Have anything to add,  
change or delete?

Call Shelley  
Cohen McKittrick at  
303.329.9379 ext. 103  
email:  
ResoluteEditor@aol.com

# ★ National AIDS Services and Publications ★

## AIDS Action

1906 Sunderland Place, NW  
Washington, DC 20036  
Call..... 202-530-8030  
Fax.....202-530-8031  
Website.....aidsaction.org

## AIDS Educational Global Information System

Website.....aegis.com

## AIDS in Prison Project

Call.....718.378.7022  
*Accepts collect calls from incarcerated.*

## AIDS Medicine & Miracles

1290 Williams St, Denver, CO 80218  
Call.....303.860.8104  
Toll Free.....800.875.8770  
Fax.....303.860.8105

## AIDS Project Los Angeles

Online Publications  
Positive Living, Impacto!, Optimist  
www.apla.org/apla/ed/publications.html

## AIDS Treatment News

C/O Philadelphia FIGHT  
1233 Locust St., 5th Fl.  
Philadelphia, PA 19107.  
Call.....800.873.2812  
Fax.....215.985.4952  
Website.....aidsnews.org

## amfAR

**American Foundation for AIDS Research**  
Website.....amfar.org

## Being Alive

621 San Vicente Blvd.  
West Hollywood, CA 90069  
Call.....310.289.2551  
Fax.....310.289.9866  
Web site.....beingalivela.org  
Website en Español:  
www.beingalivela.org/spawelcome.html

## BETA:

### Bulletin of Experimental Treatment for AIDS

**San Francisco AIDS Foundation.**  
Call.....415.487.8060  
Website.....sfaf.org/beta.html  
Email.....beta@sfaf.org

## The Body

AIDS and HIV Information Resource  
Website.....thebody.com

## Centers for Disease Control (CDC)

Website.....cdcnpin.org

## CMV Hotline

Call.....800.838.9990

## Critical Path AIDS Project

Hosts over 80 AIDS Websites  
Website.....critpath.org

## The Cutting Edge, TCE Consults

Nutritional Information on HIV/AIDS  
Website:.....tceconsult.org

## DAAIR: Direct Access Alternative Information Resources

31 East 30th Street #2A, New York, New York 10016.  
Call.....212.725.6994  
Fax.....212.689.6471  
E-mail.....info@daair.org

## Denver Public Health

Website:.....aidscentral.com

## Gay Men's Health Crisis

AIDS Hotline.....212/807-6655  
Toll free.....1-800-AIDS NYC  
TTY .....212/645-7470  
Website.....gmhc.org

## HIV/AIDS Treatment Info Service

Call.....800.448.0440  
Website.....www.hivatis.org

## HIV Resistance Web

Website.....hivresistanceweb.com

## IAPAC: International Association for Physicians in AIDS Care

*"Battling complacency, advancing commitment"*  
Website.....iapac.org

## Medscape

Online Medical Journal with excellent HIV/AIDS Information  
Website.....medscape.com

## National AIDS Hotline

Call.....800.342.2437

## NATAP: National AIDS Treatment Advocacy Project

Website.....natap.org

## NAPWA: National Association for People With AIDS

1413 K Street, NW, 7th Floor  
Washington, DC 20005  
Call.....202.898.0414  
Fax.....202.898.0435  
Website.....napwa.org

## New Mexico AIDS InfoNet

Website.....aidsinfonet.org

## NMAC:

### National Minority AIDS Council

1931 13th Street, N.W., Washington, DC 20009  
Call.....202.483.6622  
Fax.....202.483.1135  
Website.....nmac.org

## National Pediatric AIDS Network

Call.....800.646.1001  
Website.....npan.org

## Positive Living

### AIDS Project Los Angeles

3550 Wilshire Blvd., Suite 300  
Los Angeles, California 90010  
Contact Paul Serchia, Publications manager  
Call.....213.201-1362  
Fax.....213.201.1598  
Email.....Pserchia@apla.org

## Positively Aware

### Test Positive Network

1258 W. Belmont Ave., Chicago, IL 60657  
Website.....tpan.com

## POZ Magazine

349 West 12th Street, New York, NY 10014  
Call.....212-242-2163  
Website.....poz.com

## Project Inform

Treatment and Advocacy information  
205 13th St., Ste. 2001  
San Francisco, CA 94103  
Hotline.....800.822.7422  
Phone.....415.558.8669  
*Accepts collect calls from incarcerated*  
Fax.....415.558.0684  
International Callers.....415.558.9051  
Website.....projectinform.org

## Project Return to Work

Creating good work at home jobs and benefits for disabled Americans.  
PO Box 19381, Boulder, CO 80308  
Call.....303.415.9187  
Fax.....303.564.0534  
Email.....webmaster@return2work.org  
Website.....return2work.org

## RITA!

### Research Initiative/Treatment Action!

Website.....centerforaids.org/rita/

## San Francisco AIDS Nightline

Call.....415.434.AIDS

## Teen HIV Hotline

Call.....800.440.TEEN

## University of California San Francisco AIDS Program

Website.....hivinsite.ucsf.edu

## Women Alive

Call.....800.554.4876  
Website.....thebody.com

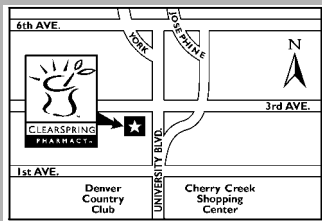
## WORLD: Women Organized Responding to Life Threatening Diseases

PO Box 11535, Oakland, CA 94611  
Call.....510.986.0340

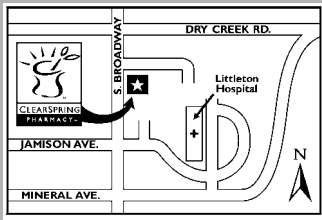
# ClearSpring Pharmacy



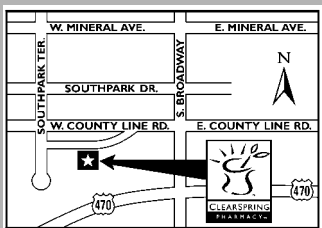
Cherry Creek  
201 University Boulevard  
Denver, CO 80206  
303.333.2010



Littleton  
7720 South Broadway  
Littleton, CO 80122  
303.795.4300



Highlands Ranch  
206 W. County Line Road  
Highlands Ranch, CO 80129  
303.707.1500



**ClearSpring specializes in providing personalized, effective pharmacy services to assist our patients managing HIV/AIDS**

- **Source for all of your medication needs**
- **HIV-trained pharmacists**
- **Private one-on-one pharmacist consultations**
- **Coordination of benefits and filing of insurance**
- **All insurance types accepted including Medicaid**
  - ✓ **Medicaid patients have no co-pay (\$0)**
- **Automatic refill service**
- **Citywide delivery**
- **All medication profiles are screened and reviewed for potential drug interactions, side effects and adverse drug reactions**

**Adherence programs and tools are available; pillboxes, timers, alarms, journals, etc.**

**Call today to start receiving the personalized pharmacy services that you deserve!**