PA

POSITIVELY AWARE

JULY/AUGUST 2010

WHEN SHOULD YOU START TREATMENT?

Debate continues over how soon to start treating HIV

THE POWER OF ADVOCACY

How testimony helped approval of a new drug

SISTERS ARE DOING IT FOR THEMSELVES

Black women talk about life, family, and living with HIV

THE HIV TREATMENT & HEALTH JOURNAL OF
TEST POSITIVE AWARE NETWORK

ABOUT PREZISTA

PREZISTA® (darunavir) is a prescription medicine. It is one treatment option in the class of HIV (human immunodeficiency virus) medicines known as protease inhibitors.

PREZISTA is always taken with and at the same time as ritonavir (Norvir®), in combination with other HIV medicines for the treatment of HIV infection in adults. PREZISTA should also be taken with food.

- The use of other medicines active against HIV in combination with PREZISTA/ritonavir (Norvir®) may increase your ability to fight HIV. Your healthcare professional will work with you to find the right combination of HIV medicines
- It is important that you remain under the care of your healthcare professional during treatment with PREZISTA

PREZISTA does not cure HIV infection or AIDS, and does not prevent passing HIV to others.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PREZISTA?

- **PREZISTA, together with Norvir®, has rarely been observed to cause liver problems which may be life-threatening. It was not always clear if PREZISTA caused these liver problems because some patients had other illnesses or were taking other medicines. Your healthcare professional should do blood tests prior to starting combination treatment including PREZISTA. If you have chronic hepatitis B or C infection, your healthcare professional should check your blood tests more often because you have an increased chance of developing liver problems**

  Talk to your healthcare professional about the signs and symptoms of liver problems. These may include yellowing of your skin or whites of your eyes, dark (tea-colored) urine, pale-colored stools (bowel movements), nausea, vomiting, loss of appetite, or pain, aching or sensitivity on your right side below your ribs

- **Skin rashes have been reported in patients taking PREZISTA. Rarely, PREZISTA has been reported to cause a severe or life-threatening rash. Contact your healthcare professional immediately if you develop a rash. Your healthcare professional will advise you whether your symptoms can be managed on therapy or whether PREZISTA should be stopped**

Can PREZISTA be taken with other medications?

- **Taking PREZISTA with certain medicines could cause serious and/or life-threatening side effects or may result in loss of its effectiveness. Do not take PREZISTA if you are taking the following medicines:** alfuzosin (Uroxatral®), dihydroergotamine (D.H.E.45®, Migranal®), ergonovine, ergotamine (Wigraine®, Ergostat®, Cafergot®, Ergomar®), methylergonovine, cisapride (Propulsid®), pimozide (Orap®), oral midazolam, triazolam (Halcion®), rifampin (Rifadin®, Rifater®, Rifamate®), sildenafil (Revatio®) when used to treat pulmonary arterial hypertension, indinavir (Crixivan®), lopinavir/ritonavir (Kaletra®), saquinavir (Invirase®), lovastatin (Mevacor®, Altoprev®, Advicor ®), pravastatin (Pravachol®), simvastatin (Zocor®, Simcor®, Vytorin®), salmeterol (Serevent®), or products containing St. John's wort
- Before taking PREZISTA, tell your healthcare professional if you are taking sildenafil (Viagra®), vardenafil (Levitra®), tadalafil (Cialis®, Adcirca®), atorvastatin (Lipitor®), atorvastatin/amlodipine (Caduet®), rosuvastatin (Crestor®), or colchicine (Colcrys®). **This is not a complete list of medicines. Be sure to tell your healthcare professional about all the medicines you are taking or plan to take, including prescription and nonprescription medicines, vitamins, and herbal supplements**

Belief { in myself in my doctor in my meds

ONCE-DAILY PREZISTA FOR ADULTS TAKING HIV MEDS FOR THE FIRST TIME

In a clinical study* of almost 2 years (96 weeks) in people who had never taken HIV meds before, ONCE-DAILY PREZISTA with low-dose ritonavir plus Truvada®...

- Helped 8 out of 10 people achieve undetectable viral load (less than 50 copies/mL)
- May help to increase T-cell count
- Was associated with low rates of diarrhea, stomach pain, nausea, and vomiting
  - Diarrhea (8%), stomach pain (5%), nausea (3%), and vomiting (2%) were reported as moderate to severe

PREZISTA must be taken with and at the same time as 100 mg of Norvir® (ritonavir), and with other HIV meds and with food.

Once-daily dosing of PREZISTA is not recommended for adults who have taken HIV meds in the past.

Please read Important Safety Information below and ask your doctor if once-daily PREZISTA is right for you.

Individual results may vary.

- Tell your healthcare professional if you are taking estrogen-based contraceptives (birth control). PREZISTA might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control, such as condoms

What should I tell my doctor before I take PREZISTA?

- Before taking PREZISTA, tell your healthcare professional if you have any medical conditions, including allergy to sulfa medicines, diabetes, liver problems (including hepatitis B or C), or hemophilia
- Tell your healthcare professional if you are pregnant or planning to become pregnant, or are breastfeeding
  - The effects of PREZISTA on pregnant women or their unborn babies are not known. You and your healthcare professional will need to decide if taking PREZISTA is right for you
  - Do not breastfeed if you are taking PREZISTA. You should not breastfeed if you have HIV because of the chance of passing HIV to your baby

What are the possible side effects of PREZISTA?

- High blood sugar, diabetes or worsening of diabetes, and increased bleeding in people with hemophilia have been reported in patients taking protease inhibitor medicines, including PREZISTA
- Changes in body fat have been seen in some patients taking HIV medicines, including PREZISTA. The cause and long-term health effects of these conditions are not known at this time
- As with other protease inhibitors, taking PREZISTA may strengthen the body's immune response, enabling it to begin to fight infections that have been hidden. Patients may experience signs and symptoms of inflammation that can include swelling, tenderness, or redness
- The most common side effects related to taking PREZISTA include diarrhea, nausea, rash, headache, stomach pain, and vomiting. Uncommon but severe side effects such as inflammation of the pancreas and increased blood fat levels have also been rarely reported. This is not a complete list of all possible side effects. If you experience these or other side effects, talk to your healthcare professional. Do not stop taking PREZISTA or any other medicines without first talking to your healthcare professional
- Please refer to the ritonavir (Norvir®) Product Information (PI and PPI) for additional information on precautionary measures

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

- **For adults taking HIV meds for the first time:** PREZISTA 800 mg (two 400-mg tablets) must be taken at the same time with 100 mg Norvir® once daily *every day.* PREZISTA must be taken with food

Please see Important Patient Information on the next page for more information, or visit www.PREZISTA.com.

If you or someone you know needs help paying for medicine, call 1-888-4PPA-NOW (1-888-477-2669) or go to www.pparx.org.

*343 adult patients (30% women) received combination therapy with PREZISTA/ritonavir. At the start of the study, the average T-cell count was 245, and 66% of patients had a viral load less than 100,000 copies/mL.

PREZISTA® (darunavir) tablets

ONCE DAILY

www.PREZISTA.com/patient

Distributed by: Tibotec Therapeutics/Division of Centocor Ortho Biotech Products, L.P. Titusville, NJ 08560

IMPORTANT PATIENT INFORMATION

PREZISTA® (pre-ZIS-ta) [(darunavir) (da-ROO-nuh-veer)] Tablets

ALERT: Find out about medicines that should NOT be taken with PREZISTA. Please also read the section "Who should not take PREZISTA?".

Please read this information before you start taking PREZISTA. Also, read the leaflet each time you renew your prescription, just in case anything has changed. Remember, this leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss your treatment with PREZISTA prior to the first time you take your medicine and at regular checkups. You should remain under a doctor's care when using PREZISTA and should not change or stop treatment without first talking with a doctor.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT PREZISTA?

PREZISTA, together with NORVIR® (ritonavir), has rarely been observed to cause liver problems which may be life-threatening. It was not always clear if PREZISTA caused these liver problems because some patients had other illnesses or were taking other medicines. Your healthcare professional should do blood tests prior to initiating combination treatment including PREZISTA. If you have chronic hepatitis B or C infection, your healthcare professional should check your blood tests more often because you have an increased chance of developing liver problems. Please also read the section "What are the possible side effects of PREZISTA?".

Rarely, PREZISTA has been reported to cause a severe or life-threatening rash. Contact your healthcare provider immediately if you develop a rash. Your healthcare provider will advise you whether your symptoms can be managed on therapy or whether PREZISTA should be stopped.

WHAT IS PREZISTA?

PREZISTA is an oral tablet used for the treatment of HIV (Human Immunodeficiency Virus) infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). PREZISTA is a type of anti-HIV medicine called a protease (PRO-tee-ase) inhibitor.

HOW DOES PREZISTA WORK?

PREZISTA blocks HIV protease, an enzyme which is needed for HIV to multiply. When used with other anti-HIV medicines, PREZISTA can help to reduce the amount of HIV in your blood (called "viral load") and increase your CD4 (T) cell count. HIV infection destroys CD4 (T) cells, which are important to the immune system. The immune system helps fight infection. Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system and, thus, reduce the risk of death or infections that can happen when your immune system is weak (opportunistic infections).

PREZISTA is always taken with and at the same time as ritonavir (NORVIR®), in combination with other anti-HIV medicines. PREZISTA should also be taken with food.

DOES PREZISTA CURE HIV OR AIDS?

PREZISTA does **not** cure HIV infection or AIDS. At present, there is no cure for HIV infection. People taking PREZISTA may still develop infections or other conditions associated with HIV infection. Because of this, it is very important for you to remain under the care of a doctor. Although PREZISTA is not a cure for HIV or AIDS, PREZISTA can help reduce your risks of getting illnesses associated with HIV infection (AIDS and opportunistic infection) and eventually dying from these conditions.

DOES PREZISTA REDUCE THE RISK OF PASSING HIV TO OTHERS?

PREZISTA does **not** reduce the risk of passing HIV to others through sexual contact, sharing needles, or being exposed to your blood. For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom or other barrier method to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood. Never re-use or share needles.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

WHAT SHOULD I TELL MY DOCTOR BEFORE I TAKE PREZISTA?

Tell your doctor about all of your medical conditions, including if you:

- are allergic to sulfa medicines.
- have diabetes. In general, anti-HIV medicines, such as PREZISTA, might increase sugar levels in the blood.
- have liver problems, including hepatitis B and/or C.
- have hemophilia. Anti-HIV medicines, such as PREZISTA, might increase the risk of bleeding.
- are pregnant or planning to become pregnant. The effects of PREZISTA on pregnant women or their unborn babies are not known. You and your doctor will need to decide if taking PREZISTA is right for you. If you take PREZISTA while you are pregnant, talk to your doctor about how you can be included in the Antiretroviral Pregnancy Registry.
- are breastfeeding. Do not breastfeed if you are taking PREZISTA. You should not breastfeed if you have HIV because of the chance of passing HIV to your baby. Talk with your doctor about the best way to feed your baby.

WHO SHOULD NOT TAKE PREZISTA?**

Together with your doctor, you need to decide whether taking PREZISTA is right for you.

Do not take PREZISTA if you:

- are allergic to darunavir or any of the other ingredients in PREZISTA
- are allergic to ritonavir (NORVIR®)
- take any of the following types of medicines because you could experience serious side effects:
  - alfuzosin (Uroxatral®)
  - dihydroergotamine (D.H.E. 45®, Migranal®), ergonovine, ergotamine (Cafergot®, Ergomar®), methylergonovine
  - cisapride
  - pimozide (Orap®)
  - oral midazolam, triazolam (Halcion®)
  - St. John's wort (*Hypericum perforatum*)
  - lovastatin (Mevacor®, Altoprev®, Advicor®), simvastatin (Zocor®, Simcor®, Vytorin®)
  - rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®)
  - sildenafil (Revatio®) when used to treat pulmonary arterial hypertension

CAN PREZISTA BE TAKEN WITH OTHER MEDICATIONS?**

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. PREZISTA and many other medicines can interact. Sometimes serious side effects will happen if PREZISTA is taken with certain other medicines (see "Who should not take PREZISTA?").

Tell your doctor if you are taking estrogen-based contraceptives (birth control). PREZISTA might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control such as a condom.

Tell your doctor if you take other anti-HIV medicines. PREZISTA can be combined with some other anti-HIV medicines while other combinations are not recommended.

Tell your doctor if you are taking any of the following medicines:

- bepridil, lidocaine, quinidine, amiodarone (Cordarone®), digoxin (Lanoxin®), flecainide (Tambocor®), propafenone (Rythmol®),
- warfarin (Coumadin®)
- carbamazepine (Tegretol®, Carbatrol®), phenobarbital, phenytoin (Dilantin®, Phenytek®)
- trazodone (Desyrel®), desipramine (Norpramin®)
- colchicine (Colcrys®)
- clarithromycin (Biaxin®)
- ketoconazole (Nizoral®), itraconazole (Sporanox®), voriconazole (Vfend®)
- rifabutin (Mycobutin®)
- metoprolol (Lopressor®, Toprol-XL®), timolol (Betimol®, Combigan®, Istalol®, Cosopt®, Timoptic®)
- midazolam administered by injection
- felodipine (Plendil®), nifedipine (Adalat®), nicardipine (Cardene®)
- dexamethasone, fluticasone (Advair Diskus®, Cutivate®, Flonase®, Flovent Diskus®)
- bosentan (Tracleer®)
- atorvastatin (Lipitor®), pravastatin (Pravachol®), rosuvastatin (Crestor®)
- cyclosporine (Sandimmune®, Neoral®), tacrolimus (Prograf®), sirolimus (Rapamune®)

- salmeterol (Serevent®)
- methadone, buprenorphine/naloxone
- risperidone (Risperdal®, Risperdal® Consta®,Risperdal® M-TAB®), thioridazine
- sildenafil (Viagra®), vardenafil (Levitra®), tadalafil (Cialis®)
- tadalafil (Adcirca®)
- paroxetine (Paxil®), sertraline (Zoloft®)

Tell your doctor if you are taking any medicines that you obtained without a prescription.

This is **not** a complete list of medicines that you should tell your doctor that you are taking. Know and keep track of all the medicines you take and have a list of them with you. Show this list to all of your doctors and pharmacists any time you get a new medicine. Both your doctor and your pharmacist can tell you if you can take these other medicines with PREZISTA. Do not start any new medicines while you are taking PREZISTA without first talking with your doctor or pharmacist. You can ask your doctor or pharmacist for a list of medicines that can interact with PREZISTA.

HOW SHOULD I TAKE PREZISTA?

Take PREZISTA tablets every day exactly as prescribed by your doctor. You must take ritonavir (NORVIR®) at the same time as PREZISTA.

- For adults who have never taken anti-HIV medicines, the usual dose is 800 mg (two 400 mg tablets) of PREZISTA, together with 100 mg (one 100 mg capsule) of ritonavir (NORVIR®), once daily *every day*.
- For adults who have taken anti-HIV medicines in the past, the usual dose is 600 mg (one 600 mg tablet or two 300 mg tablets) of PREZISTA, together with 100 mg (one 100 mg capsule) of ritonavir (NORVIR®), twice daily *every day*. Do not take PREZISTA once daily if you have taken anti-HIV medicines in the past.

PREZISTA and ritonavir (NORVIR®) should be taken together at the same time every day. If you have questions about when to take PREZISTA and ritonavir (NORVIR®), your doctor can help you decide which schedule works for you.

Take PREZISTA and ritonavir (NORVIR®) **with food**. Swallow the whole tablets with a drink such as water or milk. Do not chew the tablets.

Continue taking PREZISTA and ritonavir (NORVIR®) unless your doctor tells you to stop. Take the exact amount of PREZISTA and ritonavir (NORVIR®) that your doctor tells you to take, right from the very start. To help make sure you will benefit from PREZISTA and ritonavir (NORVIR®), you must not skip doses or interrupt therapy. If you don't take PREZISTA and ritonavir (NORVIR®) as prescribed, the beneficial effects of PREZISTA and ritonavir (NORVIR®) may be reduced or even lost.

Patients taking PREZISTA once daily

If you miss a dose of PREZISTA or ritonavir (NORVIR®) by more than 12 hours, wait and then take the next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time. If you miss a dose of PREZISTA or ritonavir (NORVIR®) by less than 12 hours, take your missed dose of PREZISTA and ritonavir (NORVIR®) immediately. Then take your next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time.

Patients taking PREZISTA twice daily

If you miss a dose of PREZISTA or ritonavir (NORVIR®) by more than 6 hours, wait and then take the next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time. If you miss a dose of PREZISTA or ritonavir (NORVIR®) by less than 6 hours, take your missed dose of PREZISTA and ritonavir (NORVIR®) immediately. Then take your next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time.

You should always take PREZISTA and ritonavir (NORVIR®) together with food.

If a dose of PREZISTA or ritonavir (NORVIR®) is skipped, do not double the next dose. Do not take more or less than your prescribed dose of PREZISTA or ritonavir (NORVIR®) at any one time.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF PREZISTA?

Like all prescription drugs, PREZISTA can cause side effects. The following is **not** a complete list of side effects reported with PREZISTA when taken either alone or with other anti-HIV medicines. Do not rely on this leaflet alone for information about side effects. Your doctor can discuss with you a more complete list of side effects.

PREZISTA, together with NORVIR® (ritonavir), has rarely been observed to cause liver problems which may be life-threatening. It was not always clear if PREZISTA caused these liver problems because some patients had other illnesses or were taking other medicines. Your healthcare professional should do blood tests prior to initiating combination treatment including PREZISTA. If you have chronic hepatitis B or C infection, your healthcare professional should check your blood tests more often because you have an increased chance of developing liver problems.

