

# AIDS

## INFO SOURCE

Treatment Issues & Information

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### AIDS CONFERENCE NEWS

## Update Briefs from the 39th ICAAC Conference in San Francisco

by Matthew Sirinek, MD

### Norvir increases drug levels of Viagra

Norvir has been shown to greatly influence the drug levels of Viagra in the blood. This effect is so great that major dose adjustments are recommended. The normal dose of Viagra is 50 mg. This dose should be reduced to 25mg if taking Norvir. It has also been shown that Norvir also prolongs the amount of time Viagra stays in the blood, so one 25 mg dose may last up to 48 hours. Viagra was shown to have no effects on Norvir's blood levels. No dose adjustments have been recommended for other protease inhibitors.

### New data on drug holidays

With the great success of viral suppression achieved with HAART, many patients and doctors are wondering about stopping HAART in patients with long-term undetectable viral loads. Can our bodies keep HIV at bay if therapies are stopped? Unfortunately the answer appears to be a

resounding "NO!" Dr. Davey from the NIH studied 18 HIV+ patients who had undetectable viral loads (less than 50 copies/ml) on HAART for at least 12 months. He asked them to stop all HAART at once and observed the results. All 18 patients rebounded to more than 50 copies within 2 months. T-cell counts dropped about 200 points on average over a few weeks in all patients. 15

*All 18 patients rebounded to more than 50 copies within 2 months. T-cell counts dropped about 200 points on average over a few weeks in all patients.*

of the 18 patients restarted HAART after it was clear they were rebounding. All 15 were able to suppress the virus to undetectable levels within 2 months.

### Leukine in Advanced HIV

Leukine is an injectable drug that has been known to increase human immune responses. It has also been shown to decrease HIV replication. A study by Dr. Angel examined the effect of giving leukine to HIV+ patients with T-cell counts less than 100 who were on stable HAART

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### RECREATIONAL DRUG DANGERS

## Pursuing Pleasure Through The Use of Recreational Drugs: Hidden Dangers

*The weekend is coming. You hear about a circuit party happening over the weekend. Some of your friends are intending to go. It's been a hard week. You are looking for an outlet to let go and to have some fun. The image of hot men, muscles bulging beneath tight shirts and jeans, bodies moving to the sounds of club music, excites you. Your mind explores the possibilities- dancing, sweating, grinding all night in a club filled with men. How can you pass up the opportunity? You say "yes" to your friends' invitation to join them.*

In the past, few people with HIV would entertain the possibility of attending a party lasting all night, often across several weekend nights. Recent medical advances in the treatment of HIV, however, have improved the health status of people impacted by the disease. People with HIV are living longer and better quality lives. People's time, energy, and attention, previously focused on getting physically well, have been freed to focus on other activities and pursuits, including creating a

*(continued on page 3)*

regimens. He found that patients given leukine three times per week had increased T-cell counts at every point studied. This trend was not seen in the placebo group. They also observed that those patients who had viral loads less than 400 copies and were taking leukine were able to maintain this low viral load for a much longer period of time than those patients not taking leukine. While these results appear promising, further research is needed using Leukine as an adjunct therapy to HAART.

#### Using T-20 in Multi-drug Salvage Therapy

T-20 is an HIV drug that has a novel mechanism of action. It is a fusion inhibitor that prevents HIV from attaching to T-cells. This drug may be valuable since HIV has become increasingly resistant to the current classes of drugs. One study at ICAAC was designed to see how patients who had developed resistance to all three current classes of drugs (NRTIs, NNRTIs, and PIs) responded to new regimens consisting of T-20 and the currently available drugs. 60% of patients achieved at least a one log drop in viral load at week 16, which appeared to remain stable over the following weeks. 36% had viral loads less than 400 copies, and 20% achieved a viral load below 50 copies. Since T-20 was used in various combinations with different patients, the exact efficacy of T-20 cannot be determined. Still, these results appear to be better than what is generally seen when highly resistant HIV patients are put on a salvage regimen using only combinations of the three available classes of drugs. As a component of a new cocktail, T-20 may be a key agent for those with resistance to the current medications.

#### ABT 378 data looks promising in naive and PI-experienced patients

In two studies presented at ICAAC, the protease inhibitor ABT-378 showed encouraging results. One study examined d4T, 3TC, and ABT-378 given to naive patients. 95% of these

patients achieved a viral load less than 400 copies at week 36. The other study examined ABT-378 in PI-experienced patients. These patients had failed one PI-containing regimen and had never been on an NNRTI. All patients were given ABT-378 in combination with nevirapine and 2 nukes. 78% of these patients achieved a viral load below 400 copies at week 36. Additionally, the ABT-378 combinations were very well tolerated. The major side effect was loose stools, but this led to only 1% of patients stopping the drug.

#### Once-a-day Dose Protease Inhibitor Combo?

Several studies have shown that Norvir greatly increases the levels of Fortovase and Crixivan in the blood. This has already allowed us to combine Norvir with either Fortovase or Crixivan in convenient twice a day dosages. One study by Dr. Saag, et al. at UAB studied the possibility of using the combination of Norvir and Fortovase in a once-a-day dose. The study suggested when a small amount of Norvir is combined with regular amounts of Fortovase, it is possible to achieve appropriate blood levels in a once-a-day dose. The combination was also shown to be reasonably well tolerated with diarrhea and bloating to be the major side effects.

#### New treatment for Hepatitis C

Although not presented at ICAAC, it is worth mentioning that a new drug developed by Roche called Pegasys may be much more effective in treating Chronic Hepatitis C than conventional treatments. In one study, this drug was combined with ribavirin, another common Hep C drug, and 70% of patients with Chronic Hepatitis C achieved an undetectable HCV viral load by week 48. In comparison, current therapy results in a success rate of less than 33%. The combination in the study had mild to moderate adverse events including fatigue, fevers, chills, nausea/vomiting, and anorexia, similar to side-effects of current therapies. ■

*This drug may be valuable since HIV has become increasingly resistant to the current classes of drugs.*



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Treatment Issues & Information

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#### Editor

Daniel S. Berger, MD, FACN

Clinical Assistant Professor of Medicine, University of Illinois at Chicago; Medical Director, NorthStar Medical Center

#### Contributors

Greg Sarlo, MA, LCPC  
Matthew Sirinek, M.D.  
Cheryl Mejta, Ph.D.

#### Consultants

Michael Martino

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#### Mission Statement

It is the mission of AIDS Info Source to provide free, timely, accurate, educational information pertinent to all persons living with HIV disease, their caregivers and healthcare professionals. AIDS Info Source attempts to service every educational aspect of the disease without regard to ones race, religion or sexual orientation.

