The Twelfth World AIDS Conference
The Beginning of the End of the Beginning

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OVERVIEW

Geneva proved to be a frustrating and a confusing experience, both during the meeting and upon returning home. The frustration at the conference arose from the seeming lack of a theme. At the Eleventh Conference in Vancouver the theme was clear, the success of highly active anti-retroviral therapy (HAART). Much of the most important data presented in Geneva provided updates on available therapies, presented new data on the real world clinical challenges associated with HAART, shared new information on immunology and immune-based therapies, offered new proofs of the cost-effectiveness of HAART, and delineated in excruciatingly painful detail the nearly unstoppable spread of HIV throughout the rest of the world.

The hundreds of posters and presentations offered every day in rooms that seemed miles apart made covering sessions difficult on even a limited range of topics. Returning to the states also led to additional frustrations. Very little of the dense web of complicated and important information presented at the conference was digestible to the lay press. They were much happier with Vancouver and the simple “cure” stories they could file based on the breaking information on the new multi-drug regimens. Their difficulties in assimilating the more complicated and nuanced information presented in Geneva led to two serious problems:

1 Most of the stories presented were imbued with an alarmist pessimism that resulted in stories that we now know were disturbingly misleading to many readers. Little data presented in Geneva could be accurately understood unless presented in the context of other related information. One example was the plethora of stories about lipodystrophy, the fat redistribution syndrome now associated with HAART. The presentations on the syndrome at the conference were incredibly variable with reported incidence rates ranging from 5% to 65%.

This variability led many scientists to question the nature of the relationship between the syndrome and HAART. The media, however, chose to present the information in a context suggesting that the side-effects of HAART therapy somehow compromised its importance in drastically reducing death rates in populations that had access to it. These side-effects were also mentioned in stories...
It's that time of year again—election season. Around the nation, the primary elections for the US House of Representatives and the US Senate have already passed, but it is not too late to make a difference in November. Candidates can be encouraged to address issues facing people living with HIV/AIDS, their families and their loved ones. People in the AIDS advocacy community can reach out to politicians through candidate forums and roundtables, or by sending questionnaires for candidate responses and publishing answers in a local newsletter. These activities bring candidates into contact with advocates and PWAs and demonstrate to politicians that we are caring people who have concerns like everyone else. Most of your elected representatives in Washington will be in their home states and districts this fall, campaigning for reelection. Contact them and set up a forum or a meeting. To place AIDS issues on their agendas, we have to make the first call.

You can also influence current legislative issues in the Congress (and at the White House). To reach your Congressperson or the two Senators from your state, call the Capitol switchboard at 202/224-3121 or 202/225-3121. To reach the White House comment line, call 202/456-1414. Now, what to talk about when you call:

1. **Aids Funding Issues:** Ask them to support full funding for AIDS programs. Specifically request full-funding for the Ryan White CARE Act, the AIDS Drug Assistance Program (ADAP), CDC prevention money, National Institutes of Health AIDS research funding, and the Housing Opportunities for People With AIDS program (HOPWA). Due to the historic Balanced Budget Act of 1997, spending caps on federal domestic programs such as these are in place for this and future years. Therefore, the funding competition for health and human service programs is very real. Our community must raise its voice in support of these programs to our elected representatives.

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**House Cuts HOPWA Funding**

In July, an amendment offered on the floor of the House of Representatives struck the $21 million increase in FY 99 funding recommended for HOPWA by the House VA/HUD Appropriations sub-committee. The amendment then transferred those funds to Veteran’s housing, State Extended Care facilities.

Now that the House has passed its version of the VA/HUD Appropriations bill, a joint House-Senate conference committee will meet to iron out differences between the House and Senate bills. The Senate bill, unlike the House’s, included the additional $21 million for HOPWA in FY 99. To save these desperately needed funds, the joint House-Senate conference committee will have to accept the Senate recommended increase for HOPWA. The conference committee will be made up of the House and Senate VA/HUD Appropriations subcommittees and the Chairs and Ranking Members of both the House and Senate Full Appropriations committees.

