What’s New in Treatment Information?

Expanded Access Confusion
According to the Access Project, the only HIV drug that is in expanded access currently is atazanavir (Zridava). T-20 is in open label trials (a type of drug trial in which researchers and participants know who is taking the experimental drug or treatment being given), which can be easily confused with expanded access programs (programs designed to make experimental drugs available on a wide basis to people who do not qualify for the drug trials or who live too far from a trial site). According to our IA department, T-20 should be coming out in expanded access sometime after mid-July.

For more information on the atazanavir expanded access program, check out the Access Project website at www.atdn.org/access/index.html and click on the Expanded/ Early Access Programs link.

Valganciclovir Added to the ADAP Formulary
The drug valganciclovir which is used to treat the symptoms of cytomegalovirus (CMV) retinitis— an infection in the eyes associated with HIV— has been successfully added to the ADAP Formulary!!

Although valganciclovir will not cure CMV, it may help to keep the symptoms such as floaters (small spots in the vision), decreased visual activity loss of peripheral vision, blurred vision and blind spots from becoming worse. Please note that many people with CMV retinitis have no symptoms.

There are some side effects such as black, tarry stools; blood in urine or stools; chills; cough; fever; hoarseness; lower back or side pain; painful or difficult urination; pale skin; pinpoint red spots on skin; sore throat; seeing flashes or sparks of light; seeing floating spots before the eyes; troubled breathing; ulcers, sores, or white spots in the mouth; unusual bleeding or bruising; unusual tiredness or weakness; veil or curtain appearing across part of vision and less common such as changes in facial skin color; fast or irregular breathing; hives, itching, and skin rash; large, hive-like swellings on eyelids, face, lips, mouth, and/or tongue; puffiness or swelling of the eyelids or around the eyes; runny or stuffy nose; shortness of breath; tightness in chest and/or wheezing. These side effects may arise for a person taking valganciclovir so as always encourage the caller to talk to their doctor about any and all changes or difficulties.

Company Halts Production of Deca-durabolin (Nandrolone)
Organon, the company that makes the anabolic steroid deca-durabolin (Nandrolone), halted the manufacturing of the product in early June. The Food and Drug Administration approved the decision. People using deca-durabolin can expect difficulty getting it, if they have not already experienced it. When pharmacies run out, no replacement is expected. Also, generic products are not available to serve public programs, like ADAPs.

Organon sites extensive off label use of deca-durabolin as the reason for stopping the manufacturing. Off label use is when a therapy is being used for conditions for which it has not been FDA-approved. For example, this therapy is not approved for treating HIV-related weight loss, but many people with HIV use deca-durabolin off label for treating the condition.

A number of therapies are approved for treating HIV-related weight loss. They include:
- Megesterol acetate (Megace) - This female sex hormone is shown to be effective in promoting weight gain in people with HIV-related wasting syndrome. Studies suggest that the weight gain associated with its use is primarily fat gain, as opposed to lean body mass, like muscle. People with HIV-related wasting syndrome often experience a decrease in both fat and lean body mass. While fat weight gain is important, experts propose that lean body mass gain is likely more important. Therefore, megesterol may be a less desirable option. Also, its side effects include developing secondary female sex characteristics (like development of breasts in men), making it a less desirable option for many.
- Human Growth Hormone (Serostim) - This anabolic agent

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is associated with increases in lean body mass and is approved for treating HIV-related wasting syndrome. Studies show that growth hormone preferentially promotes developing lean body mass and seems to result in further loss of body fat. This therapy is also being tested for its usefulness for treating some manifestations of lipodystrophy (central obesity or protease paunch and dorsal fat pad or buffalo hump). Growth hormone is very expensive and not without side effects. Because of its expense, many hospital and reimbursement plans require people to try less expensive products (like deca-durabolin) before being allowed to try growth hormone.

- Dronabinol (Marinol) - This synthetic pill is a form of THC, the psycho-active ingredient in marijuana. It is approved for treating loss of appetite (anorexia) in people with HIV. Essentially it works by giving people the "munchies." Some studies suggest that the primary form of weight gain from using this product is fat gain. However, not everyone with HIV who experiences unwanted weight loss also experiences a loss of appetite. For this reason, the drug is not useful for many people.
- PPN or TPN - This form of giving nutrients intravenously is called partial or total parenteral nutrition. This treatment is very expensive and invasive, and it's often reserved for more severe cases of wasting syndrome.