## Pursuing Pleasure Through The Use of Recreational Drugs: Hidden Dangers

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a more pleasant lifestyle. This often poses a dilemma for people with HIV: how does one sustain his or her physical health while participating more fully in the social and recreational activities of the community? This conflict especially presents itself in decisions to socialize at circuit parties.

*Upon arriving at the circuit party, your senses are filled with the sights, sounds, and smells of the party. Some men are drinking, other men are using recreational drugs to enhance their experiences and to heighten their sensations. You are tired from the week. You do not want to get intoxicated on alcohol, but some drugs to increase your energy and to intensify your sensations sounds appealing. For \$25, the cost of 4-5 drinks, you can purchase some Ecstasy or Crystal to get you through the night and into the party.*

The use of recreational drugs at dance bars and parties is not new to the gay community. During a weekend night at a dance bar in the 1980's, it was not unusual to see men using "poppers," amyl nitrate or butyl nitrite, to enhance

sexual experience and pleasure. In the 1990's, there was a drop in the use of "poppers" within the gay community. Several factors contributed to this drop in the use. In 1991, butyl nitrite, as well as other nitrites, were banned. The use of amyl and butyl nitrites also have been associated with Kaposi's sarcoma (KS). Early studies found that many people with HIV who developed KS also used nitrites; the exact nature of this relationship, however, is still under investigation (National Institute on Drug Abuse, 1999a).

Other drugs have emerged at bars and clubs to replace "poppers." These drugs, often referred to collectively as "club drugs," include MDMA (3,4 methylenediozymethamphetamine) or Ecstasy, methamphetamine or Crystal, and GHB (gamma-hydroxybutyrate) or Liquid Ecstasy. Each of these synthetically-produced drugs have powerful effects on the central nervous system, increasing physical energy, enhancing sexual performance, heightening sensitivity to stimulation, and promoting a sense of euphoria. The effects of these drugs, which can last up to 24 hours, can be appealing to people seeking to re-engage or to more fully participate in the gay community, especially socially and sexually. However, these drugs also can have immediate and longer-term effects on people's health. Additionally there are many potential drug interactions with protease inhibitors and other antiretroviral agents that can pose added risks.

### More about MDMA (3,4 methylenediozymethamphetamine) or Ecstasy:

MDMA is also known as Ecstasy, X, X-TC, Adam, Clarity, Lover's Speed, Stacy, and Beans. This is a synthetic drug that combines properties of mescaline (an hallucinogen) and methamphetamine (a stimulant). For between \$7 and \$30 a tablet, capsule, or powder containing MDMA could be purchased. If you were to orally ingest, snort or smoke the MDMA, you may experience the following:

*Shortly after taking MDMA, you may experience a sense of euphoria or an intense rush followed by an abundance of energy, a heightened sensitivity to stimulation, greater mental and emotional clarity, an enhanced sense of pleasure, an increase in self-confidence, and a sense of acceptance and closeness to others. These effects may last up to 24 hours, although they more typically last between 4 to 8 hours.*

So you may think- "What's the problem?" "This sounds great!" However, in addition to, or instead of these pleasant and positive experiences, you

may have the following unpleasant and negative experiences:

*You may react psychologically to the MDMA with depression, anxiety or panic attacks, paranoia, irrational thoughts or behaviors, and violent thoughts or behaviors. You may find it difficult to remember what you saw, read, or heard, to reason and think clearly, and to sustain your attention to what you are doing. You also may experience physical symptoms including a sense of hyper-excitability, increased heart rate and blood pressure, nausea and vomiting, lack of appetite, insomnia, chills and sweating, faintness, and tremors. These symptoms may persist between 1 day and 14 days. Recent studies also implicate the use of MDMA with long-lasting depletion of brain serotonin levels-the neurotransmitter substance that regulates aggression, mood, sexual activity, sleep, and sensitivity to pain. With a high potential for abuse, it may be difficult for some people to stop using the drug even when they have the desire to stop (Bolla, McCann, & Ricaurte, 1999; Hatzidimitriou, McCann, & Ricaurte, 1999; McCann, Merti, Eljgulashvili, & Ricaurte, 1999; McCann, Szabo, Scheffel, Dannals, & Ricaurte, 1999).*

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# Understanding Physical Fitness & Anabolism

Part II of a Series of articles for developing a deeper understanding for the promotion of lean body mass and improved nutritional status

*Daniel S. Berger MD, FACN*

The basis for promoting physical fitness for patients with HIV infection, has come from practical scientific knowledge, and studies in patients with wasting syndrome. In HIV, nutritional status plays an important role in determining patients' prognosis and survival. It makes sense that keeping ones' body mentally and physically strong can help promote immune competency with enhancement and develop better resistance against infections. It is for these reasons that this series of articles on the promotion of physical fitness were written.

Wasting syndrome occurs in HIV infection as a manifestation of abnormal metabolic processes that occur; the primary manifestation is a loss of lean body mass. Lean body mass status is the primary component of body composition that affects overall health and prognosis in patients with HIV disease. In fact, decrease in body cell mass was associated with decreased survival independent of an individual's T cell count or body fat.

## MEASURING LEAN BODY MASS

Various techniques such as anthropometry (measuring skin fold thickness) and bioelectric impedance testing (BIA) are used easily in the clinic, practitioner's office, or the gym, to measure body composition. At NorthStar Medical Center, physicians often utilize this technique to monitor a patient's progress with physical fitness training and or nutritional therapies; BIA can often provide a composite of overall health status. Additionally, BIA is critical for monitoring a patients' progress in treatment for wasting syndrome. The use of BIA can be helpful in various situations: to monitor progress regarding physical fitness; oversee lean body mass changes as a marker of overall health status; and monitor the effect of specific treatments for HIV-related weight loss.

## DIET

Dietary supplements are no substitute for a well balanced diet. And the fresh quality with a changing variety of food, enables one to capture the many needed vitamins and minerals as well as fiber and phytochemicals. Also, a proper diet can help boost energy levels throughout the day.

## CARBOHYDRATES

Glucose or sugar is an important component of one's diet. When blood sugar rises, insulin secretion is triggered allowing for glucose to penetrate the cells thus supplying energy and fuel to cells. However, if too much sugar persists in the blood stream, this can have effects that actually lower energy levels. High blood sugars can act as a diuretic causing dehydration. Also quick increases in blood sugar can cause a neurotransmitter in the brain, serotonin, to be released which causes drowsiness. Eating the right balance, with mixing complex carbohydrates that tend to become metabolized more slowly, can help maintain a steadier blood sugar level.