Talk to your healthcare professional about the signs and symptoms of liver problems. These may include yellowing of your skin or whites of your eyes, dark (tea colored) urine, pale colored stools (bowel movements), nausea, vomiting, loss of appetite, or pain, aching or sensitivity on your right side below your ribs.

Rash has been reported in 10.3% of patients receiving PREZISTA. In few patients, PREZISTA has been reported to cause a severe or life-threatening rash. Contact your healthcare provider immediately if you develop a rash. Your healthcare provider will advise you whether your symptoms can be managed on therapy or whether PREZISTA should be stopped.

Other relevant severe side effects reported at an uncommon or rare frequency were inflammation of the liver or pancreas, increased blood fat levels, diabetes, and changes in body fat.

Some side effects are typical for anti-HIV medicines in the same family as PREZISTA. These are:

- high blood sugar (hyperglycemia) and diabetes. This can happen in patients taking PREZISTA or other protease inhibitor medicines. Some patients have diabetes before starting treatment with PREZISTA which gets worse. Some patients get diabetes during treatment with PREZISTA. Some patients will need changes in their diabetes medicine. Some patients may need new diabetes medicine.
- increased bleeding in patients with hemophilia.
- changes in body fat. These changes can happen in patients taking anti-HIV medicines, including PREZISTA. The changes may include an increased amount of fat in the upper back and neck, breast, and around the back, chest, and stomach area. Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- immune reconstitution syndrome. In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment, including PREZISTA, is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.

The most common side effects include diarrhea, nausea, rash, headache, abdominal pain and vomiting.

Tell your doctor promptly about these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

This medication is prescribed for your particular condition. Do not use it for any other condition or give it to anybody else. Keep PREZISTA and all of your medicines out of the reach of children. If you suspect that more than the prescribed dose of this medicine has been taken, contact your local poison control center or emergency room immediately.

This is a brief summary of information about PREZISTA for adult patients with HIV. If you have any questions or concerns about either PREZISTA or HIV, talk to your doctor.

For additional information, you may also call Tibotec Therapeutics at 1-877-REACH-TT or 1-877-732-2488.

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TPAN empowers people living with HIV through peer-led programming, support services, information dissemination, and advocacy.

We also provide services to the broader community to increase HIV knowledge and sensitivity, and to reduce the risk of infection.

POSITIVELY AWARE

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TPAN recommends that all medical treatments or products be discussed thoroughly and frankly with a licensed and fully HIV-informed medical practitioner, preferably a personal physician.

A model, photographer, or author's HIV status should not be assumed based on their appearance in POSITIVELY AWARE, membership in TPAN, or contributions to this journal.

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DEPARTMENTS

COVER FEATURE

FEATURES

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THIS PAGE: BETTY PREVO PHOTOGRAPHED BY CHRIS KNIGHT

EDITOR'S NOTE
JEFF BERRY

What makes a good advocate?

I'VE HAD ADVOCACY ON MY MIND A LOT LATELY, AND WHAT IT REALLY means to be an advocate. Webster's defines an advocate as a person who pleads another's cause, or who speaks or writes in support of something. A lawyer is an advocate when he represents his client in a courtroom. A case manager will advocate for her client by helping them to access services, such as food, housing, and medical care. And in HIV, advocates work with government, academia, researchers, and pharmaceutical companies in the areas of prevention, access to care and treatment, drug development, and clinical trial design, just to name a few.

A good advocate does his or her homework, and follows through on what they say they're going to do. Many HIV advocates volunteer their time and are compensated very little for the amount of advocacy work that they do, especially when it's part of their job.

A effective advocate knows how to persevere and not give in, but also knows when it's an appropriate time to try to reach a compromise, always keeping in mind who they are there for and what they are trying to accomplish. They understand that they have a responsibility, first and foremost, to those they serve—in our case, people living with HIV who otherwise would not have a voice.

An honorable advocate is someone who is not afraid to stick their neck out or be the "lone wolf." They are sometimes ostracized at first for their unpopular stance, only to be thanked later for their insight, courage, and forward-thinking views. They are not afraid to ask the difficult or uncomfortable questions. They also build consensus, lead by example, and try to bring the best out in others by using words of encouragement, and by giving honest feedback and criticism.

But maybe I should back up and say what I think does not make a good advocate.

What does not constitute a good advocate is someone, or some entity, that takes the credit for the work done by others, for their own personal gain or for funding purposes. We see it happen time and time again.

Another thing that does not a good advocate make is constant dissent and disagreement. After a while, this type of advocate begins to sound like a broken record. It brings me back to the age-old axiom, if you can't be a part of the solution, then you're part of the problem. It's okay to disagree or to be critical, but come to the table with solutions. Have recommendations on what can be done to make things better. And then, offer to ensure that those recommendations become a reality. Mentor others to become better advocates. Start a working group to tackle the problem. And follow through!

Recently I attended an FDA Advisory Committee meeting regarding the approval of tesamorelin, a potential treatment for people with lipohypertrophy. I was one of three people that day who spoke during the Open Public Hearing, advocating for recommending approval of the drug. The entire experience taught me a lot about what it means to be an advocate, even though I've purportedly been doing advocacy work for years (see page 27 for more on this story).

What do you know? It is possible to teach an old advocate new tricks.

Which brings me to my final point about what I believe it means to be a good advocate—be humble, not proud. There are many people who have paved the way in this fight, and some of us who carry it on—too many of us—are battle-scarred, if we're not already dead or burned out. So you sometimes have to bear that in mind while doing this work. You need to have a thick skin, be able to take a lot of criticism, and just let it roll off of you at times—and not take anything too personally. When you focus on why you are here, who you are advocating for, and whose voices are not being heard, it helps to keep it all in perspective.

So you know what? I can't let it bother me when someone else takes the credit. Stuff happens. What's most important is that the work gets done, thanks to those whose motives are unselfish and who keep their eyes on the prize. And to me, that is what truly makes a good advocate.

Be good to yourself, and each other.

PHOTO: JOSHUA THORNE

Common sense

I always look forward to seeing what Jeff has written in each Positively Aware. This time, once again he hit the nail on the head—art and science—and some hard facts of common sense.

"Am I ready to take the medications, as prescribed, every day for the rest of my life?" When people ask me how I've lived so long, what I have to say is, "Good doctors who listen, taking my meds when and like I am supposed to, and bucking up when I don't like the side effects, *and*, yes, LUCK and a good attitude doesn't hurt either.

—Greg
Via the Internet

THANKS FOR THE DRUG GUIDE

I just wanted to write to thank you for putting together your annual Drug Guide.

As someone who was diagnosed in 2009, it has been an anchor in the storm for me.

The first issue of Positively Aware that I read was the January/February issue which, I have to say, blew my mind. I live in a small town and your article about access to care in rural areas really hit home. I travel almost 200 miles to see a doctor, but thanks to that article, I researched my area until I found the one HIV specialist within driving distance.

And then I got the Drug Guide. My doctor had put me on Atripla right away and though I've had no problem with it and my viral load has come down, reading about the other drugs, the side effects, and the drugs being developed really opened my eyes. Before, I guess I was just in shock and willing to do anything to stay healthy. After reading the Drug Guide, I'll do my "homework" before just agreeing to any particular treatment. It has also helped me in talking to my doctor, who told me he always has a copy on hand and the chart picturing the drugs hangs in his office.

You guys do a great job and I will look forward to reading every issue of Positively Aware.

—Marlen P.
Lacey, WA

A CAPTIVE AUDIENCE

Greetings from a California state prison. I am truly blessed to receive a subscription to your invaluable magazine.

Not only have I been HIV-positive since 2001, a prisoner, but I am also a male-to-female transgender person. Your magazine is surely a God-send.

I was wondering if you could do an article on hormone treatment and HIV and also HIV meds. I know there are many who could use this information.

Thank you for all your insights, hints, and articles—I truly appreciate this much-needed resource.

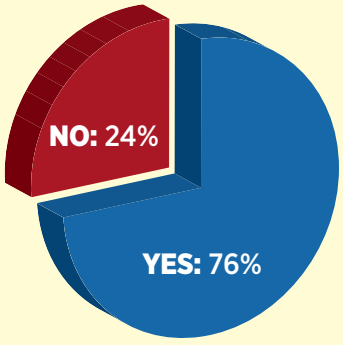
We don't have a death sentence; we just share our bodies with a virus. I always say, "I don't live with HIV—it has to live with me!"

—Nathan

Positively Aware will treat all communications (letters, faxes, e-mail, etc.) as letters to the editor unless otherwise instructed. We reserve the right to edit for length, style, or clarity. Please advise if we can use your name and city. Write to: **Positively Aware**, 5537 N. Broadway St., Chicago, IL 60640
E-mail: **readersforum@tpan.com**

POSITIVELYAWARE.COM

LAST ISSUE'S POLL QUESTION:
Have you ever been treated for depression?



COMMENTS:

"I'm a type 2 diabetic and poz for over two years. I've long since absolved myself of any shame in seeking professional help with the depression that's part of living with these two chronic diseases."

"As a PWA of 18+ yrs, I have sought treatment for depression several times. I think it's crucial to a larger treatment scheme as one's overall health can suffer from untreated depression."

THIS ISSUE'S POLL QUESTION:
When deciding whether or not to go on HIV meds, what concerned you more—the effects of untreated HIV, or the long-term side effects of the drugs?

CAST YOUR VOTE ON POSITIVELYAWARE.COM

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Important Safety Information and Indication

INDICATION

ATRIPLA® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate [DF] 300 mg) is a prescription medication used alone as a complete regimen or with other medicines to treat HIV-1 infection in adults.

ATRIPLA does not cure HIV-1 and has not been shown to prevent passing HIV-1 to others.

Do not stop taking ATRIPLA unless directed by your healthcare provider. See your healthcare provider regularly.

IMPORTANT SAFETY INFORMATION

Contact your healthcare provider right away if you get the following side effects or conditions associated with ATRIPLA:

- **Nausea, vomiting, unusual muscle pain, and/or weakness. These may be signs of a buildup of acid in the blood (lactic acidosis), which is a serious medical condition.**
- **Light-colored stools, dark-colored urine, and/or if your skin or the whites of your eyes turn yellow. These may be signs of serious liver problems.**
- **If you have HIV-1 and hepatitis B virus (HBV), your liver disease may suddenly get worse if you stop taking ATRIPLA.**

Do not take ATRIPLA if you are taking the following medicines because serious and life-threatening side effects may occur when taken together: Vascor® (bepridil), Propulsid® (cisapride), Versed® (midazolam), Orap® (pimozide), Halcion® (triazolam), or ergot medications (for example, Wigraine® and Cafergot®).

In addition, ATRIPLA should not be taken with: Combivir® (lamivudine/zidovudine), EMTRIVA® (emtricitabine), Epivir® or Epivir-HBV® (lamivudine), Epzicom® (abacavir sulfate/lamivudine), SUSTIVA® (efavirenz), Trizivir® (abacavir sulfate/lamivudine/zidovudine), TRUVADA® (emtricitabine/tenofovir DF), or VIREAD® (tenofovir DF), because they contain the same or similar active ingredients as ATRIPLA. ATRIPLA should not be used with HEPSERA® (adefovir dipivoxil). Vfend® (voriconazole) or REYATAZ® (atazanavir sulfate), with or without Norvir® (ritonavir), should not be taken with ATRIPLA since they may lose their effect and may also increase the chance of having side effects from ATRIPLA. Fortovase® or Invirase® (saquinavir) should not be used as the only protease inhibitor in combination with ATRIPLA.

Taking ATRIPLA with St. John's wort or products containing St. John's wort is not recommended as it may cause decreased levels of ATRIPLA, increased viral load, and possible resistance to ATRIPLA or cross-resistance to other anti-HIV drugs.

This list of medicines is not complete. Discuss with your healthcare provider all prescription and nonprescription medicines, vitamins, or herbal supplements you are taking or plan to take.

Tell your healthcare provider if you:

- **Are pregnant: Women should not become pregnant while taking ATRIPLA and for 12 weeks after stopping ATRIPLA.** Serious birth defects have been seen in children of women treated during pregnancy with one of the medicines in ATRIPLA. Women must use a reliable form of barrier contraception, such as a condom or diaphragm, even if they also use other methods of birth control while on ATRIPLA and for 12 weeks after stopping ATRIPLA.
- **Are breastfeeding: Women with HIV should not breastfeed** because they can pass HIV through their milk to the baby. Also, ATRIPLA may pass through breast milk and cause serious harm to the baby.
- **Have liver problems, including hepatitis B or C virus infection.**
- **Have ever had seizures:** Seizures have occurred in patients taking a component of ATRIPLA, usually in those with a history of seizures. If you have ever had seizures, or take medicine for seizures, your healthcare provider may want to switch you to another medicine or monitor you.
- **Have ever had mental illness or use drugs or alcohol.**

Contact your healthcare provider right away if you experience any of the following serious or common side effects:

Serious side effects associated with ATRIPLA:

- **Severe depression, strange thoughts, or angry behavior** have been reported by a small number of patients. Some patients have had thoughts of suicide and a few have actually committed suicide. These problems may occur more often in patients who have had mental illness.
- **Kidney problems** (including decline or failure of kidney function). If you have had kidney problems, or take other medicines that may cause kidney problems, your healthcare provider should do regular blood tests. Symptoms that may be related to kidney problems include a high volume of urine, thirst, muscle pain, and muscle weakness.
- **Bone changes.** Lab tests show changes in the bones of patients treated with tenofovir DF, a component of ATRIPLA. Some HIV patients treated with tenofovir DF developed thinning of the bones (osteopenia) which could lead to fractures. Also, bone pain and softening of the bone (which may lead to fractures) may occur as a consequence of kidney problems. If you have had bone problems in the past, your healthcare provider may want to check your bones.

Common side effects:

- **Dizziness, headache, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams.** These side effects tend to go away after taking ATRIPLA for a few weeks. These symptoms may be more severe with the use of alcohol and/or mood-altering (street) drugs. If you are dizzy, have trouble concentrating, and/or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.
- **Rash** is a common side effect that usually goes away without any change in treatment, but may be serious in a small number of patients.
- **Other common side effects include:** tiredness, upset stomach, vomiting, gas, and diarrhea.

Other possible side effects:

- Changes in body fat have been seen in some people taking anti-HIV-1 medicines. The cause and long-term health effects are not known.
- Skin discoloration (small spots or freckles) may also happen.
- If you notice any symptoms of infection, contact your healthcare provider right away.
- Additional side effects are inflammation of the pancreas, allergic reaction (including swelling of the face, lips, tongue, or throat), shortness of breath, pain, stomach pain, weakness and indigestion.

You should take ATRIPLA once daily on an empty stomach. Taking ATRIPLA at bedtime may make some side effects less bothersome.

ATRIPLA is one of several treatment options your doctor may consider.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Patient Information on the following pages.

Patient model.
Individual results may vary.

If you or someone you know needs help paying for medicine, call 1-888-4PPA-NOW (1-888-477-2669). Or go to www.pparx.org

Partnership for Prescription Assistance

Bristol-Myers Squibb GILEAD

697US09AB07011/TR3982 01/10

"My entire HIV regimen in one pill daily. For me, that's great."

Phillip
on ATRIPLA for 2 years

ATRIPLA is the #1 prescribed HIV regimen.*

- Only ATRIPLA combines 3 HIV medications in 1 pill daily.
- Proven to lower viral load to undetectable† and help raise T-cell (CD4+) count to help control HIV through 3 years of a clinical study.
- **ATRIPLA does not cure HIV-1 and has not been shown to prevent passing HIV-1 to others.**
- **Selected Important Safety Information:** Some people who have taken medicine like ATRIPLA have developed the following: **a serious condition of acid buildup in the blood (lactic acidosis),** and **serious liver problems (hepatotoxicity). For patients with both HIV-1 and hepatitis B virus (HBV), hepatitis may worsen if ATRIPLA is discontinued.**

Talk to your doctor to see if ATRIPLA is right for you.
Your doctor may prescribe ATRIPLA alone or with other HIV medications.

ATRIPLA®
(efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) Tablets

Please see Important Safety Information, including bolded information, on adjacent page.

*Synovate Healthcare Data; US HIV Monitor, Q2 2009. †Defined as a viral load of less than 400 copies/mL.

To learn more, visit
www.ATRIPLA.com

Patient Information
ATRIPLA® (uh TRIP luh) Tablets

ALERT: Find out about medicines that should NOT be taken with ATRIPLA.

Please also read the section **"MEDICINES YOU SHOULD NOT TAKE WITH ATRIPLA."**

Generic name: efavirenz, emtricitabine and tenofovir disoproxil fumarate (eh FAH vih renz, em tri SIT uh bean and te NOE' fo veer dye soe PROX il FYOU mar ate)

Read the Patient Information that comes with ATRIPLA (efavirenz/emtricitabine/tenofovir disoproxil fumarate) before you start taking it and each time you get a refill since there may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. You should stay under a healthcare provider's care when taking ATRIPLA. **Do not change or stop your medicine without first talking with your healthcare provider.** Talk to your healthcare provider or pharmacist if you have any questions about ATRIPLA.

What is the most important information I should know about ATRIPLA?

