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increases in bilirubin levels. People using the higher dose of atazanavir were more likely to stop taking it due to side effects.

There was, on average, very little change in triglyceride or cholesterol levels among the people taking atazanavir while those on nelfinavir had significant increases in these lab markers. Changes in these markers have sometimes been associated with changes in body shape, called *lipodystrophy*. For more information on lipodystrophy, call Project Inform's Hotline or visit [www.projectinform.org](http://www.projectinform.org).

**Indinavir or Boosted Indinavir?**

Results from the Danish BEST study suggest that taking indinavir with low dose ritonavir may not be well tolerated. This study enrolled 323 people, all taking indinavir 800mg three times a day in addition to two other anti-HIV drugs at study entry and had viral load below 500 copies. Volunteers either continued taking indinavir three times a day or switched to indinavir/ritonavir (800mg/100mg both taken twice a day) in addition to their other anti-HIV therapies.

After 48 weeks, 74% of the people who stayed on indinavir had viral load below 500 compared to only 58% of those who switched to indinavir/ritonavir. This difference is almost entirely due to an increase in side effects among those on indinavir/ritonavir. Over twice as many people had to stop and/or switch therapy because of side effects compared to those on the three times daily indinavir regimen. Most side effects included gastrointestinal intolerance, kidney stones, blood in the urine (hematuria) and elevations in lipid levels (lab markers for triglycerides and cholesterol).

**TMC-125: A New NNRTI**

Early results show that a new NNRTI, TMC-125, has potent activity against HIV. We have previously reported on a related drug, TMC-120, which also showed potent activity and is still in development. Eighteen people, all of whom had not taken anti-HIV therapy before, participated in this study. Twelve received 900mg TMC-125 twice a day for seven days and six received a placebo. After seven days of therapy, people on TMC-125 had an average viral load decrease of about 2 logs (99%) and an average CD4+ cell count increase of 100.

**New-Fill Injections: Cosmetic Surgery for Facial Wasting**

Results from a French pilot study of New-Fill (polyactic acid) shows that it may help increase the thickness of the cheek fat pad. Some people have experienced fat loss (*lipoatrophy*), thought to be associated with anti-HIV therapy and in particular the nucleoside analogue (NRTI) drugs. This study involved four injections of New-Fill (3cc in each cheek) at days 0, 15, 30 and 45. A fifth injection was given at day 60 if there was inadequate response.

Fifty people participated and all had a marked reduction in fat tissue in the cheeks (sunken cheeks) as measured by *ultrasonography* (ultrasound that produces an image). At the time of the report, four

**What's New in Treatment Information?**

**Atazanavir: A New Protease Inhibitor**

Results from a study comparing two doses of atazanavir (BMS-232632, Zrivada) to nelfinavir were recently presented in Athens, Greece. Both drugs are protease inhibitors. The study enrolled 467 people with a median viral load of about 50,000 copies HIV RNA and CD4+ cell count of about 275.

None of the volunteers had taken anti-HIV therapy before, and they all received nelfinavir (1,250mg twice a day) or atazanavir (400mg or 600mg once a day). In addition, all of them took d4T and 3TC.

Not surprisingly, people on nelfinavir were more likely to develop diarrhea, a well-known side effect of the drug. Those taking atazanavir were more likely to have headaches, abdominal pain and

**Results after 48 weeks**

	% <400 copies HIV RNA	% <50 copies HIV RNA	HIV RNA drop
ATV (400mg)/d4T/3TC	65%	31%	2.51 logs
ATV (600mg)/d4T/3TC	62%	36%	2.58 logs
NFV/d4T/3TC	59%	38%	2.31 logs

ATV=atazanavir NFV=nelfinavir

people had received three injections, 29 had four injections and 17 had five. All dramatically improved, with most having “normalized” cheeks. Some experienced some swelling at the injection site.

## Lipodystrophy: Do Some Therapies Pose More of a Threat?

Interim analysis of a study shows that different potent anti-HIV regimens have different effects on cholesterol and triglyceride levels. This study enrolled 258 people (half women), all had not taken anti-HIV therapy before. Average viral load at study entry was about 30,000 copies and average CD4+ cell count was about 350. Volunteers took abacavir/Combivir, nelfinavir/Combivir or d4T/3TC/nelfinavir.