Recently, protease inhibitors have been shown to promote glucose intolerance in some patients. In that regard, patients who have symptoms (extreme thirst and frequent urination) should bring this to the attention of their physician. These individuals may need to be tested for glucose tolerance and diabetes. Some patients on protease inhibitors may not have overt diabetes but may have mild and variable symptoms, such fatigue and dry mouth. These individuals may have mild

and variable levels of glucose tolerance problems and should seek the advice of their physician along with an experienced dietitian. Modifying diet can have a positive effect on controlling sugar problems.

## PROTEIN

Protein supplementation has become a hot topic and a large industry moneymaker. While protein requirements in normal adults is 0.8-1.5 grams/kg per day, individuals with chronic disease, metabolic stress and certain athletes can require 2-3 grams/kg/day. There are different sources of proteins that each have advantages and disadvantages. These sources include, whey, casein, milk-protein isolate, soy protein, egg protein and wheat-protein hydrolysate. Most individual's goals are to increase muscle mass while not adding much fat. Thus, combining protein supplements with a balanced diet can be advantageous.

## FAT

One of the most important changes one can make is to monitor the quantity of fat in the diet. High fat intake has been implicated in cardiovascular disease, hypertension (high blood pressure), colon cancer, diabetes, and gallbladder stones. Generally, the amount of fat in one's diet contributes greatly to determination of one's body weight. Also the fat component of body composition has not been shown to improve health status in HIV infection. However, with the emergence of fat redistribution syndromes and lipodystrophy in HIV positive individuals, body fat has become an important issue. Many patients often ask about the quantity of body composition that should be from fat and quantity of fat to be contained in one's diet. It is important to maintain a certain percentage of fat. Studies report that 10-20% of body weight should be as fat. Although individuals at the extreme of leanness as with some athletes and patients with some wasting diseases, 5-6% body fat can be observed. However as a guide to physical training, one should limit daily fat consumption, depending on one's

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baseline body composition and goals of training. Buying a pocket fat gram counter is highly recommended and often an eye opening experience for many. However, with the development of lipodystrophy and body composition changes occurring in HIV infection, it should be stressed that drastic dietary changes in fat intake should be avoided, in order to avoid developing body composition abnormalities

### VITAMINS AND MINERALS

Large quantities of vitamins can be hard to swallow, especially while having to consume possibly twelve protease inhibitor pills, two to four reverse transcriptase inhibitors and miscellaneous antibiotics for prophylaxis and medicines. So for many, the thought of having to take more pills is frightful. And when cruising through the display shelves at the local vitamin store, the array of pills can be overwhelming. Often the most practical solution is a good multivitamin and mineral. Often, by consuming a well fortified diet, one may already get much of what is needed

However, individuals that train heavily and patients with chronic infections such as HIV may require greater amounts of micronutrients and protein. Many patients want to go that extra mile and feel good about taking extra vitamins and supplements.

Although vitamins have not been studied as therapy for anabolism in HIV, there is evidence that specific vitamins or minerals are important in HIV disease. Magnesium is important for muscle functioning, and deficiency has been correlated with stage of disease, and symptoms of fatigue and muscle-aches. Impaired immune function has been associated with deficiencies in vitamins A, B6, B 12, zinc and selenium. Vitamins B6 and B 12 have also been implicated in neurological functioning; when deficient they can exacerbate peripheral neuropathy and dementia. Beta-carotene, an important antioxidant, supplementation has been associated with increased CD4-T cell count. Finally, zinc may have advantages in supporting T-cell functioning.

### NUTRITIONAL SUPPLEMENTS

Differing disease complications among individual HIV infected patients make the choice of nutritional supplements more complex than for persons with normal gastrointestinal function. The challenge of managing with different supplements may be compounded by frequently associated diarrhea with malabsorption and common intestinal infections. Additionally, little information exists regarding what supplemental products are most useful for HIV infection and combining them with protease inhibitors and the other multiple anti-retroviral drugs. Nutritional supplementation may need to be individualized for both need as well as tolerance.

### CREATINE

Creatine is a natural constituent of muscle cells. It is synthesized in the liver as well as pancreas and kidneys and is made up of amino acids, methionine, arginine and glycine. It is transported in the blood to muscle cells and converted into creatine phosphate by the enzyme creatine kinase. The addition of the phosphate group with an oxygen atom is where energy is stored. During muscle contraction or work, creatine is cycled back and forth to creatine phosphate supplying energy to muscle cells. It is believed that if more creatine is stored, more energy is consequently available and that more work can be done with less fatigue. Additionally, when muscle takes up creatine, more water is absorbed into muscle tissue along with it; this gives muscle fibers a larger appearance. This is the concept of cell volumizing, but has not been proven. Various studies have been done; the majority of controlled studies involved small groups of individuals.

Nevertheless the findings have been consistent. Demonstrated increases in the following measured parameters and specific athletic activities included enhanced performance in high-intensity cycling, increased weight lifted and the number of repetitions in bench press. A further study also demonstrated that during high intensity pedaling creatine monohydrate supplementation resulted in greater time to exhaustion by 62% and

oxygen consumption was significantly lower with lower serum lactate concentration.

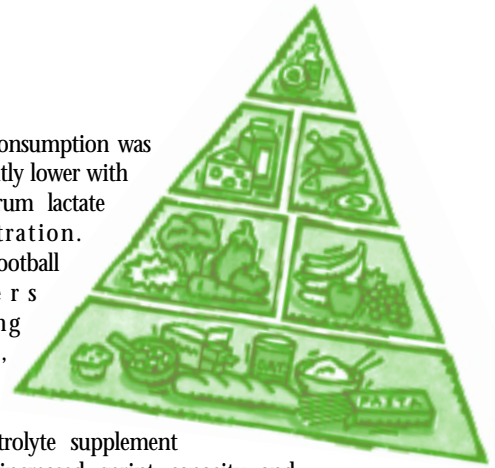
Finally, football players receiving creatine, glucose, taurine

and electrolyte supplement showed increased sprint capacity and strength compared with players receiving the same supplement without the creatine.

A recent study published in the International Journal of Sports Nutrition studied body composition changes by dual energy X-ray absorptiometry (DEXA). Fat free mass or lean tissue mass increased significantly versus patients consuming a protein plus carbohydrate or carbohydrate -only supplements.