- **Some people who have taken medicine like ATRIPLA (which contains nucleoside analogs) have developed a serious condition called lactic acidosis** (buildup of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your healthcare provider right away if you get the following signs or symptoms of lactic acidosis:**
  - You feel very weak or tired.
  - You have unusual (not normal) muscle pain.
  - You have trouble breathing.
  - You have stomach pain with nausea and vomiting.
  - You feel cold, especially in your arms and legs.
  - You feel dizzy or lightheaded.
  - You have a fast or irregular heartbeat.
- **Some people who have taken medicines like ATRIPLA have developed serious liver problems called hepatotoxicity,** with liver enlargement (hepatomegaly) and fat in the liver (steatosis). **Call your healthcare provider right away if you get the following signs or symptoms of liver problems:**
  - Your skin or the white part of your eyes turns yellow (jaundice).
  - Your urine turns dark.
  - Your bowel movements (stools) turn light in color.
  - You don't feel like eating food for several days or longer.
  - You feel sick to your stomach (nausea).
  - You have lower stomach area (abdominal) pain.
- **You may be more likely to get lactic acidosis or liver problems** if you are female, very overweight (obese), or have been taking nucleoside analog-containing medicines, like ATRIPLA, for a long time.
- **If you also have hepatitis B virus (HBV) infection and you stop taking ATRIPLA, you may get a "flare-up" of your hepatitis. A "flare-up" is when the disease suddenly returns in a worse way than before.** Patients with HBV who stop taking ATRIPLA need close medical follow-up for several months, including medical exams and blood tests to check for hepatitis that could be getting worse. ATRIPLA is not approved for the treatment of HBV, so you must discuss your HBV therapy with your healthcare provider.

What is ATRIPLA?

ATRIPLA contains 3 medicines, SUSTIVA® (efavirenz), EMTRIVA® (emtricitabine) and VIREAD® (tenofovir disoproxil fumarate also called tenofovir DF) combined in one pill. EMTRIVA and VIREAD are HIV-1 (human immunodeficiency virus) nucleoside analog reverse transcriptase inhibitors (NRTIs) and SUSTIVA is an HIV-1 non-nucleoside analog reverse transcriptase inhibitor (NNRTI). VIREAD and EMTRIVA are the components of TRUVADA®. ATRIPLA can be used alone as a complete regimen, or in combination with other anti-HIV-1 medicines to treat people with HIV-1 infection. ATRIPLA is for adults age 18 and over. ATRIPLA has not been studied in children under age 18 or adults over age 65.

HIV infection destroys $CD4^+$ T cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops.

ATRIPLA helps block HIV-1 reverse transcriptase, a viral chemical in your body (enzyme) that is needed for HIV-1 to multiply. ATRIPLA lowers the amount of HIV-1 in the blood (viral load). ATRIPLA may also help to increase the number of T cells ($CD4^+$ cells), allowing your immune system to improve. Lowering the amount of HIV-1 in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

Does ATRIPLA cure HIV-1 or AIDS?

ATRIPLA does not cure HIV-1 infection or AIDS. The long-term effects of ATRIPLA are not known at this time. People taking ATRIPLA may still get opportunistic infections or other conditions that happen with HIV-1 infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium complex* (MAC) infection. **It is very important that you see your healthcare provider regularly while taking ATRIPLA.**

Does ATRIPLA reduce the risk of passing HIV-1 to others?

ATRIPLA has not been shown to lower your chance of passing HIV-1 to other people through sexual contact, sharing needles, or being exposed to your blood.

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
- **Do not have any kind of sex without protection.** Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions, or blood.

Who should not take ATRIPLA?

Together with your healthcare provider, you need to decide whether ATRIPLA is right for you. Do not take ATRIPLA if you are allergic to ATRIPLA or any of its ingredients. The active ingredients of ATRIPLA are efavirenz, emtricitabine, and tenofovir DF. See the end of this leaflet for a complete list of ingredients.

What should I tell my healthcare provider before taking ATRIPLA?

Tell your healthcare provider if you:

- **Are pregnant or planning to become pregnant** (see "What should I avoid while taking ATRIPLA?").
- **Are breast-feeding** (see "What should I avoid while taking ATRIPLA?").
- **Have kidney problems or are undergoing kidney dialysis treatment.**
- **Have bone problems.**
- **Have liver problems, including hepatitis B virus infection.** Your healthcare provider may want to do tests to check your liver while you take ATRIPLA.
- **Have ever had mental illness or are using drugs or alcohol.**
- **Have ever had seizures or are taking medicine for seizures.**

What important information should I know about taking other medicines with ATRIPLA?

ATRIPLA may change the effect of other medicines, including the ones for HIV-1, and may cause serious side effects. Your healthcare provider may change your other medicines or change their doses. Other medicines, including herbal products, may affect ATRIPLA. For this reason, **it is very important to** let all your healthcare providers and pharmacists know what medications, herbal supplements, or vitamins you are taking.

MEDICINES YOU SHOULD NOT TAKE WITH ATRIPLA

- The following medicines may cause serious and life-threatening side effects when taken with ATRIPLA. You should not take any of these medicines while taking ATRIPLA: Vascor (bepridil), Propulsid (cisapride), Versed (midazolam), Orap (pimozide), Halcion (triazolam), ergot medications (for example, Wigraine and Cafergot).
- ATRIPLA also should not be used with Combivir (lamivudine/zidovudine), EMTRIVA, Epivir, Epivir-HBV (lamivudine), Epzicom (abacavir sulfate/lamivudine), Trizivir (abacavir sulfate/lamivudine/zidovudine), SUSTIVA, TRUVADA, or VIREAD.
- Vfend (voriconazole) should not be taken with ATRIPLA since it may lose its effect or may increase the chance of having side effects from ATRIPLA.
- **Do not take St. John's wort *(Hypericum perforatum)*, or products containing St. John's wort with ATRIPLA.** St. John's wort is an herbal product sold as a dietary supplement. Talk with your healthcare provider if you are taking or are planning to take St. John's wort. Taking St. John's wort may decrease ATRIPLA levels and lead to increased viral load and possible resistance to ATRIPLA or cross-resistance to other anti-HIV-1 drugs.
- ATRIPLA should not be used with HEPSERA® (adefovir dipivoxil).

It is also important to tell your healthcare provider if you are taking any of the following:

- Fortovase, Invirase (saquinavir), Biaxin (clarithromycin); or Sporanox (itraconazole); **these medicines may need to be replaced with another medicine when taken with ATRIPLA.**
- Calcium channel blockers such as Cardizem or Tiazac (diltiazem), Covera HS or Isoptin (verapamil) and others; Crixivan (indinavir); the immunosuppressant medicines cyclosporine (Gengraf, Neoral, Sandimmune, and others), Prograf (tacrolimus), or Rapamune (sirolimus); Methadone; Mycobutin (rifabutin); Rifampin; cholesterol-lowering medicines such as Lipitor (atorvastatin), Pravachol (pravastatin sodium), and Zocor (simvastatin); or Zoloft (sertraline); **these medicines may need to have their dose changed when taken with ATRIPLA.**
- Videx, Videx EC (didanosine); tenofovir DF (a component of ATRIPLA) may increase the amount of didanosine in your blood, which could result in more side effects. **You may need to be monitored more carefully** if you are taking ATRIPLA and didanosine together. Also, the dose of didanosine may need to be changed.
- Reyataz (atazanavir sulfate) or Kaletra (lopinavir/ritonavir); these medicines may increase the amount of tenofovir DF (a component of ATRIPLA) in your blood, which could result in more side effects. Reyataz is not recommended with ATRIPLA. **You may need to be monitored more carefully** if you are taking ATRIPLA and Kaletra together. Also, the dose of Kaletra may need to be changed.
- Medicine for seizures [for example, Dilantin (phenytoin), Tegretol (carbamazepine), or phenobarbital]; your healthcare provider may want to switch you to another medicine or check drug levels in your blood from time to time.

These are not all the medicines that may cause problems if you take ATRIPLA. Be sure to tell your healthcare provider about all medicines that you take.

Keep a complete list of all the prescription and nonprescription medicines as well as any herbal remedies that you are taking, how much you take, and how often you take them. Make a new list when medicines or herbal remedies are added or stopped, or if the dose changes. Give copies of this list to all of your healthcare providers and pharmacists **every** time you visit your healthcare provider or fill a prescription. This will give your healthcare provider a complete picture of the medicines you use. Then he or she can decide the best approach for your situation.

How should I take ATRIPLA?

- Take the exact amount of ATRIPLA your healthcare provider prescribes. Never change the dose on your own. Do not stop this medicine unless your healthcare provider tells you to stop.
- You should take ATRIPLA on an empty stomach.
- Swallow ATRIPLA with water.
- Taking ATRIPLA at bedtime may make some side effects less bothersome.
- Do not miss a dose of ATRIPLA. If you forget to take ATRIPLA, take the missed dose right away, unless it is almost time for your next dose. Do not double the next dose. Carry on with your regular dosing schedule. If you need help in planning the best times to take your medicine, ask your healthcare provider or pharmacist.
- If you believe you took more than the prescribed amount of ATRIPLA, contact your local poison control center or emergency room right away.
- Tell your healthcare provider if you start any new medicine or change how you take old ones. Your doses may need adjustment.
- When your ATRIPLA supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to ATRIPLA and become harder to treat.
- Your healthcare provider may want to do blood tests to check for certain side effects while you take ATRIPLA.

What should I avoid while taking ATRIPLA?

- **Women should not become pregnant while taking ATRIPLA and for 12 weeks after stopping it.** Serious birth defects have been seen in the babies of animals and women treated with efavirenz (a component of ATRIPLA) during pregnancy. It is not known whether efavirenz caused these defects. **Tell your healthcare provider right away if you are pregnant.** Also talk with your healthcare provider if you want to become pregnant.
- Women should not rely only on hormone-based birth control, such as pills, injections, or implants, because ATRIPLA may make these contraceptives ineffective. Women must use a reliable form of barrier contraception, such as a condom or diaphragm, even if they also use other methods of birth control. Efavirenz, a component of ATRIPLA, may remain in your blood for a time after therapy is stopped. Therefore, you should continue to use contraceptive measures for 12 weeks after you stop taking ATRIPLA.
- **Do not breast-feed if you are taking ATRIPLA.** The Centers for Disease Control and Prevention recommend that mothers with HIV not breast-feed because they can pass the HIV through their milk to the baby. Also, ATRIPLA may pass through breast milk and cause serious harm to the baby. Talk with your healthcare provider if you are breast-feeding. You should stop breast-feeding or may need to use a different medicine.
- Taking ATRIPLA with alcohol or other medicines causing similar side effects as ATRIPLA, such as drowsiness, may increase those side effects.
- Do not take any other medicines, including prescription and nonprescription medicines and herbal products, without checking with your healthcare provider.
- **Avoid doing things that can spread HIV-1 infection** since ATRIPLA does not stop you from passing the HIV-1 infection to others.

What are the possible side effects of ATRIPLA?

ATRIPLA may cause the following serious side effects:

- **Lactic acidosis** (buildup of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your healthcare provider right away if you get signs of lactic acidosis.** (See "What is the most important information I should know about ATRIPLA?")
- **Serious liver problems (hepatotoxicity),** with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your healthcare provider right away if you get any signs of liver problems. (See "What is the most important information I should know about ATRIPLA?")
- **"Flare-ups" of hepatitis B virus (HBV) infection,** in which the disease suddenly returns in a worse way than before, can occur if you have HBV and you stop taking ATRIPLA. Your healthcare provider will monitor your condition for several months after stopping ATRIPLA if you have both HIV-1 and HBV infection and may recommend treatment for your HBV. ATRIPLA is not approved for the treatment of hepatitis B virus infection. If you have advanced liver disease and stop treatment with ATRIPLA, the "flare-up" of hepatitis B may cause your liver function to decline.
- **Serious psychiatric problems.** A small number of patients may experience severe depression, strange thoughts, or angry behavior while taking ATRIPLA. Some patients have thoughts of suicide and a few have actually committed suicide. These problems may occur more often in patients who have had mental illness. Contact your healthcare provider right away if you think you are having these psychiatric symptoms, so your healthcare provider can decide if you should continue to take ATRIPLA.
- **Kidney problems** (including decline or failure of kidney function). If you have had kidney problems in the past or take other medicines that can cause kidney problems, your healthcare provider should do regular blood tests to check your kidneys. Symptoms that may be related to kidney problems include a high volume of urine, thirst, muscle pain, and muscle weakness.
- **Changes in bone mineral density (thinning bones).** Laboratory tests show changes in the bones of patients treated with tenofovir DF, a component of ATRIPLA. Some HIV patients treated with tenofovir DF developed thinning of the bones (osteopenia) which could lead to fractures. If you have had bone problems in the past, your healthcare provider may need to do tests to check your bone mineral density or may prescribe medicines to help your bone mineral density. Additionally, bone pain and softening of the bone (which may contribute to fractures) may occur as a consequence of kidney problems.

ATRIPLA® (efavirenz/emtricitabine/tenofovir disoproxil fumarate)

Common side effects:

Patients may have dizziness, headache, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams during treatment with ATRIPLA. These side effects may be reduced if you take ATRIPLA at bedtime on an empty stomach. They also tend to go away after you have taken the medicine for a few weeks. If you have these common side effects, such as dizziness, it does not mean that you will also have serious psychiatric problems, such as severe depression, strange thoughts, or angry behavior. Tell your healthcare provider right away if any of these side effects continue or if they bother you. It is possible that these symptoms may be more severe if ATRIPLA is used with alcohol or mood altering (street) drugs.

If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.

Rash may be common. Rashes usually go away without any change in treatment. In a small number of patients, rash may be serious. If you develop a rash, call your healthcare provider right away.

Other common side effects include tiredness, upset stomach, vomiting, gas, and diarrhea.

Other possible side effects with ATRIPLA:

- Changes in body fat. Changes in body fat develop in some patients taking anti-HIV-1 medicine. These changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these fat changes are not known.
- Skin discoloration (small spots or freckles) may also happen with ATRIPLA.
- In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor immediately.
- Additional side effects are inflammation of the pancreas, allergic reaction (including swelling of the face, lips, tongue, or throat), shortness of breath, pain, stomach pain, weakness and indigestion.

Tell your healthcare provider or pharmacist if you notice any side effects while taking ATRIPLA.

Contact your healthcare provider before stopping ATRIPLA because of side effects or for any other reason.

This is not a complete list of side effects possible with ATRIPLA. Ask your healthcare provider or pharmacist for a more complete list of side effects of ATRIPLA and all the medicines you will take.

How do I store ATRIPLA?

- **Keep ATRIPLA and all other medicines out of reach of children.**
- Store ATRIPLA at room temperature 77 °F (25 °C).
- Keep ATRIPLA in its original container and keep the container tightly closed.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away make sure that children will not find them.

General information about ATRIPLA:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use ATRIPLA for a condition for which it was not prescribed. Do not give ATRIPLA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about ATRIPLA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ATRIPLA that is written for health professionals.

Do not use ATRIPLA if the seal over bottle opening is broken or missing.

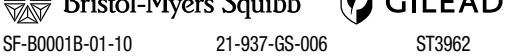
What are the ingredients of ATRIPLA?

Active Ingredients: efavirenz, emtricitabine, and tenofovir disoproxil fumarate

Inactive Ingredients: croscarmellose sodium, hydroxypropyl cellulose, microcrystalline cellulose, magnesium stearate, sodium lauryl sulfate. The film coating contains black iron oxide, polyethylene glycol, polyvinyl alcohol, red iron oxide, talc, and titanium dioxide.

℞ ONLY

January 2010



SF-B0001B-01-10 21-937-GS-006 ST3962 January 2010

BRIEFLY

REPORTED BY ENID VÁZQUEZ

Truvada, TMC278 combo dose

Good news—the fixed dose combination of Truvada and the still-in-the-works drug TMC278 **met primary efficacy points in clinical studies** of people taking HIV medication for the first time (treatment-naïve). The combination was found to be non-inferior to Sustiva/Truvada based on the proportion of people achieving less than 50 copies viral load at 48 weeks.

Gilead Sciences, the maker of Truvada, also recently announced a bioequivalent formula of Truvada and TMC278 has been achieved; that is, a formulation that achieves the same blood levels of medicine when the medications are taken together as when they are taken separately. TMC278 (rilpivirine hydrochloride) is being developed by Tibotec, and is a non-nucleoside reverse transcriptase inhibitor, like Sustiva. If it succeeds, the new fixed dose combination will become the second HIV drug on the market to comprise a complete regimen in one tablet taken once daily. (The first was the ultra-popular Atripla, which combines Truvada with Sustiva.)

National AIDS Fund announces grants

On May 13, the National AIDS Fund (NAF) announced the awarding of **major grants that will enable more than 35 community-based organizations** to help improve access to care for HIV-positive people in Chicago, New York, and Oakland/San Francisco, and the states of North Carolina and Louisiana. According to the press release, "The grant awards provide an opportunity for geographically and culturally diverse organizations within a region to combine their expertise in the development of community-driven solutions to help enable greater access to HIV/AIDS care and treatment."

The community grants were made possible through a separate grant from pharmaceutical company Bristol-Myers Squibb (BMS) to the NAF. The collaboration between BMS and the NAF is one of the key components of Positive Charge, a BMS initiative that aims to enable people living with HIV/AIDS to access care and treatment; contribute to the scientific agenda; and demonstrate advocacy leadership. —Sue Saltmarsh

Senate acts to ease states' ADAP crisis

In a press release issued by the Community Access National Network (CANN) on May 26, CANN commended North Carolina senator Richard Burr and Senator Tom Coburn of Oklahoma "for their **leadership in solving the ongoing AIDS Drug Assistance Program (ADAP) crisis**. The ACCESS ADAP Act, introduced in the Senate, provides $126 million to ADAP for the remainder of fiscal year 2010 to address the immediate need of individuals on waiting lists, to prevent these lists from expanding to more states, and to recover every patient who has been taken off their comprehensive drug regimen."