Because of the drawbacks of other strategies for treating wasting syndrome, testosterone-like therapies have become popular. Hospital and HMO administrators readily approve and encourage syndrome, testosterone-like therapies have become popular. Because of the drawbacks of other strategies for treating wasting syndrome.

Nandrolone (Deca Durabolin) Shortage: The Saga Continues

The following article regarding the supply problem with the anabolic agent, nandrolone, appeared in John James' AIDS Treatment News:

Nandrolone (Deca Durabolin) Disappears in U.S., Generic May Return in July: The last regularly available version of nandrolone, a drug widely used to treat AIDS wasting, was suddenly withdrawn in the U.S. in May, and has largely disappeared from pharmacies. A new generic version may be available now. We suggest some Web sites to check for information if your doctor or pharmacy has trouble getting this drug.

Nandrolone (Deca Durabolin) Disappears in U.S., Generic May Return in July

In late May or early June treatment activists learned that the only version of nandrolone currently available in the U.S. (brand name Deca Durabolin) was being discontinued. Soon we started hearing from patients whose pharmacies told them they could not find the drug. Nandrolone is approved for anemia due to renal insufficiency, but many doctors use it off label for AIDS wasting. Usually the patients, doctors, and pharmacists had heard nothing about the drug going away. It just disappeared from the supply chain.

Nandrolone remains available in other countries. But because it is a controlled substance due to abuse by body builders, patients cannot import these products for personal use. Until three years ago there were lower-cost generic nandrolone products available in the U.S. Then they also disappeared with little notice.

Other anabolics that had also been used off label in AIDS have been discontinued— and then later come back with an HIV label. (1,2,3) Usually the patients, doctors, and pharmacists had heard nothing about the drug going away. It just disappeared from the supply chain.

Activists have investigated and been told that a new generic nandrolone will be available after the July 4 weekend. But what we have heard so far is confusing and contradictory.

Recently we heard that a compounded version of nandrolone is available now.

Because the situation is unclear and rapidly changing, check Web sites of organizations that have been following this issue, including www.houstonbuyersclub.com, www.atac-usa.org, and www.medibolics.com for the latest information.

References

2. Strawford A, Barbieri T, Neece R, and others. Effects of nandrolone decanoate therapy in borderline hypogonadal men with HIV-

What's New in Outreach?

National Peer Treatment Education Program Update
The National Peer Treatment Education Program: Pathfinders launched its pilot training program in Newark, New Jersey on July 21. The HIV peer treatment educators who attended the initial training were from Missouri, Michigan, Ohio, Massachusetts, New York and New Jersey. Overall, the training was well received and an overwhelming success. At the end of the training, participants were asked to reflect and share their thoughts about the program in a group discussion. Some of the comments shared included “We are going to change the way we do education in my agency. It will become more than just giving out information—it will be active,” and “It makes me want to work harder and think outside of the box.”

The National Peer Treatment Education Program: Pathfinders is a collaborative program led by Howard University in partnership with Hyacinth AIDS Foundation, Project Inform and the Latino Commission on AIDS. The program is FREE and is composed of a two-week residential program coupled with mentorship for the participant and technical assistance support for the participant’s program post training. The training program topics covered include basic HIV pathogenesis and HIV care and treatment, network building, working within care teams, service planning, communication, computer/internet basics and more. The training utilizes an active; learner centered design with the program underpinned by Paulo Freire’s education philosophy. The Western Regional training will be held in San Francisco from August 18–30 and the Southern Regional training will be held in Washington D.C. area from September 15–27. Currently, NPTEP is fully enrolled; however, more information about upcoming trainings will be posted to the Project Inform website, www.projectinform.org.

What’s New in Public Policy?