Athletes often practice a method of creatine loading to increase creatine stores in muscle cells. Once creatine is transported into muscle cells it is converted to the phosphate form and is then trapped there. Since its' half life is particularly long (4-6 weeks) and not degraded with exercise one can load the muscle through this method for at least 5 weeks. Some advise loading with 5 gram doses four times per day for five consecutive days (20 gms/d)

The form of creatine most studied and used is creatine monohydrate and contains more creatine per weight than other forms. The most efficient way of making use of creatine is to supplement it with an insulin stimulating sugar and a small quantity of sodium. Creatine phosphate, however, is probably not a useful oral supplement since it may not penetrate muscle cells as readily. Also this phosphate form actually contains less creatine per gram than the monohydrate form. Creatine citrate also contains less free creatine, and is also more expensive.



### HMB

HMB, or beta-hydroxy beta-methylbutyrate is an important metabolite of the essential amino acid leucine. Leucine is transaminated to alpha-ketoisocaproate which then undergoes various biochemical reactions, one of which is the conversion to small amounts of HMB that occurs primarily in muscle and liver. In general HMB is thought to lower cholesterol while increasing muscle mass and muscle strength and improved immune function. It is thought that HMB is important for muscle cell membrane production via intracellular synthesis of cholesterol, thereby it may also be important for immune function vis-a-vis increasing white blood cell production.

Various studies have been done investigating the effects of HMB. It appears that HMB is of benefit if used with concurrent exercise regimens. In a very small study of five men who were monitored in a cross-over study in which during the first two weeks they had taken placebo and then were given HMB daily. All meals were provided in a stabilized condition of a clinical research unit. HMB was found to increase nitrogen utilization by 18%. (Less nitrogen is lost when there is increased protein synthesis). During the placebo phase of the study, urinary nitrogen actually increased; in other words, protein was broken down during placebo which reversed to nitrogen gains during the HMB supplementation phase.

Multiple exercise studies were done with HMB demonstrating improvement in the areas of body composition, resistance training, strength, and muscle function. Various Olympic and professional athletic teams, including the sports of football, swimming and weight training have credited improvements using HMB.

In the areas of aerobics, endurance trained cyclists were given one of three supplements: HMB, leucine or placebo. HMB was found to improve in maximal oxygen consumption which measures oxygen capacity to transport and utilize oxygen during exercise. Additionally, lactate threshold, which measures the

intensity at which one can perform exercise before anaerobic metabolism occurs (preventing fatigue), was higher in the leucine and HMB supplemented groups.

HMB supplementation has been found to be safe in normal adults; HMB itself is a natural metabolite of leucine but should be studied in a control manner in AIDS.

*HMB is thought to lower cholesterol while increasing muscle mass and muscle strength and improved immune function.*

Most proponents of HMB recommend that one to two grams daily is enough to see results. However athletes involved in heavy training, will benefit from 3 grams of HMB daily. It is also thought that HMB supplementation should continue even on days that one is not exercising. Higher levels do not seem to be advantageous.

### PROTEIN SUPPLEMENTS

Whey protein is isolated during cheese production. Actually when milk is curdled, the curd is cottage cheese or casein protein and the whey is separated off. Milk-protein therefore, is a combination of whey and casein. Whey-protein is high in intact immunoglobulins and branched-chain amino acids. It also has a high amino acid profile and has been purported to increase glutathione production, an important antioxidant. However, whey protein supplements tend to be on the pricey side. Casein protein is as cheap as buying cottage cheese. Low-fat cottage cheese is one of the best sources. It forms a gel during intestinal digestion, which may slow intestinal transit time thus improving absorption. However, it is lactose containing and thus may cause diarrhea in some HIV positive individuals. Casein also is high in glutamine, an amino acid that is important in maintaining gut structure and function.

Soy proteins (tofu) has not been popular due to its' taste, and the protein concentration is highly variable from product to product. Overall, soy is high in branched-chain amino acids, and essential amino acids, glutamine and arginine. Also studies have demonstrated reduction in

cholesterol and triglyceride levels.

Egg protein used to be considered the gold standard for many years. It's a high quality whole-food protein source with a high amino acid profile. Eggs and thus egg whites are an old stand-by for a high protein breakfast and egg white powder supplements taste good and are often fortified with other amino acids such as 1-glutamine.

### DHEA

DHEA, dehydroepiandrosterone is a hormone produced by the adrenal glands. DHEA is one of several building blocks (precursors) for both androgens (testosterone derivatives) and estrogens. During normal life span, an individual's DHEA level peaks at age twenty, and then declines progressively as part of the aging process. DHEA has been supplemented by athletes but has not been studied for its anabolic effects. Studies of DHEA supplementation for other diseases such as for chronic fatigue, and systemic lupus, however, have demonstrated improved stamina, strength and physical or psychological well-being. In HIV positive persons, DHEA was found to be associated with reduction in HIV RNA levels (viral load). No proposed mechanism of viral load changes has been invoked, nor has this been confirmed.

Although not a prescription drug, and without the potency of conventional anabolic steroids, DHEA does carry with it potential side effects including androgenic effects that include acne, hair loss, hirsutism and deepening of the voice, when used in woman. Precaution for the potential of stimulating the growth of certain cancers is also of concern.

The promotion of lean body mass accrual is of prime importance to the health of HIV positive individuals. The primary goal of this article is not to promote any of the above supplements nor recommend their specific use. Moreover one hopes that the information carried here is used as a spring-board for further individualized reading, inspiration and further discussion among patient and physician.

*In HIV positive persons, DHEA was found to be associated with reduction in HIV RNA levels.*

# PIPELINE MANIA

## New and Promising Anti-HIV Drugs in Development

Daniel S. Berger MD, FACN

### FTC

(Emtricitabine), a nucleoside reverse transcriptase inhibitor, presently is in phase III trials and appears to be very promising. FTC has activity against HIV, as well as, Hepatitis B. Additionally, preliminary studies showed FTC to be more potent than 3TC with demonstrable 2.0 log drop in HIV RNA. FTC can be dosed once daily, but has a similar resistance profile to that of 3TC (184 codon mutation). and will probably replace 3TC.