According to the release, the money for ADAP is to be allocated from funds that are to be used for improving and preserving health care, as well as promoting prevention, and wellness.

"At a time when waiting lists are growing with no end in sight and these patients no longer have access to their life-saving drugs through ADAP, there couldn't be a more appropriate funding stream to deal with the preservation of healthcare and the promotion of these individuals' wellness," commented William Arnold, executive director of CANN. "Keeping folks alive is stimulus." —Sue Saltmarsh

Tesmorelin wins unanimous FDA panel approval

On May 27, Theratechnologies announced that the U.S. Food and Drug Administration's (FDA) **Endocrinologic and Metabolic Drugs Advisory Committee recommended by a 16 to 0 vote** that tesamorelin, a growth hormone releasing factor, should be granted marketing approval by the FDA based on a favorable benefit-risk profile, for the treatment of excess abdominal fat in HIV-positive patients with lipohypertrophy (excess fat surrounding organs in the abdominal area), a condition that affects up to 30% of people living with HIV.

Although advisory committees provide their recommendations to the Agency, the final decisions on marketing approvals are made by the FDA. The FDA has indicated that the target date for the FDA to complete its review of the tesamorelin New Drug Application, will be July 27, 2010.

In 2008, Theratechnologies entered into a collaboration and licensing agreement with EMD Serono, Inc., an affiliate of Merck KGaA in Darmstadt, Germany, for the exclusive commercialization rights to tesamorelin in the United States.

Mr. Yves Rosconi, President and Chief Executive Officer of Theratechnologies said, "The Advisory Committee recommendation is another important step forward for the Company. It is especially significant for those patients who suffer from this serious metabolic complication, where today no treatment option exists."

Positively Aware editor Jeff Berry was one of three public speakers testifying to the committee on the importance this drug could play in the lives of people living with HIV. For a first-hand account of the hearing which led to the panel's vote, see "The Power of Advocacy," on page 27. —Sue Saltmarsh

PHOTO: JOSHUA THORNE

WEST SIDE STORIES

Stella Rivers-Goolsby (left) and Betty Prevo overcame issues in their lives to help other women.

PHOTO: CHRIS KNIGHT

Black women discuss life, family, and HIV

BY ENID VÁZQUEZ

In the Clinical Sciences Building at the University of Illinois at Chicago, the Project WISH clinic, run by Dr. Richard Novak, provides services to women from Chicago neighborhoods with the highest HIV risks, and searches for a vaccine against the virus. Since the nearby West Side communities have a high rate of HIV infection, the clinic is strategically located.

But it's out in the streets where Project WISH does much of its work. There, outreach workers Stella Rivers-Goolsby and Betty Prevo, themselves former sex workers and intravenous drug users, talk to neighborhood women (and now men, for the newest study) about lending their bodies to science.

As a member of the Community Advisory Board (CAB) for the STEP vaccine study, I was able to sit in on a meeting of the Participant CAB. These were young women who overcame community pressure to join the search for an HIV vaccine by participating in the study.

In the first gathering of the PCAB, (see the November/December 2009 issue), I heard some disturbing things about domestic violence, both physical and emotional, that I thought must influence the rate of HIV infection and I wanted to learn more.

Another PCAB meeting recently took place, again at Edna's soul food restaurant, a community institution located off the corner of Kedzie and Madison, straight west from downtown Chicago, and we discussed some of the problems facing the community that affect the spread, treatment, and prevention of HIV. —Enid Vázquez

Project WISH administrator Parrie Graham: There's a perception that people are willing to do things that put them at risk but not willing to talk about it. I'd like to know how that happens.

Shakeela: I think it's a low self-esteem issue. Some people just don't care. If you know that this can give you HIV and you do it anyway, then there's something wrong with your inner self. It could have come from things that your mother or father told you, or even your friends.

Patrice: Sometimes it comes from [misplaced] trust. I put my trust in you and the HIV thing goes out the window. Sometimes a guy physically beats you down and gets mind control. The guy says only trust him and nobody else, not even the doctor. Sometimes people don't go out [and are forced to stay at home, isolated]. Sometimes people make you do things you don't want to do.

Parrie: How?

Patrice: Mind control. "He smacks me, he loves me." For some people that doesn't make sense. For some people it makes a lot of sense. [Stella's journey, on page 21, illustrates how that happens.]

Clara: What they've seen. It's known that people who see violence, like a parent who is abused—it's more likely they become a victim, or become an abuser. So sometimes it's a learned reaction, because they think it's normal.

With low self-esteem, it comes from different ways. You might be trying to compare yourself to everybody. When you tell a child they're slow or they're stupid, people don't realize that impacts the child, no matter what age they are. When a person has low self-esteem, they tend to have destructive behavior. But really it depends on what kind of person you are, because when you tell a child to be strong, "don't worry about what other people say and think for yourself," they let things roll off their back.

Patrice: It goes back to what they were subjected to. People tell you you're ugly. You drop a plate and they say you're stupid.

Shante: My son was in the first grade and he came home one day and said, "Ma, our teacher was cursing at us!" and I said, "She was?" And he said, "Yeah!" I go there and the whole class was just in disarray, and she said, "Y'all are just a bunch of bad-ass kids." I was like, "Do you see me sitting here?! I am a parent!" She was like, "Oh, but these kids in this class, oh my god. They curse and they do everything." And I'm like, "Well, you're cursing too. My son doesn't curse, but you're cursing my son out for what other kids are doing." But it's the security guard too. He said, "Here comes his bad ass." Maybe that boy can't read and they're making fun of him, and he reacts and gets angry. The secretary in the office, she's like, "Yeah, you're a bad-ass little girl." This is the school, for real.

And then parents. I'm from the projects. Everybody's just cussing their kids. I guess that's their way of life. Generation after generation and they're all cursing—the kids, the parents, the grandparents.

Betty (outreach worker): How does that happen, when there are people who grew up in the projects and they don't do that? They change their whole dynamic.

Shante: I have a cousin like that. Her mother was on drugs and everything. She's in the army. But it isn't a lot. So many are dead, but there are a few who have made it or actually have respect.

Parrie: We all know people in really bad situations and they turn around. Why is it that some do it and some don't?

Patrice: Some people have a positive influence in their life. Like a friend's house and they see the people in their house and they want better. So I want better too. I don't want to be like these people in my household. I don't want to be beat down so now I'm looking at these people in their household and I'm gonna strive for their goals.

Shante: Afterschool programs. It can be one of your friend's mamas. We were just talking about this in church Sunday. There could be a child who comes over to play with your child and you're just feeding them and loving them and all of a sudden, they want to be at your house all the time. You wake up and the child is already there: "Can I spend the night?" My preacher said not to push them away, because they might be getting their only love from you.

Clara: I came from one of those backgrounds where my momma's on drugs, my daddy's on drugs, and all that. But it takes willpower and it takes commitment to try to break down that pattern. Don't get me wrong. I did my dirt back in the day. When I got out of the penitentiary, I went to the old neighborhood, but I saw it in a different light. And I said, "Man, I refuse to let my child go through this." I just refuse to, because look at all the heartache and all the pain and everything that you did to yourself. And I couldn't blame anybody. At first you could though. At first you point to everybody. Look at what my momma did, my daddy did this, so that's why I'm like this. But the truth of the matter is, it's all about me.

Now I see people that you look up to, because they don't do drugs, they don't have [negative] influences. But then you see them on the streets again and they got influences. It just hurts your heart. I say, "Man, what is it that I got to do to straighten out?" 'Cause I ain't gonna lie. It's hard to try to sit up here and do right constantly, and then you know there're always downfalls and struggles that come your way.

At the end of the year for the past two years, I took stock of my life. If a person is not productive in my life, then I cut them out. I don't call them. It's just over with. I don't want to be stuck in the same place.

PHOTO: CHRIS KNIGHT

"I made up my mind that I wanted to be something different. People always told me, 'Betty, you're smart. Why do you do the things you do?' And I was like, 'Well, I have to survive.' I had to go to therapy."

—BETTY PREVO

You have to think, "What do you want better for yours?" I have three kids and I went back to school when I got pregnant with my first daughter and got my high school diploma.

Shante: I think it comes from not having it when you're little. Some people are like, "I'm not going to be like this. I'm gonna go to school and I'm going to work for this," and some people are like "What?!" I think that's what happened to my brother. Once my momma moved, my brother started selling drugs. He's looking at his friends and they got the nice baseball jerseys and the Jordans, and he's walking around with the Payless, and it didn't sit well with him. But now he's 24 and he's got three kids, and he understands the value of a dollar because he works two jobs. He refuses to sell drugs again and go to jail again. I don't think they are bad people. I think it's from not having anything. And that's how people see you.

Clara: It motivates you. You decide. Some people just want to live off of you. I had people like that and you know, it hurts to turn them away. I have a good heart, but I'm paying your way and my kids are not eating right, because I'm using my money to help you out.

Shante: I think it hits people differently. I tell my sister, you could take the good and the bad that momma put us through in life, and then you could apply it to your kids. Like my momma didn't let my brothers sell drugs. They tried, but she was like, "I'm going to call the police on you, the server, the packer. I'm gonna send everybody to jail." So that's how I feel about my son. When it comes time, I'm gonna do the same thing.

My kids aren't going to see all these men, either. My kids aren't gonna have 30 uncles. (The other women laugh.) For real. My momma did that. We had 60 uncles. [Pauses.] My momma was abused and from there, I feel like after that man, she was never gonna love anybody else. So no, nobody comes before my kids. He had to eat before we ate. What?! We get food stamps. You don't get food stamps. [Everyone laughs.] My sister says Momma never did anything for us. I was like, "Baby, we were never homeless. We were never hungry." Six kids by yourself, that's a lot. I think that's why my momma always got those men who wanted to lay hands upon her, because she played those victim roles. "Oh, I've got six kids and I need help." I didn't understand that. Now I'm the only one out of all her kids that talks to my momma. And she'll call up drunk, "Ohhh, f-off all of ya mf's." I tell her, "I love you, Mom. Good night. I'll talk to you in the morning."

Clara: Your mother was there. I never knew my mother. I thought she was dead until I was 21.

Shante: My momma might as well have been dead. I cooked, I cleaned. She just stayed in the room, or made a meal for the man.

Clara: After my grandmother died, I was in foster homes and when I moved, I had those abandonment issues.

Betty: You don't know what happened to your mom. She probably thought she left you in a better place. Forgive your mother. I had to forgive mine. Even my grandmother said, "Your mom did the best she could do. Even when she ran off on a drinking binge and left you all in the house, I was there." I was the only one of four kids with a different father, and I suffered whuppings. People in the neighborhood called me names. I was always told "you are a nothing, you will always be nothing." And I believed that for the longest time, and I said, "Well, I'm gonna do the same as my momma did and I'm going to be a drunk," and I went from the drink to the drugs, until I made up my mind that I wanted to be something different. People always told me, "Betty, you're smart. Why do you do the things you do?" And I was like, "Well, I have to survive." I had to go to therapy. Therapy helped me because I was gone. And by the grace of God, I'm on this side now. A lot of stuff happened. I was molested at a young age. All that. And that was because my mom was not there. The guy who used to rape me—my momma'd be right in the bed, drunk. She couldn't do anything. She was an alcoholic. And when I told her, she said, "You probably led him on."

Shante: My momma said the same thing. "You wanted my boyfriend." I said, "What kind of momma was this?!"

Patrice: They don't know how to act, so that's why sometimes that's how parents react to their child being hurt. "You put it on yourself," so they could make up for their lack of love or the protection that they should have given you. That's what they do, they say, "Uh, you put it on yourself because you were being fast," because that's how they know to solve their problems.

Shante: What happens too with the parents [pauses]... they can't protect themselves.

Patrice: They can't protect themselves, how can they protect their child?

Shakeela: In my house, it wasn't talked about. I was getting molested. I was pregnant when I was 15 and I didn't know until I was nine months.

Patrice: I saw my mother getting whupped. It takes a lot out of you. I was beaten with sticks and everything. I was immune to it. I left home and I thought, "If it happened at home, why can't my partner do it?" I used to like to have a man hit me. It's crazy.

It goes back to us not knowing about the disease. I learned when people I knew had it. It was knocking on our door.

Shante: I've got a sister who was just like her. And I have a brother who wouldn't hit a woman for anything.

Enid (of Positively Aware): There are 30, 40 families on a block. How many do you think were abusive?

[Several individuals]: About every other household.

Stella (outreach worker): You know what I think hinders all of us? We put labels on these people. When you say "mother," there are expectations with that. But honestly, there are some no-good people. If they don't meet those expectations, it hurts us more. That's why I had nothing to do with my mother after a while. I tried, just like you did. I only got back with her when she died, at her funeral, because she was so toxic. When I removed the label that she was my mother and realized that she was just an unhealthy woman, I was able to move on. We have to remove those labels and remove those expectations, and we'll be okay.

Clara: My father was in and out of jail, but he had respect on the streets. My mother was a "ho," and I just wanted to be the opposite. I was car-jacking and robbing homes, and I was selling drugs, but I wasn't selling myself, so that was okay. I used to go with whoever had the biggest guns. The tougher the guy, the bigger the gun, the more I liked him. It was crazy. I started to go to jail when I was 15. One addiction leads to another. I know it's an addiction. You get the same adrenaline from driving [the getaway car] as you get from robbing. It's a power trip. I still have to learn how to calm down.

Parrie: What about your attitudes about people with HIV before you started this study?

Clara: My dad died when I was 14. I was fed up with him. We didn't know he had HIV. We didn't know that HIV made you skinny. He stopped taking his medicine after my grandma died and that's when everybody found out that he had AIDS. He didn't even tell me. I found out from somebody else. I didn't go to him or talk to him and I just feel bad about that now because... I was so scared that I couldn't get close to him.

Patrice: It goes back to us not knowing about the disease. I learned when people I knew had it. It was knocking on our door, people who lived three blocks away. I asked myself, "Why am I still having unprotected sex when this virus is out here?"

Shante: We had to take health class again. They said there's a new virus out there called [HIV]. I was like, "Does it have something to do with that cancer virus?" I thought they're just going to kill us all! Before I got into the vaccine study, I was like, "How do you know he's got it? Nah, he looks good." [Someone laughs.] I was scared for real. You just look at people. Suppose someone tried to talk to you, you'd be like, "Show me the [test] results."

Then in the projects too, they'd be coming through with the white van, picking up all the people with syphilis and herpes and stuff. That white van comes out and they don't even hide your business. They'd be talking straight out, "Tyrone Walker! Where you at?!" [Everyone laughs.] I was like, "Oh, my god. Who's got something?" That van came to get you, I'm not messing with you. I thought, "Condoms can't help this."

Clara: Yolanda [a former outreach worker who suffered a fatal heart attack a few years ago] helped me when I went to jail, and talked to me about it. And I learned about it in the penitentiary. They had HIV seminars. Some of the people in there—you couldn't even tell they had it. They looked healthier than me, and happy.

Tinika: I learned from older people on the streets. They said, "Don't sleep around, use condoms."

Patrice: I didn't know about HIV. I just read what I read. They didn't give you any knowledge about HIV. Until we got into the study, that's when I said, "Well, this is not something that I want. I don't want this."

Enid: If you read about it, why do you say you didn't know about it?

[Everyone begins talking at once, wanting to explain.]

Patrice: It didn't tell you what HIV was. And our doctor in our community just said use condoms. So when we were young, when we were told someone had HIV, we didn't want to touch them because we thought that's how we'd get it. When we got in this study, we learned the different ways we could catch HIV, not just through sex.

Parrie: Who did you go to when you had questions? Who was the authority?

Patrice: For real, in the black community, it wasn't even talked about. It was always a secret. If you catch an STD, you don't tell your momma.

Shante: I didn't know you could catch them. I didn't know you could have all of them at the same time.

Shakeela: I was with the father of my kids for 10 years and I didn't know he had it. That was one situation that changed me because ... you live with a man and have unprotected sex. I was lucky not to get it—I had to wake up.

Parrie: So basically you used your friends?

Shante: Yeah! Not even friends. Enemies. Someone standing outside. "Yeah, you got gonorrhea?" Me, I was going to school. I was going to the library. "Excuse me, what is gonorrhea? What is syphilis? That girl got a rash—what is that?" They didn't give us a pamphlet. They showed us a banana and put a condom on it and told us to use a condom every single time. They didn't tell us we could die.

Day 1

Of my next treatment regimen: KALETRA once a day with my other HIV medicines.

Ask your doctor if KALETRA once daily is right for you.

KALETRA once daily should not be given to children. KALETRA once daily should not be taken with efavirenz (Atripla® and Sustiva®), nevirapine (Viramune®), amprenavir (Agenerase®), nelfinavir (Viracept®), carbamazepine (Tegretol® and Epitol®), phenobarbital (Luminol®), or phenytoin (Dilantin®). There may be a greater chance of getting diarrhea with the once daily regimen compared with the twice daily regimen.

Use

KALETRA® is a prescription anti-HIV-1 medicine called a protease inhibitor that contains lopinavir and ritonavir. KALETRA is used with other anti-HIV-1 medicines to increase the chance of treatment response in people with human immunodeficiency virus (HIV-1) infection. It is not known if KALETRA is safe and effective in children under 14 days old.

KALETRA does not cure HIV-1 infection or AIDS and does not reduce the risk of passing HIV-1 to others. People taking KALETRA may still get opportunistic infections or other conditions that happen with HIV-1.