ATAC Save ADAP Committee Announces Critical August/September Grassroots Advocacy Campaign
The Save ADAP Committee of the AIDS Treatment Advocates Coalition (ATAC) is organizing a grassroots campaign urging Congress to support a $162 million increase for the AIDS Drug Assistance Program (ADAP). ADAP provides access to treatment for low-income people living with HIV/AIDS who are either uninsured or lack adequate prescription drug coverage. The program is a lifeline for thousands of people across the country who otherwise wouldn't be able to afford HIV drugs.

Right now, many state ADAPs are in a financial crisis. Twelve states are reporting restrictions to treatment access, including waiting lists, while many other states are preparing to implement restrictions in the near future. There are over 600 people on the waiting list for treatment in North Carolina alone. Severe underfunding of ADAP constitutes a public health crisis in America, not only for people living with HIV/AIDS who rely on the program for life-extending therapies, but for all Americans invested in sound health policy. The ADAP crisis is not acceptable given Health and Human Services Secretary Tommy Thompson’s recent statement that “No administration in any nation has ever made fighting HIV/AIDS as high a priority as the United States under this administration”.

AIDS treatment policy experts have stated that an increase of $162 million from the federal government is needed to help ease the ADAP crisis and enable states to meet the demands of those who rely on the program.

The ATAC SaveADAP Committee is an ad-hoc group of activists who want to make a difference. We know that the best way to convince Congress to act on this issue is for people to communicate directly with their own elected representatives.

That’s where you come in. We encourage you to participate in this grassroots campaign by engaging in as many of the following activities as you can:

1: August Recess District Visits:
Congress will be on recess from July 29 – September 3. During this recess, most members of Congress will be in their home district offices. It is an excellent time to schedule a meeting with your Representative and Senators or their staff to discuss the need for adequate ADAP and other HIV/AIDS funding. So few people ever take the time to meet in person with their elected officials that these visits are one of the most effective ways to bring about positive change. They allow members of Congress to hear directly from those most affected by an issue, such as ADAP funding.

If you are interested in scheduling a district visit, but need some help, we have created a fact sheet with tips on getting started. For a copy of this fact sheet, contact Ryan Clary at 415-558-8669 x224 or rclary@projectinform.org.

2: “Call your District Office Week”: August 26–30
We are organizing a “call your district office week” from August 26–30. During this week, people around the country will be encouraged to call the local offices of their U.S. Representative and two U.S. Senators and ask them to support a $162 million increase for ADAP.
If enough people make these calls, it will send a clear message to Congress before they go back to D.C. to make final decisions on ADAP funding.

3: “Call D.C. Day”: September 4
We will welcome Congress back from their August recess with a national call-in day reminding them of our message: the urgent need for a $162 million increase for ADAP. Make sure you put this action in your calendar!

We are relying on you to be part of this important campaign. Without our united voices raised in action, Congress may well continue to underfund ADAP, putting thousands of lives at risk.

If you would like to make sure that you receive all of our upcoming Alerts, send an email to SAVEADAP@hotmail.com or call Ryan Clary at 415-558-8669 x224.

XIV International Conference on AIDS in Barcelona, Spain
Several Project Inform staff recently attended the XIV International Conference on AIDS in Barcelona, Spain. This bi-annual meeting, which attracts delegates from all over the world, is a key forum at which research scientists, healthcare providers, community activists, government representatives, members of the corporate sector and people living with HIV and AIDS gather to share information, develop strategies and network on issues of shared concern globally.

Project Inform staff are participating in several community reportbacks about the conference in the San Francisco Bay Area. These include:

August 14
Preservation Park, Niles Hall, 668 13th Street, Oakland, CA.
Collaboration with AMASSI and AAAPTI.

August 15
Alameda Co Publ Health Dept, 1000 Broadway @ 10th, 5th Floor, Oakland, CA. Women’s Reportback, in collaboration with WORLD and WIHS.

August 22
San Francisco AIDS Foundation, 995 Market Street @ 6th, 2nd floor, San Francisco, CA. Women’s Reportback, in collaboration with WORLD and WIHS.

Members of the public are invited to attend these free foras. For more information, please contact Paul Dalton at 415-558-8559 x212 or Shalini Eddens at 415-558-8669 x205. In addition, look for upcoming issues of PI Perspective and Wise Words for in-depth analysis of some of the key issues addressed at the conference.

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