### PMPA Prodrug Protocol 902 (Phase 2) or Tenofovir DF

is part of a new class of reverse transcriptase inhibitors called nucleotides. It is active against HIV as well as Hepatitis B. PMPA is just completing phase II studies whereby the drug was found to be both safe and effective. In an earlier study of PMPA prodrug administered to monkeys demonstrated 100% prevention of infection with simian immune deficiency virus. PMPA prodrug has a very long half life and can be taken once daily, with food (since its bioavailability is increased to 40% with food). This agent also appears to be synergistic with other antiviral agents and has shown increased susceptibility to virus resistant to AZT, ddI, ddC and a two fold increase in susceptibility to 3TC resistant virus. Additionally, preliminary information regarding prior exposure to Preveon (adefovir dipovoxil) does not affect susceptibility. Thus far, the drug appears to have little side effects nor any nephrotoxicity (kidney). We believe that PMPA looks to be one of the most promising drugs to be coming along in a while. Phase III trials have recently started and is actively enrolling at NorthStar Medical Center. For further information call Harriett Wittert at (773) 296-2400.

### MKC-442

(Emivirine) is a non-nucleoside reverse transcriptase inhibitor. Clinical trials have tested MKC-442 in combination with various antiretroviral agents and in salvage situations, patients failing protease inhibitors. This drug also appears to be more potent than nevirapine. Although it was found to be effective in earlier studies, its' effect during for salvage situations was not impressive.

### ABT-378r

This is Abbott Labs second generation protease inhibitor. The drug is formulated to include a small amount of ritonavir with each capsule, in order to increase its' levels in the blood stream. The drug is hoped to be effective against some protease inhibitor resistant virus and therefore may be useful in salvage situations. However,

the reasoning by Abbott Labs of its' use for salvage was somewhat based on a particular clinical study and is problematic. This study utilized ABT-378r with non-nuc naive and dual- protease inhibitor naive subjects in a five drug regimen. In summary, while the results showed good viral suppression, the contribution of ABT-378r to this regimen is impossible to discern. Additionally, we believe that this drug should be studied in patients with extensive dual protease inhibitor and non nucleoside experienced patients, so that its' use for the most common salvage situation can be better understood. Currently available on a compassionate access program, the drug is expected to come to market by the fall of 2000.

### Lodenosine

(F-ddA) is a fluorinated nucleoside reverse transcriptase inhibitor (NRTI) that is long acting and has a half life of 20 hours making dosing once a day possible. Additionally, and very importantly, it is active against many of the NRTI resistant virus including the Q151M mutation which confers high level of resistance to multiple nucleosides. Therefore it appears to be useful for patients in salvage situations or patients failing other available cocktails (or in whom have extensive NRTI exposure). A recent and ongoing study has examined F-ddA in combination with d4T and indinavir (Crixivan). Early indications are that this combination is active with potent anti-HIV activity. However, there have been some serious adverse events associated with the US Bioscience sponsored trial. Thus further plans for the future development of lodenosine is on hold until clarification of these adverse events and their relation to the drug is made.

### DMP 961 and DMP 083

Dupont Pharmaceuticals' second generation non-nucleoside reverse transcriptase inhibitor (NNRTI), DMP 961, was set to undergo phase III studies. However, the drug has now been placed in a holding pattern. The decision to change gears was due to some drug interaction and pharmacokinetic studies, as well as concern that 961 may not be as advantageous as previously thought for salvage situations. Alternatively, Dupont will go ahead in evaluating another NNRTI, DMP 083, which may have a better profile. Dupont Pharmaceuticals Company is committed as developing an NNRTI that will be unique in providing superiority in effect for patients that have been highly exposed to most other approved agents.

### T-20 and T-1249.

These drugs are of great interest and an exciting development in treatment for patients that are highly experienced to treatments. They belong to a new class of therapy called fusion inhibitors, because they block binding of HIV onto the receptor on the CD4 T-cell. Preliminary studies have shown that T-20 was effective in patients with resistance to other antiviral agents. Cross resistance is unlikely, due to the unique mechanism of action. Currently T-20 is administered by subcutaneous injections twice daily. The drug was developed by a small biotech company called Trimeris but was recently also acquired by the large entity, Roche Pharmaceuticals, which will aid in its' faster development and production.

### L2 form of Interleukin 2

This is Chiron Pharmaceuticals' new formulation of Interleukin 2. This new monomeric version is touted as being three times more potent as the original version and because of its' chemical structure is expected to have less side effects, especially at the injection site (IL2 is normally administered by subcutaneous injection). The drug is currently undergoing phase I and II studies.

### GW420867X

non nucleoside that appears to be very potent in its' antiviral effect. Furthermore GW420867x has a long half life thus making for once daily dosing. Its' other attributes include low drug interactions, since its' metabolism is via different pathway than protease inhibitors.

### Tipranavir

is a new and novel protease inhibitor developed by Pharmacia Upjohn. However, the drug has been recently acquired by Boehringer Ingelheim which we believe will allow for its' faster development and use. This protease inhibitor is in a new class being non-peptidic, does appear to be unrelated chemically to other available protease inhibitors with a different resistance profile. In its' current formulation one needs to take 10 large pills three times daily. As a result the drug is being studied in combination with ritonavir, thus reducing frequency of dosing and pill burden.

### dAPD

is a nucleoside reverse transcriptase inhibitor that is being developed by Triangle Pharmaceuticals. Chemically related to abacavir (Ziagen), because of it being a guanosine analog, has also potent activity against HIV as well as Hepatitis B. In-vitro (test tube) studies have demonstrated similarities in resistance mutations to ddI, ddC and abacavir.

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# STUDIES

- *Most studies provide for antiviral drugs, labs and Dr./study visits and are free of charge to the patient during the study.*
- *Think about being part of a study, or referring a friend, that is not on effective treatment*
- *Gain access to the newest generation of up and coming treatments.*

## PMPA Prodrug - Tenofovir Protocol 907 (Phase 3)

This is a part of the new class of agents called nucleotide reverse transcriptase inhibitors. The study keeps patients on their already stable cocktail but adds this new potent agent to the regimen. This phase III, 48 week study is for patients who have been on stable therapy and who have viral loads between 400 and 10,000.

## "Nice Study:" Crixivan combined with Norvir

This is a phase IV study for patients who remain with viral loads below 500 and who are on Crixivan with two other Nuc's. The study is for 24 weeks. 3 of 4 patients will have their Crixivan dose reduced to one pill twice daily in combination with 400 mg of Norvir, both to be taken with food. One patient of every 4 will continue on their regular Crixivan dosing but will eventually be changed to the Crixivan /Norvir combination regimen at 12 weeks.

## L2-7001 - Interleukin-2

This is a phase II, 6 month study examines 3 doses of a new formulation of IL-2, that appears to be three times more potent and with less side effects than the currently used IL-2. The study eligibility includes patients with T cell counts between 300 and 500 cells. Viral loads should be less than 10,000 copies. Patients will be randomized to receive either the L2 form of IL2 or Proleukin IL2 twice daily (split dosing) for 5 days every two months. Some patients will be asked to be tested for IL2 blood levels.