**TO DO:**

CALL YOUR SENATORS AND REPRESENTATIVES and explain why HOPWA needs the additional $21 million and that conference committee must accept the Senate increase for HOPWA.

Capitol Hill Switchboard: 202/224-3121

Ask for your Representative or Senator’s office.
Many, many times I have heard the same basic comment or plea from both individuals and organizations. It usually sounds something like this - “It is so hard to find and keep volunteers.” Why is it hard, or is it really hard? True there is a decrease of volunteers through burnout and for many other reasons.

As I think about the difficulties in finding, getting, and keeping volunteers a few thoughts come to mind. Volunteers are very important to any successful program. The person in charge of recruiting volunteers needs to be well organized. When volunteers come into work, everything should be ready for them, they should be made to feel welcome (especially on their first visit), and make sure they understand what is to be done. Before they leave, ask if they are interested in coming again, find out if there are certain times and days that are convenient for them, and ask if they would be interested to be included on a “call when needed list.”

Taking care of volunteers is very important. If a volunteer works on a regular basis, he/she should be treated to lunch upon one year of volunteering, or if a number of volunteers fall into this category, have a thank you luncheon. The best thing you can do for a volunteer is just a simple thank you!

Herbert Perry, LPA,EA Chair and CFO of T•11 CANN

Editor’s Note: Herb has served on numerous community AIDS related boards.

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about the transmission of multi-drug resistant HIV and about increasing rates of virologic failure (a post-therapeutic increase in viral load) being seen in patients taking HAART. These unrelated data were often pressed together into short and frightening presentations on “the failure of HAART.” This sort of imbalance has had an impact — at various data presentations offered post-Geneva, clinicians recounted stories concerning patients who had decided to stop taking HAART therapy, relating their decisions to their physicians days or weeks later.

The scarcity of positive information from Geneva delivered by the mainstream press will also have negative consequences. It was, after all, the incredible amount and kind of coverage from Vancouver that led to the rapid development of federal treatment guidelines and to the rapid acceptance of HAART by physicians, patients, and insurers throughout the country. That news also led to a phenomenal willingness by many government entities to increase funding to programs offering HAART to uninsured or under-insured people living with HIV. Tragedy will occur if the negative balance of most Geneva stories slows the development and dissemination of new information on the standard of care for doctors and patients, or lessens the willingness of government entities to make available the funding necessary to pay for the care of needy patients.

News That Could Affect Patients And Programs

NOTE: The following summaries are intended as an overview. If you need more detailed information, we suggest the following websites or publications:

GMHC Treatment Issues (www.gmhc.org), BETA (San Francisco AIDS Foundation at www.sfaf.org), AIDS Treatment News (www.immunet.org) AIDS Treatment Data Network (www.aidsinfonyc.org) or Project Inform (www.projinf.org)

New Therapies/Protease Sparing Regimens

By general agreement, the data presented on Sustiva (efavirenz, DMP-266) was the most impressive anti-viral news at the conference. In a trial designated 006, Sustiva — a non-nucleoside reverse transcriptase inhibitor (NNRT) — taken with AZT and 3TC was shown to be at least as potent as, and possibly more potent than, Crixivan/AZT/3TC in a large number of patients over twenty-four weeks. While this potency will have to be proven durable (twenty-four weeks is a relatively short time frame), the drug’s once a day dosing and relatively minor side-effect profile may, according to researchers and clinicians, change the way HIV disease is treated.

This data led to a series of presentations suggesting that HAART need not include a protease inhibitor to be viable. Other regimens that might qualify as protease-sparing pending confirmatory data include Ziagen (abacavir, Glaxo-Wellcome’s new nucleoside)
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taken with two other nucleosides and the all Bristol Myers combination of ddi, d4T and hydroxyurea, both combinations being taken twice a day.

Another therapy in late stage development is Gilead Sciences nucleotide reverse transcriptase inhibitor, Preveon brand adefovir. The good news on this compound is that it comes from a new class of therapies (nucleotide rather than nucleoside inhibitors) and, therefore, could play a useful role in multi-drug regimens for patients who are resistant to other medications. It is also made more sensitive in the presence of certain types of low-level HIV resistance. The bad news is that the drug doesn’t appear very potent and it causes some pretty severe side-effects. Data was also released on Gilead’s next stage version of this drug, PMPA. That formulation looks very potent (it may involve once a day dosing) with fewer side-effects.