KALETRA Safety Considerations

Do not take KALETRA® if you are allergic to any of its ingredients, including lopinavir or ritonavir. Do not take KALETRA with certain medicines, as they can cause serious problems, death, or make KALETRA less effective against HIV. Some patients taking KALETRA can develop inflammation of the pancreas and liver problems, which can cause death. Patients may develop changes in heart rhythm, large increases in triglycerides and cholesterol, diabetes, high blood sugar, changes in body fat, and/or increased bleeding in people with hemophilia. Some patients may develop signs and symptoms of serious infections they already have after starting anti-HIV medicines.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088 (1-800-332-1088).

If you cannot afford your medication, contact: www.pparx.org or call the toll-free number (1-888-4PPA-NOW) or (1-888-477-2669) for assistance.

For additional information about KALETRA, call 1-866-KALETRA (1-866-525-3872) or visit KALETRA.com.

Please see Brief Summary on adjacent pages.

KALETRA®
(lopinavir/ritonavir)

Model is for illustrative purposes only.

KALETRA® (kuh-LEE-tra) (lopinavir/ritonavir) Tablets
KALETRA® (kuh-LEE-tra) (lopinavir/ritonavir) Oral Solution

CONSUMER BRIEF SUMMARY
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MEDICATION GUIDE
Patient Information

Read the Medication Guide that comes with KALETRA before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment. You and your doctor should talk about your treatment with KALETRA before you start taking it and at regular check-ups. You should stay under your doctor's care when taking KALETRA.

What is the most important information I should know about KALETRA?

KALETRA may cause serious side effects, including:

- **Interactions with other medicines. It is important to know the medicines that should not be taken with KALETRA**. Read the section "What should I tell my doctor before taking KALETRA?"
- **Changes in your heart rhythm and the electrical activity of your heart**. These changes may be seen on an EKG (electrocardiogram) and can lead to serious heart problems. Your risk for these problems may be higher if you:
  - already have a history of abnormal heart rhythm or other types of heart disease.
  - take other medicines that can affect your heart rhythm while you take KALETRA.

Tell your doctor right away if you have any of these symptoms while taking KALETRA:

- dizziness
- lightheadedness
- fainting
- sensation of abnormal heartbeats

See the section below "What are the possible side effects of KALETRA?" for more information about serious side effects.

What is KALETRA?

KALETRA is a prescription anti-HIV medicine that contains two medicines: lopinavir and ritonavir. KALETRA is called a protease inhibitor that is used with other anti-HIV-1 medicines to treat people with human immunodeficiency virus (HIV-1) infection. HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

It is not known if KALETRA is safe and effective in children under 14 days old.

Who should not take KALETRA?

- Do not take KALETRA if you are taking certain medicines. For more information about medicines you should not take with KALETRA, please see **"Can I take other medicines with KALETRA?" and consult with your doctor about all other medicines you take**.
- Do not take KALETRA if you have an allergy to KALETRA or any of its ingredients, including ritonavir and lopinavir.

What should I tell my doctor before taking KALETRA?

KALETRA may not be right for you. Tell your doctor about all your medical conditions, including if you:

- have any heart problems, including if you have a condition called Congenital Long QT Syndrome.
- have liver problems, including Hepatitis B or Hepatitis C.
- have diabetes.
- have hemophilia. People who take KALETRA may have increased bleeding.
- have low potassium in your blood.
- are pregnant or plan to become pregnant. It is not known if KALETRA will harm your unborn baby. Birth control pills or patches may not work as well while you take KALETRA. To prevent pregnancy while taking KALETRA, women who take birth control pills or use estrogen patch for birth control should either use a different type of birth control or an extra form of birth control. Talk to your doctor about how to prevent pregnancy while taking KALETRA.
- take KALETRA during pregnancy, talk with your doctor about how you can take part in an antiretroviral pregnancy registry. The purpose of the pregnancy registry is to follow the health of you and your baby.
- are breast-feeding. Do not breast-feed if you are taking KALETRA. You should not breast-feed if you have HIV-1. If you are a woman who has or will have a baby while taking KALETRA, talk with your doctor about the best way to feed your baby. If your baby does not already have HIV-1, there is a chance that HIV-1 can be passed to your baby through your breast milk.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Many medicines interact with KALETRA. Do not start taking a new medicine without telling your doctor or pharmacist. Your doctor can tell you if it is safe to take KALETRA with other medicines. Your doctor may need to change the dose of other medicines while you take KALETRA.

Medicines you should not take with KALETRA.

Serious problems or death can happen if you take these medicines with KALETRA:

- ergot containing medicines, including:
  - ergotamine tartrate (Cafergot®, Migergot, Ergomar, Ergostat, Medihaler Ergotamine, Wigraine, Wigrettes)
  - dihydroergotamine mesylate (D.H.E. 45®, Embolex, Migranal®)
  - ergonovine, ergonovine and methylergonovine (Ergotrate, Methergine), ergotamine and methylergonovine
  - Ergotrate Maleate, methylergonovine maleate (Methergine)
- triazolam (Halcion®), midazolam hydrochloride oral syrup
- pimozide (Orap®)
- the cholesterol lowering medicines lovastatin (Mevacor®) or simvastatin (Zocor®)
- sildenafil (Revatio®) only when used for the treatment of pulmonary arterial

hypertension. (See "Medicines that may need changes" and "What are the possible side effects of Kaletra?" for information about the use of sildenafil for erectile problems.)
- alfuzosin (Uroxatral®)

Medicines that you should not take with KALETRA since they may make KALETRA not work as well:
- the herbal supplement St. John's Wort (hypericum perforatum)
- rifampin (Rimactane®, Rifadin®, Rifater®, or Rifamate®)

Medicines that may need changes:
- birth control pills that contain estrogen ("the pill") or the birth control (contraceptive) patches
- certain cholesterol lowering medicines, such as atorvastatin (Lipitor®) or rosuvastatin (Crestor®)
- certain other antiretroviral medicines, such as efavirenz (Atripla® and Sustiva®), nevirapine (Viramune®), amprenavir (Agenerase®), fosamprenavir calcium (Lexiva®) and nelfinavir (Viracept®)
- anti-seizure medicines, such as phenytoin (Dilantin®) carbamazepine, (Tegretol®), phenobarbital
- medicines for erectile problems, such as sildenafil (Viagra®, Revatio®), tadalafil (Cialis®), or vardenafil (Levitra®)
- medicines for tuberculosis (TB), such as rifabutin (Mycobutin®)
- inhaled steroid medicines, such as fluticasone propionate (Flonase®)
- inhaled medicines such as salmeterol (Serevent®) or salmeterol in combination with fluticasone propionate (Advair®). Your doctor may need to change to a different medicine
- medicines for gout, such as colchicine (Colcrys®)
- medicines to treat pulmonary arterial hypertension (PAH), such as bosentan (Tracleer®) or tadalafil (Adcirca®)

If you are not sure if you are taking a medicine above, ask your doctor.

How should I take KALETRA?

- Take KALETRA every day exactly as prescribed by your doctor.
- It is very important to set up a dosing schedule and follow it every day.
- Do not change your treatment or stop treatment without first talking with your doctor.
- Swallow KALETRA tablets whole. Do not chew, break, or crush KALETRA tablets.
- KALETRA tablets can be taken with or without food.
- If you are taking both Videx® (didanosine) and KALETRA:
  - didanosine can be taken at the same time as KALETRA tablets, without food.
  - take didanosine either one hour before or two hours after taking KALETRA oral solution.
- Do not miss a dose of KALETRA. This could make the virus harder to treat. If you forget to take KALETRA, take the missed dose right away. If it is almost time for your next dose, do not take the missed dose. Instead, follow your regular dosing schedule by taking your next dose at its regular time. Do not take more than one dose of KALETRA at one time.
- If you take more than the prescribed dose of KALETRA, call your local poison control center or emergency room right away.
- Take KALETRA oral solution with food to help it work better.
- If KALETRA is being used for your child, tell your doctor if your child's weight changes.
- KALETRA **should not** be given one time each day in children. When giving KALETRA to your child, give KALETRA exactly as prescribed.
- KALETRA oral solution contains a large amount of alcohol.
  - If a young child drinks more than the recommended dose, it could make them sick from too much alcohol. Contact your local poison control center or emergency room right away.
  - Talk with your doctor if you take or plan to take metronidazole or disulfiram. You can have severe nausea and vomiting if you take these medicines with KALETRA.
- When your KALETRA supply starts to run low, get more from your doctor or pharmacy. It is important not to run out of KALETRA. The amount of HIV-1 virus in your blood may increase if the medicine is stopped for even a short time. The virus may become resistant to KALETRA and become harder to treat.
- KALETRA can be taken with acid reducing agents used for heartburn or reflux such as omeprazole (Prilosec®) and ranitidine (Zantac®) with no dose adjustment.
- KALETRA should not be administered once daily in combination with carbamazepine (Tegretol® and Epitol®), phenobarbital (Luminol®), or phenytoin (Dilantin®).

Avoid doing things that can spread HIV infection. KALETRA does not stop you from passing HIV infection to others. Do not share needles, other injection equipment or personal items that can have blood or body fluids on them, like toothbrushes and razor blades. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

What are the possible side effects of KALETRA?

KALETRA can cause serious side effects.
- See **"What is the most important information I should know about KALETRA?"**
- **Liver problems.** Liver problems, including death, can happen in people who take KALETRA. Blood tests in people who take KALETRA may show possible liver problems. People with liver disease such as Hepatitis B and Hepatitis C who take KALETRA may have worsening liver disease. Tell your healthcare provider right away if you have any of these signs and symptoms of liver problems:
  - loss of appetite
  - yellow skin and whites of eyes (jaundice)
  - dark-colored urine
  - pale colored stools, itchy skin
  - stomach area (abdominal) pain.
- **Inflammation of the pancreas (pancreatitis).** Some people who take KALETRA get inflammation of the pancreas which may be serious and cause death. You have a higher chance of getting pancreatitis if you have had it before. Tell your doctor if you have nausea, vomiting, or abdominal pain while taking KALETRA. These may be signs of pancreatitis.
- **Increases in certain fat (triglycerides and cholesterol) levels in your blood.** Large increases of triglycerides and cholesterol can be seen in blood test results of some people who take KALETRA. The long-term chance of getting complications such as heart attacks or stroke due to increases in triglycerides and cholesterol caused by protease inhibitors is not known at this time.
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including KALETRA get new or more serious diabetes, or high blood sugar. Tell your doctor if you notice an increase

in thirst or urinate often while taking KALETRA.

- **Changes in body fat.** Changes in body fat in some people who take antiretroviral therapy. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the trunk. Loss of fat from the legs, arms and face may also happen. The cause and long-term health effects of these conditions are not known at this time.
- **Increased bleeding for hemophiliacs.** Some people with hemophilia have increased bleeding with protease inhibitors including KALETRA.
- **Increased risk of certain problems when you take medicines used for the treatment of erectile problems such as sildenafil (Viagra®), tadalafil (Cialis®), or vardenafil (Levitra®) with KALETRA:**
  - **low blood pressure.** If you get dizzy or faint, you need to lie down. Tell your doctor if you feel dizzy, or have fainting spells.
  - **vision changes.** Tell your doctor right away if you have vision changes.
  - **penis erection lasting more than 4 hours.** If you are a male and have an erection that lasts longer than 4 hours, get medical help right away to avoid permanent damage to your penis. Your doctor can explain these symptoms to you.

Common side effects of KALETRA include:

- diarrhea
- nausea
- stomach area (abdominal) pain
- feeling weak
- vomiting
- headache
- upset stomach

These are not all of the possible side effects of KALETRA. For more information, ask your doctor or pharmacist. Tell your doctor about any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store KALETRA?

KALETRA tablets:

- Store KALETRA tablets at room temperature, between 59°F to 86°F (15°C to 30°C).
- Do not keep KALETRA tablets out of the container it comes in for longer than 2 weeks, especially in areas where there is a lot of humidity. Keep the container closed tightly.

KALETRA oral solution:

- Store KALETRA oral solution in a refrigerator, between 36°F to 46°F (2°C to 8°C). KALETRA oral solution that is kept refrigerated may be used until the expiration date printed on the label.
- KALETRA oral solution that is stored at room temperature (less than 77°F or 25°C) should be used within 2 months.
- Keep KALETRA away from high heat.

Throw away any medicine that is out of date or that you no longer need.

Keep KALETRA and all medicines out of the reach of children.

General information about KALETRA

KALETRA does not cure HIV-1 or AIDS. The long-term effects of KALETRA are not known at this time. People taking KALETRA may still get opportunistic infections or other conditions that happen with HIV-1 infection. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium* complex (MAC) infections.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use KALETRA for a condition for which it was not prescribed. Do not give KALETRA to other people, even if they have the same condition you have. It may harm them.

This Medication Guide summarizes the most important information about KALETRA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about KALETRA that is written for health professionals. For more information about KALETRA call 1-800-633-9110 or go to www.KALETRA.com.

What are the ingredients in KALETRA?

Active ingredient: lopinavir and ritonavir

Inactive ingredients:

KALETRA 200 mg lopinavir and 50 mg ritonavir tablets: copovidone, sorbitan monolaurate, colloidal silicon dioxide, and sodium stearyl fumarate. The film coating contains: hypromellose, titanium dioxide, polyethylene glycol 400, hydroxypropyl cellulose, talc, colloidal silicon dioxide, polyethylene glycol 3350, yellow ferric oxide 172, and polysorbate 80.

KALETRA 100 mg lopinavir and 25 mg ritonavir tablets: copovidone, sorbitan monolaurate, colloidal silicon dioxide, and sodium stearyl fumarate. The film coating contains: polyvinyl alcohol, titanium dioxide, talc, polytheylene glycol 3350, and yellow ferric oxide E172.

KALETRA oral solution: acesulfame potassium, alcohol, artificial cotton candy flavor, citric acid, glycerin, high fructose corn syrup, Magnasweet-110 flavor, menthol, natural and artificial vanilla flavor, peppermint oil, polyoxyl 40 hydrogenated castor oil, povidone, propylene glycol, saccharin sodium, sodium chloride, sodium citrate, and water.

KALETRA oral solution contains 42.4% alcohol (v/v). "See How should I take KALETRA?".

KALETRA Tablets, 200 mg lopinavir/ 50 mg ritonavir
Manufactured by Abbott Pharmaceuticals PR Ltd., Barceloneta, PR 00617 for Abbott Laboratories, North Chicago, IL 60064, U.S.A.

KALETRA Tablets, 100 mg lopinavir/ 25 mg ritonavir and KALETRA Oral Solution
Abbott Laboratories, North Chicago, IL 60064, U.S.A.

Ref: 03-A363-R7

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039-373136

STELLA's JOURNEY

From survival to healing

BY ENID VÁZQUEZ

OUTREACH WORKER STELLA RIVERS-GOOLSBY REPRESENTS A perfect combination of women at risk and women who have gone on to work in the struggle against HIV.

PRECIOUS TRUTHS

Stella works with several young women who have children fathered by relatives through incest, many times more than one. She estimates that 90% were molested by an uncle, grandfather, brother, or stepfather. Other women were told, often by their mothers, that it was their own fault because they were "fast." One woman told her mother that her brother was abusing her, but her mother's response was, "That's a lie!" Stella has also heard the women say they were advised to "stay away from him"—even when the man lived under the same roof. As a result, many of these women ran away from home, but they earned money through prostitution, telling her, "It's better than being in there getting molested. At least it's on my own terms."

"In the drug families," says Stella, "I found that a lot of girls were with these guys because in their home life, they didn't get that nurturing, love, caring, and trust they needed from their parents or guardians. So when they get out to the streets, and this guy comes along and says, 'I'm going to take care of you. I might kick your ass now and then just to keep you in line, but you know I love you, don't you?'—just those words will make them disregard and minimize all the ass kicking, the black eyes, the broken jaw, and swollen lips, because he said, 'You know I love you, don't you? And I'll be there for you.' And if you've never heard anybody say that—that's a big thing. And this guy could have just stomped the shit out of you."

"So it stems from not having been nurtured at the beginning. It becomes normal to them," Stella says. "I tell them stories like mine. I let them know, this is not right, and you can get away from it.

"My mother had bipolar disorder and schizophrenia, but she wasn't diagnosed until she was in her 50s," says Stella. "Growing up, I thought she was just a mean bitch. She had nine kids by eight different men, one of whom sexually abused all of us. But I understand now that she couldn't protect us.

"It's an intergenerational effect. My grandfather was very violent towards my grandmother, and towards other women. A lot of women said, 'If he takes care of you, so what if he kicks your ass now and then? He pays the bills.' If you tell them he's cheating, 'Well, all he's doing is getting some pussy.' So women came to believe this was okay. They saw their mothers and grandmothers do it. And now they're doing it. And guys, who saw their fathers do it and their grandfathers do it,

PHOTO: CHRIS KNIGHT

My environment changed and my thought process changed. After a while of being in recovery meetings, I decided that my issue was something that I needed to talk to someone one-on-one, and I sought therapy.

now they're doing it. They don't know how to be intimate or be caring. This is the way they interact emotionally.

"So you have a guy who's unhealthy and a woman who's unhealthy. Together they make a relationship, whether it's unhealthy or not. They feel like they've got somebody to depend on. And believe it or not, in a sick kind of way, these guys think they really love you, and you think that they love you," Stella tells me. "Then it goes back to their self-esteem being so low. 'Nobody wants me. Who's going to take me with four kids? Who's going to take me when I've been a prostitute? Who's going to want me if I have no education? And I know he loves me because he loves me just like I am.' But all that can change. You can educate yourself. You can find somebody who loves you for you, who understands that that's what you used to be, that's not who you are now. A lot of women don't have anybody else but these guys. I say, 'You know, you can do better than this.'