## FTC (Emtricitabine) vs. Abacavir

FTC is a new potent nucleoside analog (NRTI). In-vitro studies have demonstrated FTC to be more potent than 3TC. This study is a randomized open-label 48 weeks trial comparing two arms: Arm 1 is FTC + d4T+ Sustiva; Arm 2 is Abacavir + d4T + Sustiva. Patients must be antiretroviral-drug naive and have a viral load greater than 5000 copies/ml.

## Protease Failure – Study NZTA4008

This is a phase IV study for patients who are failing their initial protease inhibitor containing regimen in combination with 3TC and AZT or d4T. This study investigates three alternative regimens utilizing the drugs: Abacavir, Sustiva, ddI and Hydroxyurea. Patients are randomized to an open label regimen and must have CD4 T cell count > 200 cells and viral load between 400 and 50,000 copies/ml.

## Substitution with Sustiva – Study DMP 266-049

This is a phase IV, open label randomized study to determine the safety and duration of effect of regimens comparing continued therapy with protease inhibitors vs protease inhibitor substitution with Sustiva. Randomization will occur in 3:1 ratio, substitution vs. continued treatment with protease inhibitors. Patients will have skin-fold/anthropomorphic (weight and body circumference measurements) to determine whether the patient has lipodystrophy. Laboratory tests include lipid profiles (cholesterol and triglycerides).

## PMPA PRODRUG Study (phase 2)

PMPA is a potent *nucleotide* reverse transcriptase inhibitor that inhibits HIV production in HIV infected cells. A 48 week phase II, randomized double-blind study to evaluate the safety and antiviral activity of the addition of PMPA Prodrug to stable combination regimens. Patients must have a viral load > 400 and < 50,000 copies/ml and must be on stable antiretroviral therapy (including protease inhibitors) of no more than 3 active agents for 8 weeks. Hydroxyurea as a fourth drug is permitted. Patients currently taking adefovir cannot be enrolled.

## Salvage for Protease Inhibitor Failures with MKC-442

MKC-442 is a potent non-nucleoside reverse transcriptase inhibitor (NNRTI) that inhibits HIV production. This 48 week randomized, double-blind study is enrolling patients failing protease inhibitor combinations and compares antiretroviral activity and tolerability of D4T, DDI, and Hydroxyurea with and without MKC-442. The study will involve 3 arms. Patients with viral loads >5000 and < 50,000 copies/ml will be randomized to receive either MKC-442 or placebo in combination with D4T, DDI and Hydroxyurea. Patients with viral loads > 50,000 copies/ml will receive open-label MKC-442. Patients must have failed a protease-containing regimen and be NNRTI naive.

## MKC-442 + Viracept

MKC 442 is a new non nucleoside RT inhibitor (NNRTI) in combination with Viracept, a potent protease inhibitor that is being studied in combination with a choice of reverse transcriptase inhibitors. This study is for patients of two groups: 1) patients naive to drug therapy and 2) patients having been on RT inhibitors but not experienced with protease inhibitors nor NNRTI's.

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*The following list of studies are available at the NorthStar Medical Center Dan Berger, MD and Associates*

*For further information or participation please call 773-296-2400*



**141W94 (Vertex Pharm. Protease Inhibitor) combined with 1592U89 (Abacavir) and Combivir (3TC/AZT) vs. Combivir with Viracept**  
 Open-label, randomized, to compare the long-term durability of viral suppression with a four-drug regimen to that of a three-drug regimen. Patients must be antiretroviral-naive and have a RNA PCR (viral load) of >5,000 copies/ml. Duration: 48 weeks plus extension. Failing patients will be given the option of modifying their regimen according to best practice guided by genotypic and phenotypic data.

**DMP 266 - Sustiva + Crixivan**  
 DMP 266 is a potent non-nucleoside reverse transcriptase inhibitor (NNTRI) that inhibits HIV production in HIV infected cells. A 2 year phase II/III multicenter, randomized, open-label study to compare antiretroviral activity and tolerability of three different combination regimens (DMP 266 + Crixivan, DMP 266 + AZT = 3TC, Crixivan = AZT + 3TC) in HIV-infected patients. Patients must be asymptomatic or mildly symptomatic, have a CD4 cell count greater than or equal to 50 cells/mm, and a viral load greater than or equal to 10,000 copies/mL. Patients will have received no prior treatment with DMP 266, 3TC, nevirapine, delavirdine, or any protease inhibitor.

**HIV Anemia with Weekly Procrit - Protocol PR98-29-002**  
 Erythropoietin (Procrit) is a protein hormone, normally produced by the kidneys, and has been shown to significantly increase red blood cell count. This is a 16 week open label study using weekly injections of Procrit for patients with hemoglobins less than 11 g/dl. There is no placebo treatment and all qualified patients receive open label drug. The specific dosing requirement is titrated during the study.

**Interleuken-2 (IL-2)**  
 Open-label interleuken-2 is a cytokine (natural substance produced by cells) that may stimulate T-cells increases. This off-label use of this drug for patients with CD4 T-cells greater than 100. The drug is administered by subcutaneous injection daily for 5 consecutive days every 8 weeks.

**Passive Immunotherapy with CMV Intravenous Immunoglobulin**  
 CMV IVIG is a preparation that contains high titers of antibodies of CMV (Cytomegalovirus). CMV is often a cause of opportunistic disease in AIDS. This off-label treatment is available to patients with CMV disease (i.e., CMV Retinitis, esophagitis, gastritis, or systemic disease, etc).

**Passive Immunotherapy with Intravenous Immunoglobulin**  
 IVIG is a lyophilized preparation of intact immunoglobulin G (IgG) from pooled plasma and is not chemically altered. This broad range of antibodies is capable of neutralizing microbes and toxins against bacterial and viral antigens of various infectious diseases. This off-label treatment is available to patients with recurrent bacterial infections and/or history of an opportunistic disease. IVIG is administered monthly with close monitoring.

**Lipodystrophy and Fat Redistribution Syndrome**  
 This research involves testing to examine the various relationships of a variety of factors that may contribute to the development of lipodystrophy and fat redistribution. The initial stage of the study is retrospective and examines the patient's past medical history. The second phase of the study will include DEXA testing for body composition as well as single slice abdominal cat scanning to examine visceral (internal) body fat development.