Glaxo Wellcome/Vertex also delivered the latest data on amprenivir, a new PI. The data suggested that the drug was very potent, especially at the highest dose studied. Unfortunately, the product looks as if it is cross-resistant with the already available PIs. Early data was also presented on two protease inhibitors by Abbott and Pharmacia & Upjohn that may prove to be effective against HIV that is resistant to the presently available protease formulations.

Updates On Presently Available Therapies

Many regimens that have been the subject of earlier clinical trials showed continuing and substantial potency in Geneva presentations. These included:

**Protease regimens:**

- Fortovase brand saquinavir plus two nucleosides (48 weeks)
- Fortovase, Viracept brand nelfinavir and two nucleosides (48 weeks)
- Crixivan brand indinavir plus two nucleosides (72 weeks)
- Norvir brand ritonavir plus two nucleosides (72 weeks) (See note, Page 7)
- Norvir and Invirase brand saquinavir (72 weeks) (See note, Page 7)

**And an NNRT regimen:**

- Delavirdine with AZT and 3TC (52 weeks)

Important data was also presented on the simplification of current regimens. Both Fortovase and Viracept were subjects of data presentations strongly suggesting that either of the protease inhibitors could be used twice a day instead of the current three times a day without sacrificing potency. Data on twice a day Crixivan was also presented but clinicians felt that more data was needed before they would feel comfortable using that dosing schedule.

Finally, important data was presented suggesting that many four, five, and six drug combinations were sufficiently potent to serve as salvage regimens, particularly if a patient was switched as soon as possible after exhibiting virologic failure. Available information showed that if patients remained on failing regimens, the potential of any salvage regimen was severely compromised.

Limits Of Current Therapies

Clearly, the limits of current therapies are closely intertwined; e.g., toxicities can lead to problems with adherence and the development of resistance. These issues, however, are central to any discussion of the continued viability of HAART. What became evident from numerous presentations was that regimens needing to be taken three times a day, were food or fasting dependent, and/or were highly toxic were unlikely to be useful to many — if not most — patients over the medium and long term.

Fortunately, solutions to some of these problems were suggested in Geneva. First: the current goal of most drug development is to produce regimens that are non-cross-resistant and that are more convenient without sacrificing potency. Soon to be available are Sustiva which with Combivir would entail taking one pill in the morning and four pills in the evening with no food requirements and low toxicity. Ziagen brand abacavir is also expected to provide the base for a simple and easy regimen. In addition, the news on twice a day dosing of some protease inhibitors (Fortovase brand saquinavir and Viracept) will likely give a big boost to adherence efforts. Finally, new drugs in late stages of development (such as Abbot’s ABT-378 protease inhibitor) are designed to avoid cross-resistance and to be potent enough to take once or twice a day.

**Toxicities:** Most presentations on toxicities centered on the newly characterized lipo-dystrophy syndrome which involves symptoms having to do with the redistribution of fats. Symptoms can include fat deposits (sometimes extreme) at the belly (formerly described as “Crix belly” but now known to be
related to all the PIs), at the base of the back of the neck (“buffalo hump”) and, for women, in the breasts. These fat deposits are usually accompanied by wasting in the arms, legs, and face. As is mentioned above, incidence reports ranged from 5% to 65% of various patient cohorts. While the syndrome is thought to be related to PIs, incidence of the syndrome in other diseases and among patients not on PIs suggested to some researchers that PIs might constitute a co-factor in a problem related to hormonal changes or even changes in the immune system. Finally, while no formal presentations were made on treatment for lipodystrophy, anecdotal reports described success employing low-dose human growth hormone or steroids. It is likely that more information on treatment will be available at ICAAC in the fall and at the Retrovirus Conference in February, 1999. Other problems seen in patients included diabetes (@ 1%) and hypercholesterolemia (@ 30%).