After 24 weeks, there were no real differences in anti-HIV activity among the three groups, with 49–59% of the people experiencing viral load suppression to under 400 copies. However, there were major differences in changes in triglyceride and cholesterol levels among them. People on the nelfinavir combinations saw their cholesterol levels increase substantially compared to those on abacavir who only had a slight increase. However, only people taking d4T/3TC/nelfinavir had substantial increases in triglyceride levels while the other two groups only had minor increases. Cholesterol and triglyceride increases have been associated with lipodystrophy in some people.

## Amprenavir and Lipodystrophy

A small intensive monitoring study shows that amprenavir can greatly increase triglyceride and cholesterol levels, contrary to reports that it does not affect these lipid markers. This study enrolled 16 people, all of whom had not previously taken a protease inhibitor, abacavir, d4T or 3TC. During the study, the volunteers received abacavir/3TC/amprenavir (two people used d4T instead of 3TC).

Overall there were no major changes in laboratory markers for diabetes, include fasting glucose and fasting insulin levels. There was, however, a decrease in insulin sensitivity after 48 weeks, but not before. People experienced a progressive increase in markers of fat processing, triglyceride levels and cholesterol levels. The good news is that HDL (*good*) cholesterol increased as well as LDL (*bad*) cholesterol resulting in no change in the overall ratio of HDL/LDL.

Additionally, participants saw an increase in weight, trunk fat and limb fat resulting in an overall increase in total body fat. There was also a trend towards an increase in lean tissue. One interesting observation is that insulin resistance developed *after* weight gain. This can potentially help in understanding the course of lipodystrophies.

## d4T: A New Formulation

Results have been presented for the first time of a new once-a-day d4T, called d4T extended release or d4T XR. This study enrolled 150 people who had not taken anti-HIV therapy before with viral load of about 50,000 copies and CD4+ cell counts of about 300. Participants used either d4T XR or regular d4T plus 3TC and efavirenz.

The dose of d4T XR used was 100mg once a day for people weighing over 60kg (about 130 pounds) and 75mg once a day for those weighing less than 60kg. d4T XR results in lower *peak* and

higher *trough* concentrations of the drug compared to regular d4T. *Peak concentration* refers to the highest amount of drug in the blood soon after taking a dose. *Trough concentration* refers to the lowest amount of drug in the blood after taking a dose.

*Higher* peak concentrations are sometimes associated with a higher risk of side effects. *Lower* trough concentrations are associated with developing anti-HIV drug resistance. It's assumed that *lower* peak concentrations of a drug will decrease side effects and *higher* troughs will decrease the risk of developing resistance.

At the end of 48 weeks, there was essentially no difference in response between the two groups, with about 50% of the participants having viral loads below 50 copies and an increase in CD4+ cell counts of about 200. There appeared to be a slightly fewer people experiencing peripheral neuropathy (tingling or numbness around the extremities, especially fingers and toes) among those on d4T XR, although they experienced slightly more headaches. A larger study will truly determine the safety profile and effectiveness of d4T XR.

## Tenofovir: New Kind of Anti-HIV Drug Gets Approved

Recently, the Food and Drug Administration (FDA) approved tenofovir for treating HIV infection in combination with other anti-HIV therapy. The approval was based primarily on the results from one study involving 550 people who were on anti-HIV therapy for at least eight weeks and had viral load of 400–10,000 copies.

Volunteers were randomly assigned to take tenofovir or placebo in a 2-to-1 fashion, resulting in 368 people on tenofovir and 182 on placebo. At the start the volunteers had, on average, been on anti-HIV therapy for 5.4 years and had viral load of about 2,300 copies and CD4+ cell count of about 427. The average decrease in viral load between the start of the study and week 24 was 0.59 logs among people taking tenofovir. Essentially no changes were noted among those on placebo. Additionally, about 45% and 22% of the participants had viral loads below 400 and 50 copies respectively compared to 13% and 1% respectively of those taking the placebo. Tenofovir was very well tolerated with no significant differences in moderate-to-severe side effects between the two groups.

## Community Alert! T-20 Expanded Access

Starting November 27, 2001 at 3pm EST, a study allowing for access to the fusion inhibitor T-20 (Pentafuside) will begin. However, because there's a severe supply problem, this study is very limited and will only provide drug to 168 people in the US. Further, the study is restricted to the first 56 qualified physicians who call in on November 27, and they must have three qualified patients to enroll at that time. Physicians should call 1-888-722-6321 to register.