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## Pursuing Pleasure Through The Use of Recreational Drugs: Hidden Dangers

continued from page 3

### More about Methamphetamine:

Methamphetamine is also known as Ice, Crystal, Crank, Fire, and Glass. This is a synthetically-produced stimulant that chemically closely resembles amphetamine but with more powerful effects. For about \$10 to \$25, a powder or crystal containing methamphetamine can be purchased. If you were to orally ingest, snort, or smoke methamphetamine you may have the following experiences:

*Within 3 minutes to 20 minutes, depending upon how you consumed the methamphetamine, you would experience an intense rush or flash followed by an increase in activity and decrease in fatigue, a general sense of well-being and euphoria, a decrease in appetite, and an increase in libido. While similar to the effects of cocaine, the stimulant effects of methamphetamine are more prolonged. Its effects can last up to 24 hours, although they generally last between 6 to 8 hours.*

Again, you may think that these effects are appealing and desirable. As with MDMA, you may experience undesirable and negative effects in addition to or instead of the more desirable and positive effects. These may include the following:

*Psychologically you may feel anxious, confused, agitated, intensely angry, and out-of-control. You also may experience psychotic-like symptoms such as severe mood disturbances, paranoia, auditory and visual hallucinations, and delusions. You may have difficulties remembering and thoughts of homicide and suicide. Physically, you may experience an increase in respiration, hyperthermia, cardiovascular and neurological damage, difficulties sleeping, and weight loss. These symptoms may persist for some time. Recent studies suggest that long-term exposure to even low levels of methamphetamine can damage dopamine-producing and serotonin-containing cells in the brain (National Institute on Drug Abuse, 1999b). Methamphetamine has a high potential for abuse, similar to MDMA.*

### More about Gamma-hydroxybutyrate (GHB):

GHB is also known as Grievous Bodily Harm, G, Liquid Ecstasy, and Georgia Home Boy. This is a synthetic drug that acts as a central nervous system depressant with intoxicating, sedative, and euphoric properties. In addition, its growth hormone-releasing effects may build muscles in chronic users. The drug can be easily purchased in clear liquid, white powder, tablet, or capsule form. If you were to orally ingest, snort, or smoke this drug, you may have the following experiences:

*Within 20 minutes of taking the drug, you may experience a reduction in anxiety, an increased sense of calmness and relaxation, an increase in sleepiness, and enhanced sexual performance. These effects generally last about 4 hours. Extended use of the drug may promote the building of muscles.*

As with most of the “club drugs,” GHB has several negative side effects in addition to or instead of the more positive effects. These may include the following:

*As a central nervous system depressant, GHB can slow breathing and heart rate to dangerous levels. Overdose of GHB can occur quickly producing drowsiness, nausea, vomiting, headache, loss of consciousness, loss of reflexes, impaired breathing, and ultimately death. Since GHB often is used in combination with alcohol, the potential for overdose is high (National Institute on Drug Abuse, 1999c).*

### The Appeal of Club Drugs

Sexual activity is integral to the gay community. Besides providing pleasure and release, sexual activity is a way to connect physically and emotionally with others. The bars

always have been used by the gay community as a place to socialize and to meet others, including sexual partners. The bathhouses also have been used to connect with others, especially physically and sexually. Circuit parties have emerged as new forums for people to “party” for hours or days. In the pursuit for ways to enhance sexual pleasure and satisfaction, recreational drugs, particularly MDMA or Ecstasy, Methamphetamine or Crystal, and GHB, may be appealing. These drugs may offer people sustained physical energy, increased sensitivity to physical sensations, and reductions in behavioral inhibitions. These drugs are relatively accessible to people since sources selling these drugs are easy to find and the cost to purchase these drugs is low. However, these, as well as other “club drugs,” have the potential to create physical and psychological problems.

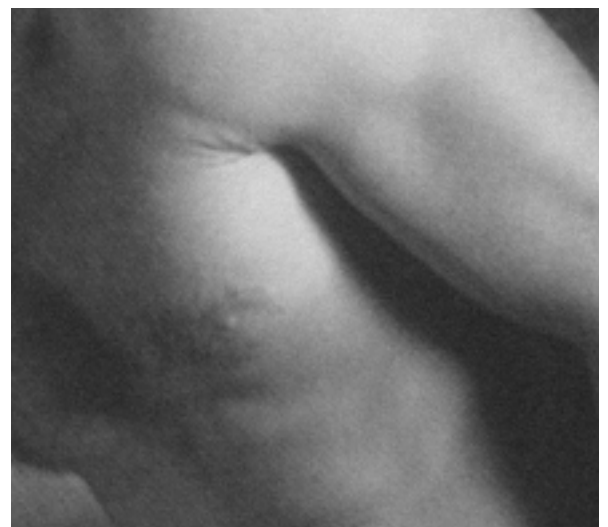
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As with MDMA, you may experience undesirable and negative effects in addition to or instead of the more desirable and positive effects.

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## Considering Your Personal Use of Club Drugs

Acquiring information about the effects of “club drugs” is important to making informed decisions about personal use of these drugs. It also is important to review honestly how these drugs play a role in your life. There are several barriers, however, to reviewing personal use of “club drugs.” No one intends to use “club drugs” or any other drug in order to create problems for himself or herself. Instead, however, most people pursue drug use to capture the positive effects and to avoid the negative effects of these drugs. Unlike other drugs which may be used daily and/or in non-social situations, people usually restrict their use of “club drugs” to weekends and special parties. People may develop a false sense that these drugs are “safe” since they tend to be used infrequently within a social context and without immediate financial, social, or career consequences. While many people do not often discuss the “lows” associated with their use, it is also accurate that people have had negative physical and psychological immediate reactions to these drugs and long-term consequences resulting from frequent use of these drugs. Additionally, many individuals are taking antiretroviral agents such as protease inhibitors that are known to have possible negative drug interactions and may therefore pose added harm or risk. To sustain your physical and mental health, it is important to look at your use of recreational drugs.

To get a sense as to whether you may be experiencing some problems with your use of “club drugs,” you may want to use one of the available screening tools for possible problems with drug use. The CAGE is one widely used screening tool initially used to screen for alcohol-related problems but modified to screen for other drug-related problems. There are four questions to answer on the CAGE:

1. Have you thought about Cutting down the amount and/or the frequency with which you use “club drugs?”
2. Has /have your partner, friends and /or family been annoyed with you because of your use of “club drugs?”
3. Have you felt Guilty about the your use of “club drugs?”
4. Have you spent extended periods of time high or recovering from the effects of “club drugs ?”