"And I want to share my story of abusive guys. One was really, really abusive, an alcoholic, and a drug addict. The first week I met him, I went with him because he had drugs. [Stella is emphatic on this point, as if to say, "It was that simple."] People told me, 'Oh, don't mess with him. He beats up women.'

"About a week later, we were walking through this alley. I can't remember the words verbatim, but he said, 'What did you say?' I said, 'Fuck you,' something like that. I woke up on the ground, because he hit me right in the face with his fist. I said, 'What the fuck did you do that for?' He said, 'You don't talk to me like that.' So I thought, 'fine,' because I didn't really know him, plus he had dope. A couple of weeks later he slapped me, and I slapped him back. And his response was: 'Uhhh, you want to fight, huh, bitch?' He literally started bobbing and weaving as if to fight me, and he nearly beat me to death.

"Eight months later, I want to leave him, but now, he's got a hold on me. He follows me everywhere I go, even to my relatives' house. He's stalking me now. So I run off from him. He paid people to find me. I went home and opened the door and all I remember was he hit me. I woke up tied to the bed, hand and foot. Because, while I was gone, he had been looking in the house and found a man's T-shirt. He thought I was with somebody else. And he beat me, tied me up, and tortured me for two days. He burned me with cigarettes, spit on me. By this time I had a baby by him and he had my son spit on me. 'Spit on the bitch. She ain't shit.'

"So after a while, I was afraid of him, and I stayed out of fear. Finally, the last straw was when he slapped my daughter because she was trying to help me fight him. That's when I tried to shoot him. Finally, I left.

"I'm just giving you the skinny version," she says. "It took that much, because he had already scared and tortured me. After a while, I felt like, maybe I deserved this. Maybe I'm doing something to make this guy feel like this. But later on, as I got in recovery and therapy, I realized that he was [pauses], a dirty muthafucker.

"You know something?" says Stella. "I used to actually brag, 'Girl, didn't you know he kicked my ass, so you know he looove me. He didn't want nobody to get this pussy.' You say stupid shit like that. I thought he loved me so much, he didn't want me to be around anybody.

"What turned me around is that I got tired of the drug use. And the drug use is connected to the violence. When I realized that I didn't have to be a dope fiend, an addict, I realized that I didn't have to accept this, but I felt like with the behavior I was doing, nobody else would accept me," Stella says.

"After I stopped using, when the clouds from the drugs started leaving, I started wondering, what's wrong with me? Why do I want to be with him? But now, of course, I'm not thinking about drugs. And my children were saying, 'Mom, why are you putting up with this? You can do better than this.' I heard those words but pushed them to the back of my mind. Then I stopped using and I started going to [Narcotics Anonymous] meetings, and hearing people talk, nothing particularly earth-shattering, but just, 'I'm working now and I bought this' and 'I did that.' 'I took my kids here.' Just hearing things that were a normal part of life. I didn't hear anything about somebody kicked my ass, somebody took my money, or somebody blacked my eyes. You know?

"My environment changed and my thought process changed. After a while of being in recovery meetings, I decided that my issue was something that I needed to talk to someone one-on-one, and I sought therapy. I found out my problems started with my mom, because she couldn't protect us. It took some time, it wasn't like [Stella snaps her fingers]. It took over three years, because I was still taking verbal abuse. No more physical, because I had started saying things like, 'You put your muthafuckin' hands on me, I'm gonna kill you.' And I meant that from the bottom of my heart. [She speaks softly, with tears in her eyes.] 'I'm paying the bills. You don't work. You sleep with other women.'

"And finally, I just said, if I want something different, I have to try something different. I've done this, and I got the same thing. Pain, physical and emotional. I would see people in a relationship interacting differently. Loving people. Not talking to their women negatively. You could hear a different tone in their voice. All these were triggers for me to say, *this* is what's real. That wasn't reality that I was living and accepting.

"I get strength when I feel the love of the women who say, 'Hi, Miss Stella! How are you?' I really do. I believe anyone surviving domestic violence… you need to seek professional help. I don't think anybody can do this without professional help. I really don't. Because there's something mentally wrong. I really believe we need to add drug treatment and work on domestic violence in all of our [HIV vaccine] studies.

"It took a long time," says Stella, "but I healed my spirit."

LESSONS FROM THE FRONTLINE

EAT AT EDNA'S: Fiona Lynch, Betty Prevo, Stella Rivers-Goolsby, and Parrie Graham gather at a soul food restaurant on Chicago's West Side.

PHOTO: CHRIS KNIGHT

Advocates discuss communities at risk

BY ENID VÁZQUEZ

I TALKED WITH SEVERAL ADVOCATES, INCLUDING A THERAPIST AND A retired nurse, about the influence that negative experiences can have on HIV transmission.

ROLLER COASTER

After our talk out on the West Side, I hitch a ride downtown with Pat Sloan, a CAB member who's a retired nurse and nursing school professor. An African American woman from Virginia, Pat became impassioned about HIV prevention when she saw the statistics for African Americans. By 1987, HIV was the ninth leading cause of death for both black men and women in the U.S., while it was the 11th leading cause of death for white men. In 1988, it climbed to the sixth leading cause of death for black men (and was 10th for both sexes combined). She added, "But we were silent and in denial—as too often we are still." In order to help combat the silence and denial, she founded the HIV/AIDS Research & Policy Institute at Chicago State University.

"What they said [in the meeting] about low self-esteem is true," Pat tells me, "but what people don't seem to realize is that self-esteem is not a steady state. You can raise self-esteem, but you have to maintain it. You can be from a happy family and have a good education, but then you get depressed and no longer think you're worth protecting.

"It's drip, drip, drip—the everyday, mundane stress of racism and other issues," she continues, "but it's also all in how the individual reacts to it. Some slight can pull you back into self-destructive behavior. And sometimes you have to make a change repeatedly before it sticks. What oftentimes happens, unfortunately, is that before a person has had a chance to practice as much as they need to, their family and society have given up on them."

Days later, being the policy wonk that she is, Pat e-mailed me a statement she found on the website of the U.S. Centers for Disease Control and Prevention (CDC), stating that those who experience both sexual and other forms of physical abuse are significantly more likely to have sexually transmitted diseases, including HIV.

She also directed me to the Institute on Domestic Violence in the African American Community (IDVAAC; 877-643-8222). The institute's website says it is "an organization focused on the unique circumstances of African Americans as they face issues related to domestic violence—including intimate partner violence, child abuse, elder maltreatment, and community violence. IDVAAC's mission is to enhance society's understanding of and ability to end violence in the African American community." It goes on to say that "the 'one-size-fits-all'

"What people don't seem to realize is that self-esteem is not a steady state. You can raise self-esteem, but you have to maintain it."

—PAT SLOAN
FOUNDER, RESEARCH & POLICY INSTITUTE
CHICAGO STATE UNIVERSITY

approach to domestic violence services being provided in mainstream communities would not suffice for African Americans, who disproportionately experience stressors that can create conditions that lead to violence in the home."

RESPECT

I sat down with Project WISH administrator Parrie Graham, the first executive director of the AIDS Services Foundation in Orange County, California, who's devoted the greater part of her life to advocating for people with HIV, and Fiona Lynch, a young German immigrant who has worked at the Project WISH clinic off-and-on for the past three years as she pursues her master's degree in medical anthropology.

"None of us are self-actualized," says Parrie. The three of us laugh. "We all have our weaknesses and beliefs that put us at risk."

What Parrie sees in community members using the services of Project WISH is a mental disconnect between risk behavior and HIV infection. Drinking, drugging, and having unprotected sex is okay, but people with HIV are seen as "bad." It makes HIV education out in the community difficult, and makes dealing with one's own infection even more so. "We find people with HIV, but getting them into care is nearly impossible," she says. "What gets to me is that all these bad things happen to the women and that's okay. That's seen as normal. But when they get infected with HIV they hide it, because the community says that if you have HIV you're 'bad.' "

"Denial," says Fiona, "and self-preservation. 'If I don't have it, then I'm not a bad person, and if I don't get treatment, I don't have it.' Yet no one judges you for getting the flu, which is also a virus."

"It's that community belief that they're a bad person that makes them work so hard not to see themselves that way," says Parrie. "We have to show some acceptability around risk. We have to say, 'What you're doing can give you HIV, but I don't see you as a bad person.' We've seen this over and over. We can't have a vaccine trial unless we don't judge people. After people are enrolled in a vaccine study, their risk goes right down. When they're seen as valuable human beings, they can then hear the [prevention] messages."

In a word, it's stigma.

Fiona points out that studies are also sources of information for the community at large. Participants always say, "I told all my friends [what I learned about HIV]."

"We have to make it part of social interaction," says Fiona, "make talk about sex and HIV neutral—release the moral component." She attended high school in a Chicago suburb and says she's amazed that in the U.S. there is such reluctance to teaching young people the facts about sex.

Parrie says she came from a drug abusing family and decided early on that it wasn't the way to go. She's fascinated by how people accept or reject the norms—the paths—shown to them, and wants to know where those messages come from.

She says the message of a poster from the Illinois Department of Health aimed at black women, "respect yourself," is "absolutely the heart of the matter."

REWIRING

For more information on protecting yourself, when you've grown up with the trauma the young women described, I turned to Jeff Levy, director of Live Oak therapy near Boystown (the gay neighborhood) in Chicago.

Jeff points to his article in the last issue of Positively Aware. "The mind affects the brain, the brain affects the body, and the body affects the mind—they all impact each other," he tells me.

Although not true for everybody, he says, part of what happens is that many children who grow up with violence, chaos, and trauma develop survival strategies that may be painful and even self-destructive, but which help them manage a difficult situation. "Like the little kid who grows up with an abusive parent and initiates something so he will get hit—that's a survival strategy because he's taking control over when the violence will occur," says Jeff. "And by initiating it, whether it's physical violence or sexual violence, the anxiety around not knowing when it will occur is lessened. So as a little kid, that's a really, really important survival strategy. As we grow older that may not be as necessary a survival strategy, but we're still using it.

"If you're a little kid and your boundaries are violated again and again," he continues, "you learn that you don't have the ability to protect yourself. So your body may now be 10 times bigger, but the lesson you've internalized is 'I can't protect myself.' "

So you're helpless, I say.

"Well, not literally, because [Jeff pauses to consider how to explain]... physically you could move your arm and push someone away, but it doesn't feel that way. It doesn't feel like you have that option."

Jeff continues. "And sometimes, the frozen feelings that people had when they were violated as kids are the same frozen

PHOTO: RICK GUASCO

PHOTO: RICK GUASCO

feelings that they have in dangerous situations when they're adults. So we physically freeze too."

He says that there's no one explanation for how or why difficult experiences early in life influence adult experiences, but that there's growing evidence of biological effects. Our brain can actually be changed by trauma, and our nervous system altered. "If we live in an environment of constant threats, we're always on high alert," he says. "Our nervous system learns to function in a state of high alert all the time, and that becomes our new normal, and we seek it out. Not consciously, but we seek out certain events and people who, on some level, elicit the same kind of neurophysiological reaction.

"More and more of the research looking at how violence and trauma and chaos affects the developing brain really points to all the neurophysiology behind why we behave the way that we do," Jeff explains. "We get caught in very strong neurophysiologic loops that we can't get out of. If I experienced terror and hopelessness over and over and over again, and that loop gets strengthened over and over and over again, when I get older and experience situations in which I feel afraid again, it activates that same loop. Even though I'm an adult, I don't feel that way.

"So it takes practice," he continues. "We can become aware of our defaults. How do we fall into these old patterns of being and moving out in the world and in relationships? By bringing them to our awareness, then experimenting with new strategies and practicing them over and over again, we can absolutely rewire ourselves in many of the issues we struggle with."

ONE-ON-ONE

As a therapist, Jeff Levy works with both individuals and support groups. Parrie, as she mentioned above, says that face-to-face interactions are crucial to HIV prevention.

After my interview with Stella (see page 21), I had lunch scheduled with Parrie and Kate Miller, a paralegal with the AIDS Legal Council of Chicago, who's also a CAB member at Project WISH. Kate told me about the time she worked on qualitative interviews for local HIV specialists and the Department of Children and Family Services. They were trying to figure out why so many women didn't tell their doctor they were HIV-positive at the time of their pregnancy.

Kate said that she became very depressed. "I was reading these intense interviews with 32 women," she said. "Not telling their doctor sounds wrong, but when you talk to the women, you find out all the things they're going through." What they learned was that "because these women were so disrespected in medical care, and in life in general, they were taking care of themselves by not disclosing, because that was one of the few means of protection they had." Some of the trauma they suffered through disclosure—such as being kicked out of their home or beaten—came from someone learning their status in a medical setting.

"Not telling their doctor sounds wrong, but when you talk to the women, you find out all the things they're going through."

—KATE MILLER
AIDS LEGAL COUNCIL OF CHICAGO

More importantly, the study learned that case managers were the only people the women trusted in a medical setting, the only ones who treated them in a respectful and caring manner. Just having someone say, "Hi, how are you?" was important, especially when there's a lack of simple courtesy and kindness from doctors.

This research confirmed the decision by PACPI (Pediatric AIDS Chicago Prevention Initiative) to hire case managers. "The idea was that engaging women in a respectful manner, building a relationship—which was shown in the research, that a respectful, caring relationship had been the start of change—was the way to help women in this situation and therefore decrease mother-to-child transmission," Kate told me.

We need qualitative interviews, Parrie points out, not just statistical information.

REVEREND GREEN

I profiled prison minister Reverend Doris Green last year (November/December 2009) and I quote her here from her talk last year to the Project WISH PCAB about HIV risk.

"Let's talk about our stressors," Rev. Green told the young women. "What can we do as women to protect ourselves? It's not about demonizing the men. How can you understand your relationship stressors and get some control?"

One PCAB member said, "Depression. They're going through something so they

"There's no slavery, but we're imprisoned in our mind. You know that saying, 'It takes a village to raise a child'? The village is sick, y'all. A sick village can't raise a child."

don't care. Cancer, HIV—you have to die of something. It doesn't matter. You need someone to talk to, like this group."

Another said, "Environment. My grandmother raised me and you don't talk about what's going on. I was in there, in and out of the penitentiary. Drug dealing. I still don't care about nothing."

A third young woman said, "People are not assertive enough to say, 'Before we have sex, let's go to this free clinic. Let's go take a test.' The same way we say, 'Let's go get that blunt,' can we say 'Let's go to the clinic'?"

"Why does the man have to talk about sex?" asks Rev. Green. "Why can't we have these candid conversations?"

"If you talk about sex, he'll wonder what's wrong with that cookie," someone responded. "Sex is like gayness," says someone else. "You couldn't talk about it. Now there are gay pride parades."

"Our youth don't feel they're going to live long, so it's like, 'whatever' [they don't care]," says Rev. Green. "Then they see Magic Johnson and they think, 'I can handle it.' The seniors, they have Viagra and think, 'I can't get pregnant.' I am not against sex, but can you say no to sex without a condom? And if we can't, what's going on with us?

"I was quoted in *Ebony* magazine years ago. They only reported, 'Rev. Green said there's no orgasm in the world worth dying for.' But I said so much more.

"I'm 60 now and I feel a measure of control. But I was once your age and I didn't feel in control. I see my daughter in a series of three-week relationships. When she gets to a month I'm going to think, 'What's going on? Is this real?' She says, 'He's my man.' I wonder, when do you talk about a condom?

"It's going to take funding for our community to provide mental health. And it's going to take a change in attitude to accept mental health. People think, 'I ain't crazy.' But stop and think: if you're doing crazy things like having sex without condoms, that's crazy.

"We have long-term issues related to slavery. But we can start working on [taps her forehead] now. I'm okay with talking about slavery as long as we say all right, now what are we going to do about it? There's no slavery, but we're imprisoned in our mind. You know that saying, 'It takes a village to raise a child'? The village is sick, y'all. A sick village can't raise a child.

"Our mental health, depression, drugs—what we're doing as a people is not working for us," Rev. Green continued, "and I'm not mad at us. We need that mental health care. We need to talk. My sisters, my aunties, even if they don't talk to us [about sexual health], I'll talk to them. Even if they throw me out, I'm going to talk to them.

"HIV was [first] identified in the gay white community," she said. "Not that it wasn't in our community, but it was identified in the gay white community. Gay men acted up and we need to act up." She looks at a sleeping baby in a stroller. "We have to do it for this baby right here." ✚

A list of resources is available online. To find help in your area, call the National Domestic Violence hotline: 1-800-799-7233.

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THE POWER OF ADVOCACY

A first-hand account of how testimony helped win an FDA panel's approval of a new drug

BY JEFF BERRY

"TODAY IS A GREAT DAY FOR PEOPLE WITH HIV." THE WORDS, spoken to me by Steven Grinspoon, a leading researcher and HIV-treating physician at Harvard who specializes in lipodystrophy, were still echoing in my head as I boarded the plane for my return trip home from the all-day meeting. I had just participated as a guest at an FDA Advisory Committee meeting regarding whether or not to recommend approval of Egrifta (tesamorelin), a human growth hormone releasing factor in development by Theratechnologies for the treatment of HIV-associated lipohypertrophy.

Lipohypertrophy, caused by excess visceral adipose (fat) tissue (VAT), has been estimated to affect as many as one-third of people living with HIV, and is associated with the use of antiretroviral therapy, as seen from studies in which treatment-naive people began therapy and accumulated fat in the abdominal area. VAT is different from subcutaneous fat, as it surrounds the vital organs and causes a hard, distended belly. It can be quite painful and extremely debilitating, and adversely affects quality of life and body image for those who have the condition. It can also put you at higher risk for cardiovascular disease (CVD).