**Resistance:** The most sensational news on resistance concerned the documented transmission of multi-drug resistant HIV to people who had never themselves taken anti-HIV therapies. The implications of these findings were unclear. First: Will the level of the resistance lead to drug failure in many/most patients who are exposed? Second: Will new non-cross resistant therapies be developed before clinical signs appear in patients exposed to antiviral resistant HIV? Only time will present answers to these questions. In the meantime, only effective prevention programs can avoid the spread of resistant virus.

Another important suggestion arising from clinical experience with the PIs is that patients must be switched from a failing regimen to a new (salvage) regimen as soon as possible after resistance appears. This may reduce the risk of developing high level resistance and maximize the chances of successful salvage options.

**Adherence:** All data on treatment failure presented in Geneva validated adherence as the Achilles heal of presently available therapies. The central message seemed to be that three times daily regimens with large pill counts would never be successful for many patients. Two studies, in fact, reported remarkably similar self-reports on missed doses: 11-12% yesterday and 11-13% the day before. The good news on adherence concerned the development of easier protease regimens (twice a day for Viracept and Fortovase) and protease sparing regimens (especially Sustiva and Ziagen).

**Costs, Cost-Effectiveness And Access**

There was a great deal of press coverage centered on the costs of HAART and how the high costs of these treatments generate access problems in many countries, even in the developed world. In addition, a great deal of attention was paid to the massive difficulties involved in providing combination therapy to the developing world where the epidemic continues to ravage entire populations. In response, some pharmaceutical companies (Glaxo-Wellcome, Bristol-Myers Squibb, Abbott Labs and Roche, among others) have joined a U.N. AIDS sponsored effort to lower the prices of their drugs in the hope that they will become more accessible to the developing world.

Ironically, many representatives from the South suggested that clean water, prophylaxis, and the simplest pain medication may be a more realistic place to start. Lost in much of this coverage were a striking number of presentations and posters on the cost effectiveness of these treatments - at least in the context of the developed world. Little or no coverage appeared on any of these important studies despite the obvious deduction that cost-effectiveness must be demonstrated in the developed world as a first step to availabilities in poorer areas.

Cites presenting studies on cost-effectiveness included St. Pauls Hospital in Vancouver, Canada; The Health Evaluation Unit in Toronto, Canada; Yale New Haven Hospital in Connecticut; Tower Infectious Diseases in San Francisco; Clinical Partners in Los Angeles; Canadian Policy Research Networks in Ottawa, Canada; The Permanente Medical Group (Southern California); The Desert AIDS Project in Palm Springs, California; San Francisco General Hospital in San Francisco; Johns Hopkins School of Public Health in Baltimore, Maryland; Hospital Rothschild in Paris, France; Colorado Health Science Center in Denver; and Berkeley School of Public Health in Berkeley, California.

In addition, T•II CANN made its first presentation of the TAEP Initiative (see May/June, The Voice) which supports the cost-effectiveness of early treatment vs. late treatment with HAART. This iteration of TAEP will be the first in a series of presentations.
T•II CANN SEEKS TO IMPROVE ACCESS TO CARE

T•II CANN is finalizing an initiative to develop alternate funding streams to pay for HIV-related drugs, easing the burden on state ADAP and related Ryan White programs. The Widened Access Project proposal is finalizing grant requests for the three-pronged plan.

1 The core effort will involve development of a workshop program to be offered to interested state and regional level advocacy, provider, and ADAP-related communities. The program will feature techniques for:

- better use of ADAP funds;
- use of state risk pools and 1996 health insurance reform legislation;
- improved coordination of ADAP management of Medicare and Medicaid spend down;
- more knowledgeable client management of Medicare and Medicaid continuation while leaving SSDI and SSI to return to work and ultimately rely on employer health coverage; and
- promoting expansion of state Medicaid, vocational rehabilitation, and health insurance to support pharmacy coverage.

2 The Project will also include national-level policy work focused on improving Social Security Continuing Disability Reviews (CDRs) to assist HIV patients returning to work and seeking continued Medicare and Medicaid; development of supportive and expansive Medicare, Medicaid, and Social Security eligibility policies with HCFA and SSA; and coordination of these efforts with other disability communities working with the Consortium for Citizens with Disabilities.