If you responded “yes” to any of these questions, you probably want to look more closely at your use of “club drugs,” including the frequency with which you use them,

the effects these drugs have upon your physical and psychological health, and the reasons you use them (e.g., what you are seeking through your use of these drugs). Your physician, psychologist, or counselor can help you determine whether you are developing a problem with “club drugs.”

Even if you responded “no” to these questions, you may want to look more closely at your use of these drugs, asking yourself some of the following questions: Do these drugs really get you what you’re looking for? Does the immediate pleasure you may get from using these drugs outweigh the potential risk these drugs pose to your health?

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## **Institution of a new oppressive policy towards PWAs by Statlanders Pharmacy.**

A prominent mail-order pharmacy, Statlanders (or 'Ratlanders' as some PWAs call them) that many HIV-positive patients utilize, has been recently acquired by Bergen Brunswig, Inc. They have recently changed their policy regarding patient burdens and responsibilities. As a result, some patients will now have to pay up front for the entire cost of their medications. One patient on growth hormone was quoted as saying that he may have to pay out up to two months in advance for his meds, which can amount to \$15,000. Most patients do not have these financial resources. He was told by this company's patient liaison to go else-where for his business. Perhaps other patients should go elsewhere as well. Statlanders will probably lose much business. Other mail order pharmacies are not requiring up front payments and would be more than happy to accommodate former Statlanders clients.

## **The latest theory for the cause of fat redistribution or lipodystrophy**

that was evoked at recent medical meetings is its' relation to mitochondrial toxicity. Mitochondria is present in all human cells and is abundant in adipocytes (fat cells). Various anti-viral drugs commonly used for the treatment of HIV disease have been shown in the test tube to cause mitochondrial dysfunction. Still many HIV clinicians are uncertain of the link between mitochondrial toxicity and lipodystrophy.

## **Viral load resurgence was observed when triple therapy (HAART) was stopped.**

An attempt to cure AIDS via treatment with HAART with interleukin-2 failed reported in USA TODAY, quoting a recent article in Nature. After halting treatment, the virus rebounded, despite the fact that early indicators showed no detectable levels of virus in the blood, initially. It was hoped that IL-2 would activate any latent infected cells so that the activated cells would then be susceptible to HAART therapy. This approach may need to be redesigned to affect HIV infected cells in other body compartments such as brain and testicular tissues.

## **Low levels of HIV were found to be replicating in the blood and genital fluids, despite "undetectability" by conventional viral load testing.**

The 22 patients in this study had undetectable virus in the blood using a hypersensitive assay for viral load to the level of less than 50 copies/ml but subsequently showed detectable HIV-RNA in selected cell types via more sensitive testing from blood plasma. The study, recently published in JAMA (782; 17: 1627-32), showed that 12 of the 22 patients had negative HIV-RNA levels in genital secretions but that 8 individuals had lower levels of HIV RNA. Presently and from this study, it is not clear where the low level of replication or residual infection is taking place, whether from lymph nodes, various immune system cells or other sanctuary sites.

## **New transmission of drug resistant HIV strains continue to appear.**

In a recent study (JAMA;282:1142-9) of 141 patients from San Diego, Los Angeles, Dallas, Denver and Boston, resistance mutations were seen in newly diagnosed patients prior to any antiretroviral exposure. One can't help believing that this situation will only accelerate over the not-too-distant future. Important to the community, safe sex should be maintained and stressed to everyone, including those individuals on antiretroviral therapy.

## **A new study shows high risk sexual behavior to be occurring in adolescent gay and bisexual males.**

The Centers for Disease Control and Prevention (CDC) conducted interviews among gay men in Baltimore, New York, Seattle, Miami, Los Angeles and San Francisco from 1994 through 1998. Over 40% of males surveyed said they engaged in unprotected sex within the previous 6 months. The growing complacency among young gay men may be due to the illusion that HIV does not necessarily progress to AIDS because of aggressive antiviral treatments. Many of these individuals have not lost friends to AIDS like older aged gay men. Additionally, young men who are just becoming sexually active may not be routinely testing for HIV. Stronger educational efforts should be implemented towards younger aged individuals.

## **Chinese herbal therapy was found NOT to show benefit, published recently in the Journal of AIDS.**

While many patients with HIV often pursue alternative therapies as treatment or as adjunctive therapy, this study is important and may help patients make a better decision on whether to add more pills and expense to their regimens. The study involved investigators from Zurich, Dublin and San Francisco and the 68 participants were patients with T-cells below 500 on stable antiviral therapy. The patients were then randomized to receive either pills containing 35 Chinese herbs or placebo for 6 months. The patients taking the herbs had more gastrointestinal side effects, however, there was no benefit in viral load, HIV symptoms nor quality of life.

## **New estimates for the start of the global AIDS pandemic has now been estimated back to the 1930's.**

Researchers presented their calculations at the Retroviral meeting in San Francisco on January 30, 2000. The calculations were based on a large computer database of HIV samples and genetic sequencing from the samples to calculate the evolutionary tree.

## **Dupont Pharmaceuticals Company has encountered a glitch in their research of their compound DPC 961.**

Preliminary findings showed the new compound to not be as advantageous nor superior to Sustiva. Thus they have shifted their efforts at developing yet another NNRTI. Phase II studies with DPC 083 are being planned; the hope is that this new compound may have the potential of being better tolerated and superior for patients failing treatment with other approved drugs.

## **A leading cause of death among priests has been attributed to AIDS.**

A new report coming out of Kansas City, where a prominent priest has recently died of AIDS has stipulated a large portion of deaths among the clergy to be secondary to HIV and AIDS. One leading AIDS caregiver has hypothesized that Catholic priests may be very closeted about their sexual preference thus inhibited about screening for HIV infection or seeking early treatment.

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### **VITAMIN CO-OP AVAILABLE AT BROADWAY VITAMINS -**

Why shop at a Vitamin super store? For people in need, a Vitamin Co-op is available providing "at cost" vitamins and nutritional supplements.

Most of the important vitamin supplements recommended for HIV+ people are included. Not all items in the store are. We strongly encourage working people who are able, to "positively" support their efforts with regular purchases. Broadway Vitamins 3321 North Broadway, Chicago, IL 60657 Full line of Vitamins & supplements, sports nutrition, shakes, herbs, teas, health foods etc., Support our community and thank them with your patronage for providing this extremely valuable service for those in need.

Utilize the co-op by appointment only.  
Contact: Dorothy Tanner  
773/404-9000.