The efficacy of the drug is modest, but studies of the drug so far have shown up to a 17% reduction in VAT for those using the drug for one year, which must be injected once daily under the skin. There is some evidence that it may lead to increased glucose intolerance and risk for diabetes in certain patients. However, the number of those developing increased glucose intolerance was only around 2-4%. And the question as to whether using the drug could lead to reduced risk for CVD, which was an initial hope, remains unanswered.

Only two weeks earlier, I had figured I would be home in Chicago that day, getting ready for a busy weekend of barbeques and some beach time for the Memorial Day holiday. But following a flurry of e-mails, phone calls, and communications between a core group of advocates that I had been working with closely for several years on development of the drug, I found myself instead at a Marriott Inn at the University of Maryland University College in Adelphi, Maryland.

Initially, when asked by some if I was coming to the meeting, I had said no, for a couple of reasons, not the least of which was the cost of the trip, but also the fact that I had some serious doubts about whether my being there could have any real effect on the panel's decision. This was the first ever Advisory Committee meeting I'd attended, so I didn't really know what to expect. When I asked my friend and colleague Tim Horn, of AIDSmeds.com, what it would be like, his reply was "fascinating, but exhausting."

As usual, he was right.

As the meeting got underway, and I listened to the presentations by the drug's

Years of studies and millions of dollars invested in research and development all boiled down to an eight-hour meeting and 16 votes—with a treatment that had the potential to benefit thousands of people living with HIV hanging in the balance.

sponsor and by the FDA representative about the studies that had been conducted so far, and the safety and efficacy data compiled to date, it quickly became clear that this was exactly where I needed to be.

I had come to testify during the Open Public Hearing portion of the meeting on behalf of the Drug Development Committee of the AIDS Treatment Activists Coalition (ATAC), in support of a letter we had submitted urging the panel to recommend approval of the drug.

I was in awe of the processes of the meeting as they unfolded that day, with all the rules, procedures, and protocols. I was also struck by how years of studies and millions of dollars invested in research and development all boiled down to an eight-hour meeting and 16 votes—with a treatment that had the potential to benefit thousands of people living with HIV hanging in the balance.

I arrived at the meeting location shortly before it started at 8 a.m., signed in, and received a badge designating me only as OPH #3, the third speaker during the Open Public Hearing. When I asked a very personable and helpful federal officer named Rheese why my name was not on the badge, she explained to me that it was to ensure confidentiality as a speaker. She then took the time to tell me exactly how the meeting would play out over the course of the entire day, and the point at which I would be speaking. She helped me put my luggage in a secure area, as I had already checked out of the hotel, and led me to my seat.

There were three public speakers for the day, and we each had been instructed prior to the meeting that we would only be allowed seven minutes to speak. A two-minute warning light would flash at five minutes, and the microphone would be cut off if we went beyond our allotted time.

The day before, I had rehearsed aloud what I was going to say several times and had timed myself—making sure to enunciate clearly and speak at an even pace, providing proper emphasis—and it came in at just under six minutes, so I felt comfortable with the length. But as I practiced, each time that I got to the part of my speech where I talked about the stigmatizing and disfiguring effects of lipodystrophy, I would start to get emotional, so I made a mental note to myself to make sure that it didn't happen on the day of the meeting.

After the morning's presentations and following a lunch break, the Open Public Hearing began promptly at 1 p.m. Debbie, a registered nurse from Florida, went first and spoke eloquently about her life living with HIV for nearly 20 years, the advocacy work she has done, and how the drug had helped her while she was in the study. In a moment of high drama, and as she neared the end of her talk, Debbie removed her pretty lime green jacket and revealed to the committee members and audience the effects that HIV and years of antiretroviral treatment had wreaked upon her body. Unfortunately, once you stop treatment with Egrifta, the visceral fat returns, so you have to remain on it indefinitely to maintain its positive effects. When the microphone suddenly cut off, the committee chair asked her to please continue, and she was allowed to speak until she was finished.

The second speaker, Lisa, talked about how painful it was for her to even just bend over, and how the treatment had helped her as well. She held up pictures for all to see how trim and fit she looked while in the study. I was amazed at both Lisa's and Debbie's strength, and by the great amount of courage it must have taken them to stand up and tell their very personal stories to a room full of complete strangers.

As I sat there listening to both of their stories, I remembered how, when I was deciding on whether or not to come to the meeting, I had wondered to myself, "How much difference can seven minutes really make?" At that instant I knew the answer to my question.

It was then my turn, and I stood up to speak. Sure enough, when I came to the part about the stigmatizing and disfiguring effects from lipodystrophy, my voice began to crack, but I quickly gathered my thoughts, composed myself, and continued on. I spoke about the need for additional post-marketing studies, and what exactly those studies might look like. I ended with the recommendation to the panel that the drug be approved as a medical and reconstructive modality, not as a cosmetic treatment, and that it was no different than breast reconstruction surgery after a mastectomy.

The committee chair and several panel members thanked the speakers for their "moving," "powerful," and "important" testimony. The panel went on with their thoughtful discussion, responding to questions from the chair, and continued to debate the pros and cons of Egrifta throughout the afternoon.

Finally, at 4 p.m., it came time to put it to a vote—the members would be given 20 seconds, at which point their vote would be locked in. You could literally hear a pin drop in the carpeted room. The results flashed on the screen: 16 "yes," zero "no," with no abstentions—unanimous. An audible gasp arose from the room. I choked up once again, and turned and smiled at Debbie and Lisa. Their chance at living a fulfilling life had just been handed back to them and thousands of others—just like that.

After the meeting, representatives from the company, the agency, researchers, and even complete strangers walked up to thank us for our words, and expressed to us how important our testimonies had been. And even though I've thought of myself as an advocate for many years, I learned a very valuable lesson that day about the power and importance of advocacy, what it means, why it's important, and the sacrifices we sometimes have to make to truly be advocates.

It *had* made a difference. It *was* worth it.

Today was a *great* day for people with HIV.

DAVID ALAIN WOHL, MD

READY, SET... *WHEN?*

JUST EXACTLY WHEN THE OPTIMAL TIME IS TO START HIV MEDICATIONS is hotly debated, with the heat supplied by a clash between the need to balance the benefits and toxicities of antiretroviral therapy (ART) and provocative new data pointing to the dangers of uncontrolled replication of HIV. Throw in a tanking economy, an aging population of people living with HIV, and some politics and you have all you need for a When To Start Smackdown. Yet, while much of the indecision regarding when it's best to initiate HIV therapy is a function of history and the gaps in the research data, the debate also reflects the love/hate relationship patients and their clinicians have with ART.

These medications restore health to an extent that few could have imagined even months before the first triple-drug cocktails became available, but it is evident that there are costs in terms of the toxicity of therapies that are intended to be taken for decades. In the absence of definitive data to tell us exactly what to do, deciding when to start taking ART requires us to look carefully at not only where we have been, but also at recent research findings that can be linked to provide a reasonable approach to this old but increasingly relevant question.

ART HISTORY

Treatment guideline recommendations for initial HIV treatment are a barometer of the collective mood regarding ART. In response to the prevailing data and available therapeutic options, these guidelines have vacillated regarding what CD4 cell count should trigger the start of HIV therapy. Early in the epidemic, HIV was often treated much like any other infection, soon after the diagnosis. Unfortunately, therapy at that time was limited to just a single drug, zidovudine (ZDV or AZT), and in the days before viral loads and drug resistance testing, clinicians did not realize they were asking too much, often too late, of this one medication. Studies quickly showed that AZT alone had only a transient benefit and the demise of those who'd been prescribed the drug as a last ditch effort seared questions regarding the safety of HIV medications into the consciousness of the community. [1,2]

In the mid-1990s, of course, additional HIV medications became available and were combined to produce potent regimens. It is difficult to overemphasize the significance of this revolution in HIV care and the effect it had on the willingness to aggressively treat HIV. In the heady days of 1998, when hitting the virus hard with the new powerful drugs was going to be able to keep the HIV genie bottled for good, the U.S. Department of Health and Human Services (DHHS) guideline panel recommended HIV therapy for those with CD4 cell counts above 500/mm.[3] [3]
However, while the success of these regimens in restoring health was dramatic, the enthusiasm for early treatment of HIV was quickly tempered by the disturbing side effects these drugs were discovered to produce. Clinics accustomed to treating AIDS-related opportunistic infections soon found themselves dealing with lactic

The enthusiasm for early treatment of HIV was quickly tempered by the disturbing side effects these drugs were discovered to produce.

acidosis, fat accumulation, dyslipidemia, diabetes, and other "metabolic" disorders among their patients taking the new cocktails. Suboptimal adherence to these twice- or thrice-a-day dosing regimens led to the emergence of drug resistance, some of which was transmitted to others, further dimming the star of these drugs.

At the same time, observational cohort studies demonstrated clear benefits of HIV therapy when started before a fall in CD4 cell count to below 200/mm^3 but less protection at higher counts.[4, 5] Guidelines responded to these data and the emergent suspicion of combination ART by advising a delay of HIV treatment until the CD4 reached 200/mm^3.[6] With additional cohort data showing benefits of HIV therapy when started between counts of 200 and 350/mm^3, the starting line moved to 350/mm^3 [7, 8] and a new standard of care was established—one that some still remain attached to.

In late 2009, the DHHS guideline panel issued an update that recommended that ART be started in patients with CD4 cell counts between 350 and 500/mm^3 after considering some of the data described below.[9] The panel was divided on whether to recommend treatment at counts above 500/mm^3 with half advocating for this recommendation and the other half considering treatment at above this count as optional.

NEW DATA INFLUENCING WHEN TO START

The recent sea change in thinking about ART and its relative benefits and risks can be traced to the early termination of the SMART study, a large clinical trial among patients with high CD4 cell counts randomized to continuous ART versus a CD4 cell count-guided interruption of HIV therapy.[10] With over 5,000 patients enrolled, the trial originally hypothesized that intermittent HIV therapy would protect patients from their adverse effects. However, the trial was stopped after it was found that interrupting therapy significantly increased the risk of opportunistic disease or death from any cause, compared with staying on ART. Additionally, conditions ascribed to ART, including cardiovascular, renal, and hepatic events, were more common in the study group stopping their HIV medications than in the group assigned to stay on their HIV therapy. Subsequent investigations to explain these unexpected findings suggest that the increased levels of HIV during periods of treatment interruptions can lead to activation of the immune system and an internal chemical cascade that produces a generalized inflammatory response.[11] This inflammation, in turn, can damage organ systems, sometimes fatally.

On the heels of this important trial came the results of two large observational cohort studies that enroll and follow large numbers of people living with HIV. The first, the NA-ACCORD, enrolls HIV-positive patients in clinical care in the U.S. and Canada.[12] To gauge the benefit of early HIV therapy, the study investigators examined the survival rates among over 9,000 patients who entered care with a CD4 cell count above 500/mm^3, comparing the outcomes of patients who did and did not start HIV therapy. They found that those who initiated ART above this high CD4 cell count threshold suffered a significantly lower risk of dying than those who elected to wait to start therapy. Similar findings of a survival benefit with ART had been found in an earlier analysis focusing on the 8,000 or so patients with a CD4 cell count over 350/mm^3 when they entered HIV care. So far, mortality data are available for only a subset of participants, but the leading causes of death were not from AIDS in these patients with generally high CD4 cell counts, but were non-HIV-related (such as hepatic, renal, and cardiovascular diseases and non–AIDS-defining cancers). Therefore, HIV therapy, even in people with what we would consider decent immune function, seemed protective against death, especially from diseases not typically linked to HIV infection.

A second observational study, the ART-CC, looked at a cohort of over 24,000 HIV-positive patients, mostly European, and found that deferring HIV therapy until a CD4 cell count of 251 to 350/mm^3 was associated with higher rates of AIDS and death compared to starting therapy in the next highest range of 351 to 450/mm^3.[13] However, there was no significant benefit seen with starting therapy at CD4 cell counts above 450/mm^3, although fewer participants with such high counts were enrolled, reducing the ability to detect differences between these and other CD4 cell groups.

Overall, both of these cohort studies point to an expectation of better clinical outcomes with earlier therapy. However, there are major limitations to observational studies and critics warn that there can be important, unmeasured factors, aside from ART, that could be associated with a reduced risk of adverse clinical events. For example, in NA-ACCORD, those with higher CD4 cell counts initiating ART could be different in some way than those who deferred therapy in terms of healthy lifestyle behaviors, potentially confounding the results. Further, while the relative risk of negative events was higher with the deferral of HIV therapy compared to early treatment, the absolute risk, that is, the excess number of people who actually suffered a worse fate with a delay in therapy, was low, as were the total number of events (deaths and/or progression to AIDS) in these studies.

Randomized, controlled trials, in which participants are assigned to treatment by chance, is considered a more rigorous study design than that of observational cohorts, as they minimize the influence of confounding factors. In a sufficiently large trial, potential influencing factors such as age, gender, socioeconomic status, healthy- and non-healthy lifestyles, should be balanced between study groups with randomization of participants to the study arms. At present, no randomized trial of early versus delayed ART has been completed, although one study (the START trial), enrolling patients

HIV therapy does not necessarily turn the clock completely back to the time before infection, and the point at which ART is started may influence how well it can reverse damage inflicted by HIV.

with a CD4 cell count above 500/mm^3 has recently opened to enrollment.

One randomized trial, albeit looking at those with lower CD4 cell counts, can shed some light on the when to start question. CIPRA HT001 was a trial conducted in Haiti that recruited 816 patients with CD4 cell counts between 200 and 350/mm^3 who were randomized to immediate ART versus ART deferral until a CD4 cell count below 200/mm^3 or development of an AIDS-defining condition.[14] This was yet another study that was stopped early when it quickly became apparent that delaying therapy was associated with a significantly higher risk of death—six in the treatment arm and 23 in the deferral arm. In addition, early ART appeared to be protective against tuberculosis. This study, although conducted in a developing nation and among those with CD4 cell counts below 350/mm^3, provides another data point that, when viewed with others, makes a case for earlier being better when it comes to HIV therapy.

PUTTING IT TOGETHER: VIREMIA, INFLAMMATION AND NADIR CD4 CELL COUNTS

The clinical research studies suggest a consequence of uncontrolled HIV, even at higher CD4 cell counts, possibly mediated by immune activation and subsequent inflammation and organ damage. This is a hypothesis and additional data are needed to confirm that this is the case, but a number of small studies do serve as backup to the tune being sung by the large cohort studies and clinical trials.

It is well known that HIV therapy reduces the levels of HIV in the blood and other compartments of the body and, therefore, the immune system's activation, or level of activity in response to the viral invader. A similar decrease in measures of inflammation are also being seen with ART. In ART treatment trials among patients who had never taken HIV medications, levels of markers of inflammation in the blood, including C-reactive protein (CRP) and a chemical messenger used by cells to trigger inflammation called interleukin-6 (IL-6), were found to fall with the start of HIV therapy.[15, 16] A study conducted by the federally funded AIDS Clinical Trials Group (ACTG) comparing three different ART combinations measured the health of the endothelium of arteries—the inner lining of the blood vessel that not only serves as a barrier but also is very active in sending signals that, among other things, control the size of the artery and its response to stress.[16] Outside of HIV, abnormal function of the endothelium is associated with the development of atherosclerosis. Using a test called flow mediated dilatation (FMD) that looks with ultrasound at the response of an artery in the arm after blood flow is temporarily shut down with a blood pressure cuff, researchers observed that endothelial function improved over the first six months after the start of any of the three regimens studied. Therefore, in these studies, HIV treatment, regardless of type, led to decreases in the markers associated with risk of heart and other organ disease, suggesting that control of HIV leads to improvements in these measures.

However, HIV therapy does not necessarily turn the clock completely back to the time before infection, and the point at which ART is started may influence how well it can reverse damage inflicted by HIV. One recently presented study measuring arterial stiffness (having stiff arteries is not a good thing) among 80 HIV-positive men on ART with undetectable viral loads, found that having had a previous CD4 cell count below 350/mm^3 was associated with having stiffer arteries.[17] Other factors for arterial stiffness included older age, higher blood pressure, and diabetes—well known risks for cardiovascular disease. Another study of over 1,500 HIV-positive patients, using complex testing, looked at cognitive disorders. This study found high rates of cognitive impairment, typically mild, but having a higher nadir (lowest ever) CD4 cell count was protective.[18] These studies share a pattern in which nadir CD4 cell count was associated with less of a benefit of ART compared with earlier treatment of HIV.