3 A third component will offer follow-up technical assistance to state-level advocates in working for reform at the state level and the preparation of resource materials, including a basic Widened Access Workbook.

James Carr, a T•II CANN Board Member, Director of Indiana HIV Consumers’ Association and a risk pool and health insurance reform veteran will co-manage the Project. Assisting him will be T•II CANN Technical Advisor Thomas McCormack, author of the AIDS Benefits Handbook, and longtime advocate who led the effort to liberalize the Social Security Disability medical regulations in conjunction with efforts by the National Association of People with AIDS (NAPWA).

“There are already many requests for Program workshops and assistance,” Carr said. “We’ll only offer help to those with the demand!”

McCormack added, “The work we’re already doing here in Washington is promising and exciting. We just won a big Medicaid expansion policy fight! And we’re well on the road with the other disability groups to protect coverage during returns to work!”

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Viral Load And Resistance Testing

The most important news concerning viral load testing was that the goal of therapy must be to reduce the patient’s viral load to below 50 employing an ultra-sensitive assay. A wealth of data was presented that strongly suggested that reducing the viral load to below 400 was insufficient to maximize the chances for durable response of therapy.

Genotypic and phenotypic HIV resistance testing were the subject of numerous reports. Many versions of these tests will become commercially available in the next twelve months. The tests themselves appear to be effective at delineating HIV strains in a patient’s blood that are resistant to one or more tested compounds. Unfortunately, the clinical application of this knowledge is not yet clear and may have to be worked out in the clinical setting.

Data Presentations And Trial Design

There was general agreement that companies use too many methods for presenting data and that the resulting mass of figures make comparing results difficult. Researchers and clinicians suggested they would like to see more coherence in the time studies were conducted and whether the data was presented as “observed” or as “intent-to-treat.” Observed data only reports data on patients who have completed the study to the reported time point (24 weeks.
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Clean Needle Exchange Programs: Contact your Senators and the White House in support of federal funding for clean needle exchange programs to help fight the spread of HIV. Let them know you oppose bill number HR 3717 and S 1959. On April 29, 1998, the US House of Representatives voted by a margin of 287 to 140 to prohibit the expenditure of federal funds on the distribution of clean needles or syringes to prevent HIV infections. However, the US Senate has not acted on these measures and may not before the current session of Congress ends in early October. President Clinton also does not support the use of federal funds for these critical prevention programs. You must make your voice heard on this issue.

Support Medicaid Expansion To Cover HIV+ Persons: Call your Member of Congress, two Senators, and President Clinton in support of this change. In the historic June 25th ruling by the Supreme Court of the United States, all people with HIV are covered under the Americans With Disabilities Act. Medicaid already provides access to health care for over 53% of adults with AIDS and over 90% of children with AIDS. Being poor does not guarantee access to the program. A potential enrollee must also fall within other eligibility categories as well, such as the disabled, women and children, and senior citizens. With the Supreme Court ruling it is unconscionable that our government denies Medicaid coverage to people who do not have full-blown AIDS. With the new available treatments, it is more cost-effective to provide medical care to people early in disease rather than later, as Medicaid does. Medicaid does not provide access to health care and drugs to prevent full-blown AIDS until one develops full-blown AIDS. We cannot pretend that changing this policy will come without cost—both the federal and state governments pay billions of dollars every year into Medicaid. We need to start getting people on the record so we can build support for expanding Medicaid in the next Congress since action on this matter is not likely this year.

This may seem like a lot of phone calls to place and letters to write to your elected officials. We here at T•II CANN are mindful of just throwing more work at already overworked people! If for any reason you might need more information to assist speaking knowledgeably on these issues, please contact us. T•II CANN has available issue papers and practical advice available to help you make your voice heard. Our elected officials must hear from us and learn how their support for these issues affects our lives.