The study is limited to individuals who need T-20 to put together a viable anti-HIV regimen, must have a viral load over 10,000 copies *and* have a CD4+ cell count below 50. Physicians are encouraged to give first preference to people who have had an AIDS-defining opportunistic infection within the last 90 days and have a CD4+ cell count below 50 while taking potent anti-HIV therapy.

Secondary preference is encouraged for people with CD4+ cell counts below 50 for the last 90 days despite taking potent therapy.

## What's New in Public Policy?

### Letters of Solidarity Needed for Treatment Action Campaign in South Africa

Last week, the Treatment Action Campaign (TAC), an organization of treatment activists in South Africa, began court hearings to require the South African government to provide access to nevirapine for HIV positive pregnant women as part of efforts to reduce mother-to-child HIV transmission. TAC and two other parties are suing the South African National Department of Health and eight of nine provincial health ministers, demanding that the government make nevirapine available (under proper medical supervision) at all public hospitals and health clinics. In addition, the suit asks that the government create and implement a comprehensive plan to reduce mother-to-child transmission.

TAC and the other plaintiffs ask that this program be created within three months. The program should include voluntary HIV/AIDS counseling and testing, the provision of nevirapine "where appropriate" and a supply of formula to help prevent HIV transmission through breast-feeding. This lawsuit has received support from over 150 health professionals, trade unions, religious organizations, and human rights groups.

Boehringer Ingelheim has offered to provide nevirapine free of charge to developing nations. Currently, South Africa only offers the drug through 18 pilot programs across the country. The government states that it is focusing on researching the issue, studying safety issues and effectiveness.

According to TAC, nearly 300,000 women with HIV will give birth in the next year. The majority do not know their HIV status and are not provided information or access to treatment that can reduce the risk of HIV transmission to their child. TAC predicts that at least 70,000 children could become infected with HIV during labor and breastfeeding.

TAC is asking for individuals and organizations around the world to send letters of support for their efforts. These letters will help with their court case and demonstrate that they are not alone in their fight. This is an easy, yet powerful, way to show solidarity for their efforts to reduce the spread of HIV in South Africa.

#### What you can do:

We encourage you to take a few minutes and write a short statement of support for TAC's efforts. You can use the enclosed sample letter to help craft your message. There are many ways that you can send your statement:

1. Faxes are preferred, because they will arrive quickly and will be in your writing or have your signature. Handwritten letters are extremely powerful and effective. You can fax your letter to ACT UP/Philadelphia (215-731-1845) or

Project Inform (415-558-0684) and it will be re-faxed to TAC. You can also scan your letter and email it as an attachment to [actupphilly@critpath.org](mailto:actupphilly@critpath.org).

2. If you do not have access to a fax machine, you can send your letter in the form of an email to the Treatment Action Campaign at [info@tac.org.za](mailto:info@tac.org.za). Make sure you include your full name and address in the email.
3. If you do not have fax or email capability, you can mail your letter to Project Inform (attn: TAN) and we will fax your letter to TAC.

Thanks to Health GAP (Global Access Project) for the information contained in this Alert. You can learn more about Health GAP at [www.globaltreatmentaccess.org](http://www.globaltreatmentaccess.org). For more information about the Treatment Action Campaign, go to [www.tac.org.za](http://www.tac.org.za).

#### Sample letter:

I am writing in support of Treatment Action Campaign's legal action to guarantee access to HIV preventive therapy for pregnant women and infants in South Africa as part of a comprehensive program for the prevention of mother-to-child transmission of HIV.

*Insert short personal statement here. If you or someone you care about is living with HIV, please consider writing a few sentences about your personal experiences.*

It has been demonstrated that access to antiretroviral drugs can dramatically reduce transmission of HIV from pregnant women to children. I strongly support TAC's efforts on this issue.

Sincerely,  
Your name

## What's New in Fund Raising?

### Evening of Hope Los Angeles

Upwards of 380 people attended the Los Angeles Evening of Hope held at the elegant Beverly Hills Hotel on November 14, 2001. This year's event brought both new and longtime Project Inform supporters together for an evening of camaraderie and conversation and we are pleased to announce that the event was a tremendous success. Project Inform Founding Director Martin Delaney opened the evening's program by reminding the gathered crowd of longtime donors and new friends of the impact Project Inform is making every day. Actress and singer Joely Fisher MC'ed much of the event, and JoBeth Williams presented the Corporate Leadership Award to Macy's West for their visionary role in the arena of corporate philanthropy. Macy's West was also honored at the San Francisco Evening of Hope six weeks ago.

Project Inform Board member Brenda Freiberg spoke movingly about her longtime dedication to organizations like Project Inform. The Advocate Award was presented to Barry Krost for investing his expertise, time, resources in Project Inform since its very early days; and comedian Bruce Vilanch spoke from the heart about his deep personal commitment to the fight against AIDS and homophobia. Singer/actress Jennifer Lewis performed a few outrageous numbers from her upcoming one-woman revue, and Tony Award winner Michael Maguire also sang several numbers. The event provided the perfect opportunity for so many from the Project Inform family to come together, to reflect on past victories and losses, and to strengthen our resolve to keep fighting HIV/AIDS.

### Get in the Holiday Spirit at Under One Roof

Under One Roof is the San Francisco non-profit gift store that raises money for dozens of AIDS service organizations. 100% of the profit from every sale is donated directly to organizations like Project Inform.

Since opening in 1990, Under One Roof has raised over 7.6 million dollars for the fight against AIDS. Nearly a decade after the store's opening, as the AIDS epidemic changes and funding sources diminish, their mission has become more critical than ever. Under One Roof continues to be, at its heart, friends helping friends.

There is a wonderful selection of clever gift ideas and seasonal merchandise in the store for everyone on your holiday list, and a

helpful volunteer sales staff. Candles, toys, housewares, gift cards and holiday trim can all be found in one convenient location!

You can look for the Under One Roof portable store at Levi's Plaza during the first week in December. Drop by their permanent, year-round location at 549 Castro in San Francisco or visit them on the web at: [www.underoneroof.org](http://www.underoneroof.org). By shopping at Under One Roof this holiday season, you truly give the gift that gives twice. Thank you!

### Shop at JustRubbers.com and Designate \$1 of Every Order to Project Inform!

Project Inform wishes to remind everyone of our continuing partnership with [www.justrubbers.com](http://www.justrubbers.com). Just Rubbers, the online condom store whose mission is to offer its clients a "discrete, professional service, providing exceptional products at an excellent value" has teamed up with Project Inform to offer a way to purchase condoms AND an easy way to make a donation to Project Inform. When you're done choosing the condoms for your online order, proceed to the online checkout and you'll have the opportunity to designate \$1 of your purchase total to Project Inform—each time you order!

No personal information is disclosed on the site, and your order—shipped within 24 hours Monday-Friday via USPS—will arrive in a plain package generally within 3-5 business days. Visit the website to read customer comments, and to review the selection of condoms available at [www.justrubbers.com](http://www.justrubbers.com). And don't forget to designate \$1 to Project Inform!

## SUPPORT PROJECT INFORM BY BECOMING A PLEDGE PARTNER

As a Project Inform Pledge Partner, you can spread your tax-deductible gift into monthly payments. Pledge Partners and Partners in Hope receive "What's New?," our monthly treatment newsletter.

### ADDRESS INFORMATION

**Yes, I want to help Project Inform remain at the forefront of HIV/AIDS treatment information!**

Mr. / Ms. / Mrs. \_\_\_\_\_ Mr. / Ms. / Mrs. \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Email \_\_\_\_\_ Phone \_\_\_\_\_ Fax \_\_\_\_\_

This is a new address. My (Our) old address was: Address \_\_\_\_\_

### DONOR FORM



**Enclosed is my . . .**

- Pledge Partner pledge of:** \$ \_\_\_\_\_ per month for \_\_\_\_\_ months (\$40 or more per month for a year entitles you to Partners In Hope membership)
- Donation of:**  \$35  \$50  \$100  \$250  Other \$ \_\_\_\_\_



**I would like to join Partners in Hope with a donation of:**

- \$500  \$1,000  \$2,500  Other \$ \_\_\_\_\_



**In Honor of / In Memory of:** (circle one) \_\_\_\_\_



**Please omit my name from any public listing of donors to Project Inform.**

### PAYMENT INFORMATION

Circle One: CHECK   

Credit Card # \_\_\_\_\_

Exp. Date \_\_\_\_\_

Print Name as Shown on Card \_\_\_\_\_

Signature \_\_\_\_\_

Phone Number \_\_\_\_\_ WNEW

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