Important Note

As we go to press, news has broken that the capsule form of Norvir brand ritonavir will not be available soon. While few facts are available, we do know that the capsule compound is crystallizing at a late stage in the manufacturing process. When patients run out of their present supply of capsules, they are advised to switch to the liquid form of the drug. That formulation, however, suffers from abhorrent taste and smell. For people taking Norvir, please check with the information providers mentioned earlier in this article for the latest news and for hints on how to take the liquid form of Norvir or contact Abbott at www.rxabbott.com/product/nor/norhome.htm or 1-800-637-2400.

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36 weeks, etc.) and ignores any patients who have dropped out or have been lost to follow up. This manner of analyzing data tends to provide the most optimistic results. Intent-to-treat analysis accounts for all patients who are randomized into a trial and if current data is unavailable, their last records are carried forward or all non-completers are considered to have failed the therapy (non-completer equals failure). These methods are considered to be more “rigorous.” Both methods have their positive and negative features.

The problem comes when comparing observed data on one drug (an optimistic view) with non-completer equals failure data on another compound. There has been some suggestion that FDA should require all trials to report intent-to-treat analyses for this reason.

A chorus of participants expressed concern that trials with arms including therapies not meeting the standard of care are unethical. Participants generally agreed that trials such as 006 which compared highly active regimens (Sustiva, AZT, 3TC vs Crixivan, AZT, 3TC vs Sustiva, Crixivan) were far more useful than trials in which one arm was CLEARLY inferior (Ziagen, AZT, 3TC vs AZT, 3TC). In fact, T•II CANN believes that trials with arms including sub-standard regimens are unethical, should no longer be permitted by IRBs to go forward, and data from such trials should be viewed with skepticism by the FDA.
**AIDS: Be Aware - Not Scared**

**Editor’s Note:** The following article was written by Suzanne R. Perry. Her brother died from AIDS in 1993. This information can be copied and used as an educational tool when speaking with people new at dealing with HIV/AIDS.

Life is worth living but if something happened one day to change your life, what would you do? If someone was sitting next to you in public, had sores on his/her face and hands, looked very underweight, and wanted to talk to you, would you? A person with AIDS deals with so many physical things, it would be unique if he/she did not have to deal with the social and physiological aspects as well. The fact is no one wants to be around, be with, or be aware of AIDS. AIDS is scary. Education so far hasn’t decreased the growing numbers, what will? We need to bring everyone into perspective about AIDS. We need to inform the public on how to prevent AIDS, how it is transmitted, and how it is growing without making people scared of those with AIDS.

If someone with AIDS comes in contact with someone that has an illness or infection, the chance of contacting something is much greater than a healthy person. When someone’s T-cells are below 200, he/she has AIDS, normal range should be 1000-2000. Knowing this, realize how Greg Louganis, 1988 Olympic Gold Medalist for diving felt when he found his T-cell count was 256. A low T-cell count is crushing news and you have to change your lifestyle dramatically. Stress is a factor that plays a part in reducing one’s T-cell count. The person needs to be at ease, as any stressful situation can cause an impact on the T-cell count.

The stopping of the spread of AIDS is essential! Individuals need to know how it is transmitted and how it can be prevented. Instead of watching news reports and reading articles on how AIDS cases are growing, people need to start practicing safe sex. The basic ways AIDS is transmitted are through blood, semen, mother’s breast milk, and vaginal fluids. People are ignorant on how it is transmitted. This is the main reason they are terrified of AIDS infected individuals. The ways individuals cannot get AIDS are hugging and kissing, sharing utensils, swimming pools, and toilet seats. I remember once when someone with AIDS handed me his spoon to share his pudding. There was no way I was touching that spoon. I did not want AIDS and didn’t want to die. It scared me to death because I was not aware that you couldn’t get AIDS from silverware. When I realized how you really got AIDS, my fear was lessened. Also, I read Greg Louganis’ book and found out you cannot get AIDS from swimming pools. The virus will die off immediately with heat, chlorine, bleach, and open air.

Abstinence from sexual intercourse is the only 100 percent effective prevention against sexually transmitted diseases. If you are sexually active, please be smart, use a condom. Another prevention of AIDS is not sharing needles. If you work in an environment where precautions are recommended, use Universal Precautions - which means deal with everyone as if they are infected.