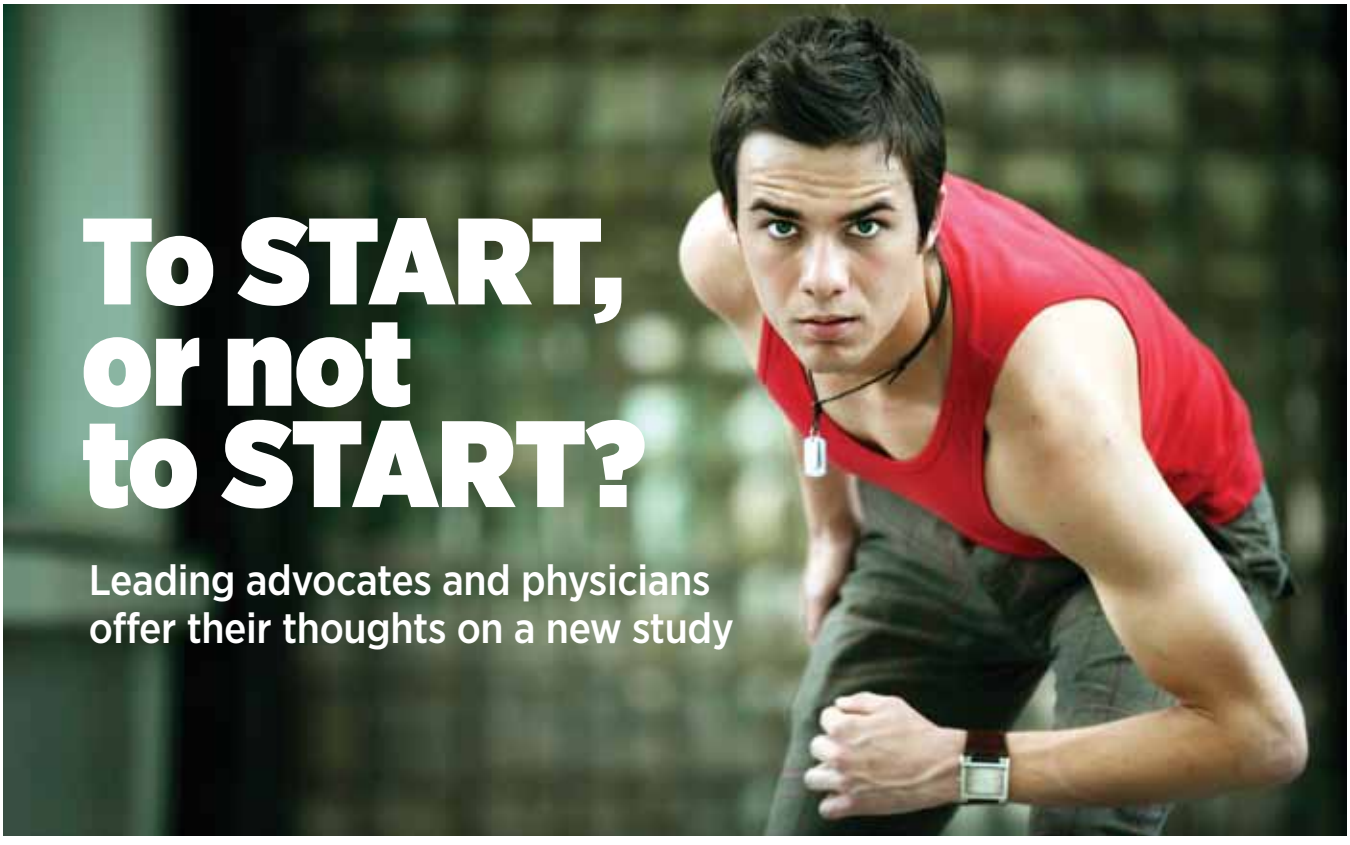
CONCLUSIONS

An increasing number of studies point in the direction of favoring earlier HIV therapy. However, there remain concerns. Truly long-term data regarding the safety of most HIV regimens is lacking, and there are legitimate worries about the effects of these medications on long-term health. Recent studies suggest accumulated effects of ART on bone density, renal function, and cardiovascular disease. However, the question may come down to which is worse, HIV or its therapies. For many clinicians and researchers, the adverse effects of this virus trump those of present-day ART. The SMART trial and other studies are making it clearer that HIV itself does some nasty things to the body and the typically prolonged period from the time of infection to eventual treatment may be when lasting damage occurs—damage that later threatens health and shortens survival. Now that ART has been recognized to be a potent HIV prevention measure there are also public health arguments for more widespread use of HIV therapy.

We do not have a "homerun" of a study that tells us for certain when is the perfect time to start HIV medications. Until we do, those deciding when to start ART can only look to the data we have and connect the dots to see if what emerges is a case for starting HIV medications now or too many questions to do anything else but wait.

Footnoted references are available online.

Dr. Wohl is an Associate Professor of Infectious Diseases and Co-Director of the AIDS Clinical Trials Unit at the University of North Carolina. Metabolic complications associated with HIV infection and the nexus between HIV and incarceration are his major areas of research interest. His e-mail address is wohl@med.unc.edu.



To START, or not to START?

Leading advocates and physicians offer their thoughts on a new study

START (Strategic Timing of Anti-Retroviral Therapy) is a large, six-year international study which will enroll 4,000 treatment-naive individuals who have a CD4 count greater than 500. The purpose of this randomized, controlled study (the gold standard) will be to find out if the chance of developing a serious illness or of developing AIDS is less if patients start taking HIV medicines at a time when their CD4 cell count is still fairly high.

PA asked several leading physicians and advocates to give us their thoughts on START, the pros and cons, and what some of the issues are, especially in regards to enrollment of the study here in the U.S. with the recent changes to the Department of Health and Human Services (DHHS) treatment guidelines on recommending when to start HIV therapy.

To learn more about the study, and to find sites in your area that are enrolling, visit www.clinicaltrials.gov, click on "Search for Clinical Trials," and enter "START HIV".

—Jeff Berry

JOEL GALLANT, MD, MPH
Professor of Medicine and Epidemiology at the Johns Hopkins University School of Medicine's Division of Infectious Diseases, and Associate Director of the Johns Hopkins AIDS Service

A clinical trial to determine when to start ART sounds like a no-brainer. Trials give us definitive answers, without the bias and confounding that plague cohort studies. But will START give us the answers we're looking for?

START will take a long time and will be hard to recruit. People are already divided over the issue—some embracing the "hit early" approach, others wanting to wait. It's a rare combination of clinician and patient willing to put the question up to the toss of a coin, and opinions will solidify further over the next few years. The new guidelines only make it harder to enroll a trial in which participants must be willing to be less aggressive than what is now considered standard of care.

Deciding to start therapy has always been a question of weighing risks and benefits. We know that HIV replication is bad for you, even at high CD4 counts, but starting early didn't make sense 10 to 15 years ago, when treatment had inevitable toxicity. The

The drugs we use today are safer, easier, and more convenient than the ones we used then. Their toxicities may be small compared to the long-term risks of HIV infection.

drugs we use today are safer, easier and more convenient than the ones we used then. Their toxicities may be small compared to the long-term risks of HIV infection.

Speaking of long-term risk, let's say START shows no benefit to early therapy over a five to six year period. Does that prove we should defer ART? Not if you believe that untreated HIV infection has long-term consequences. For decades, we thought of HIV infection as a disease of immunosuppression: your CD4 count fell, and you became vulnerable to opportunistic infections and malignancies. But that wasn't the whole story. Even at high CD4 counts, HIV causes chronic inflammation and immune activation that can increase the risk of diseases we didn't before think of as being HIV-related, such as heart disease and non-AIDS–defining malignancies. HIV replication in the brain can cause cognitive deficits that won't necessarily get better with therapy. Deferring therapy may not cause problems in the short-term, but will it increase the risk of heart disease, lymphoma, or dementia 10-20 years from now? START can't answer that question, so it won't satisfy those of us who believe that HIV infection is always bad for you and should be treated.

Many view the decision to start ART as a decision that requires solid evidence, waiting being the natural default in the absence of data. But is that just an accident of history? In the early '80s we had no treatment. Then we had lousy therapy until the mid-'90s, when we got therapy that was effective but difficult and toxic. It's no wonder we needed clinical trials to prove we should treat people who were doing well. But if we'd had the drugs we have now in 1986, would anyone have insisted on a clinical trial before recommending early treatment? The decision not to treat is still a decision.

Prevention has been a dismal failure: People have abandoned condoms. People who proclaim the virtues of abstinence end up having babies or getting syphilis. Vaccines may be decades away. Circumcision is great if you're a heterosexual African man. Microbicides haven't worked yet, and PrEP isn't ready for prime time. Treating people with HIV may be the best form of prevention we have, and it's the only one that improves the health of the people who use it.

I would encourage those who haven't made up their mind about early ART to enroll in START, and I'll be very interested in seeing the results. In the meantime, I'm taking an "opt-out" approach to antiretroviral therapy; recommending ART unless there's a good reason not to treat.

Dr. Gallant is a member of the DHHS Guidelines Panel. The opinions he expresses in this piece are his own, and do not necessarily reflect those of the other guidelines panel members.

DAVID WOHL, MD
Associate Professor of Infectious Diseases and Co-Director of the AIDS Clinical Trials Unit at the University of North Carolina **(see page 29)**

I think a randomized trial comparing the strategies of initiation of HIV therapy above and below a CD4 cell count of 500, if feasible, would be of great interest. However, there remains the feasibility issue (regardless of guideline recommendations), the cost of this study, and the time until results will flow from such an effort. In addition, we should understand that those enrolling in such a trial may well be somewhat like those who opted to start HIV medication in the NA-ACCORD cohort, that is, folks diagnosed early in infection, motivated to consider starting therapy, and with perhaps better health-maintaining behaviors. Therefore, a randomized trial does not eliminate all biases and may not include those more likely to meet up with hard adverse endpoints (like death).

The December 2009 DHHS treatment guidelines, in my personal view, make it clear that there is considerable debate in the HIV community regarding starting therapy above a CD4 cell count of 500. The panel, like the rest of the world, was split on the issue. Those patients and clinicians who believe the data support a benefit of HIV treatment at higher counts may be less inclined to participate in such a study, as will those who want to avoid and delay therapy until absolutely necessary. Those who are unsure are perfect for the trial and there are many who remain in this category.

Lastly, we should avoid hyperbole and oversimplifications. The recent statements in support of the START trial that are e-circulating have a partisan tone and have made inaccurate assumptions regarding the change in the treatment guidelines that do not serve them or the trial well. The scientific and advocacy communities need to maintain an open mind regarding the when to start question. No one knows the correct answer and it may be that there is not a simple, single answer at all, but a much more complicated approach that takes into account a number of individual variables. Until more definitive data are available, no one should be faulted for taking stock of the information, albeit incomplete, and making a decision on what is best for them or their patient. That is called best judgment.

No one knows the correct answer and it may be that there is not a simple, single answer at all, but a much more complicated approach.

BOB HUFF
treatment activist

According to research presented at the 2010 CROI, San Francisco has already made significant progress in expanding treatment access, which may have resulted in lowering community viral load rates. It makes sense that they press forward to try and achieve even more success. The potential payoff for the campaign would be halting the spread of new HIV infections in the city and surrounding areas—an important and amazing outcome if they succeed.

I understand why some are worried that the professional consensus about when to start treating HIV might shift without a basis in high quality evidence from a clinical trial. People are concerned that the opportunity to enroll and conduct such a trial might be lost—and we will never be sure if the benefits of treating HIV whenever it is diagnosed outweigh the risks. I agree that a large clinical trial (the START study) of this question is essential, but I don't think communities should be restricted from doing what they think is best. And as evidence accumulates that viral suppression restricts transmission, this is a factor that individuals may also consider when deciding to begin treatment.

Randomized, controlled studies are the best way we know to produce evidence to support making critical medical decisions. The evidence about the best time to start treating HIV with antiretroviral drugs is still ambiguous. If immediate treatment prevents cumulative damage from ongoing HIV replication, then the right trial should show that. If the long term use of ARVs is more harmful than the untreated infection, then the trial should shed light on that as well. There are several theories, and many opinions, and some are convinced that early treatment is the way to go. But nothing changes medical consensus as decisively as results from a randomized trial. That's why it is essential that the START trial be given every opportunity to enroll and proceed and why doctors and people with HIV should do what they can to support START. The information produced by START will impact how millions of people with HIV around the world will be treated for decades to come.

The reports presented at CROI on lowering community viral load helped solidify my support for the idea of treating HIV whenever it is diagnosed (and not waiting for a CD4 count trigger). I hope Project Inform also reports on its experiences with communicating what it learns about the range of individual experiences with quality of care, protection of rights, and respect for people with HIV as this program goes forward. If universal testing and treating become the standard of care in the future, other cities and organizations will look to the experiences in San Francisco, Washington D.C., and other pioneer cities to learn what worked and what didn't.

For nearly 15 years, people living with HIV have been pulled in different directions.

TIM HORN
President & Editor-in-Chief, AIDSmeds.com

START naysayers argue compellingly that it takes, on average, three years for someone with HIV infection to progress from 500 CD4 cells to 350 CD4 cells in the absence of treatment. Considering that most people living with HIV will spend decades on antiretroviral treatment regardless of when they start, what difference does three years make?

A big difference, actually.

True, three years seems puny when considering the overall length of time a person will ultimately remain on antiretroviral therapy. But to someone newly diagnosed with HIV, they are three very important years. It is an intense period of adjustment for many people living with HIV—a time to prepare for a long life with HIV and the lifetime of treatment that makes this possible.

More times than not, newly diagnosed people enter care with much more on their plates than an immune-deficiency virus taking up residence in their bodies. Many are still reeling from shock, fear, stigma, and shame. Many have not yet learned to communicate effectively with health care providers. Many still lack a basic understanding of HIV, including its treatment and prevention. Many need to be lined up with vital support programming such as housing, mental health services, and drug addiction counseling. Finally, many need to begin taking appropriate steps to manage risk factors for co-morbidities including diabetes and cancer, along with liver, cardiovascular, kidney, and pulmonary disease.

The onus is on START to confirm, once and for all, whether antiretroviral therapy should be given top billing in the long list of priorities virtually all newly diagnosed individuals face upon entering care. If this randomized, controlled trial confirms profound disease-free survival benefits associated with early treatment—without increases in the risks of side effects, adherence problems, and drug resistance—the heightened priority will be justified. If, however, START ultimately concludes that treatment can be safely delayed until CD4s hit 350, clinicians and patients can remain confident in approaching care in a stepwise fashion.

For nearly 15 years, people living with HIV have been pulled in different directions based on (often persuasive) theories regarding the big treatment questions. START raises one of the most important questions of all. We owe it to ourselves, and to those who will inevitably come after us, to answer it.

CAL COHEN, MD, MS
Research Director of Harvard Vanguard Medical Associates and Community Research Initiative of New England, and Clinical Instructor at Harvard Medical School

Ever since we have had HIV treatment, there has been discussion about the benefits versus the risks and burdens of these medications, such as side effects or changes to lab tests. However, when HIV antivirals were given to people with significant damage to their immune system—as measured by a CD4 count below 200—the benefits of treatment were dramatic and obvious. There was no doubt that someone on antivirals would clearly have a decrease in their chance of developing AIDS-related illnesses and death.

Two things happened. One, better and safer HIV treatments were developed, and two, there was a multi-year era of studying treatment interruption—a strategy designed to preserve the benefits of these medications to the immune system, but also giving the body time off of them to minimize their cumulative side effects. That led to the definitive SMART study—a large study comparing continuous treatment to a strategy of treatment interruptions—using a CD4 count of 250 as the time to restart treatment. It is widely known that this study was stopped earlier than planned, as treatment interruptions using this strategy led to an increase in the risks of serious medical conditions such as heart disease and malignancies. While these events were rare, they were important enough to lead to the now accepted conclusion that once started, it is best to maintain treatment.

So, in the past year, groups of HIV experts met on behalf of the Department of Health and Human Services (DHHS) and reviewed all of these data plus other important studies and came to two conclusions. First, the committee recommended that anyone with a CD4 count between 350 and 500 start antivirals. Second, that while half of the experts felt that anyone with a CD4 count above 500 should start treatment, the other half said they weren't convinced. This should inspire researchers to do the definitive study comparing the two approaches.

But if the guidelines panel all agreed about starting between 350 and 500, why doesn't the START trial change the starting criteria to be in that same range? One answer is that the study is consistent with the panel. But more importantly, the data about starting treatment with a CD4 count above 500 has some important flaws and gaps—and the panelists were split. It is important to note that these same data informed the discussion and decision about what to do between 350 and 500. And just as there are no definitive data with a CD4 count above 500, there are no definitive data between a CD4 count of 350 to 500 either. Thus, the START trial is addressing the data gaps in both ranges and will provide the definitive answer.

Note that for anyone with a CD4 count above 350, the issue in starting HIV treatment is no longer a question about preventing AIDS-related illnesses by starting ART. These are fortunately rare in this higher CD4 range. The question is the issue of serious medical events, highlighted by the SMART study. Will HIV treatment minimize these events in people with these higher counts? This is the focus of the START trial. If most people are likely to be doing well without treatment for a few years, should we still start treatment? And what about the impact of HIV and the timing of treatment decisions on brain function, on bone, on blood vessels, on lungs, and even on transmission of HIV? What about the long-term side effects of even our best treatment now? Is it better to start everyone with HIV on treatment, to provide some benefits for some or maybe all of these outcomes? Or can someone postpone treatment for a few years, and then start with a good CD4 count without having lost any ground by waiting?

The short answer is that we all have opinions about what is best to do now, since without definitive data, this is the best we can do. For some, the answer about starting treatment is that therapy is right for anyone below 500; for others it is anyone at any CD4 count. And either of these may turn out to be the case. If treatment was perfect and all bad outcomes were reduced with treatment, of course we would recommend it to everyone at any CD4 count. But the challenge is to separate what we believe and want to believe from what we will learn from a study, where we can demonstrate the actual benefits and risks rather than just predict what we'd see if we had that study. And that is the role of the START trial. To provide the definitive data so we can move beyond a comparison of opinions and varying certainty, to an era in which we can see what does happen.

The short answer is that we all have opinions about what is best to do now, since without definitive data, this is the best we can do.

ASK THE HIV SPECIALIST

BRUCE RASHBAUM, MD, AAHIVS

Dear HIV Specialist,

I HAVE BEEN HIV-POSITIVE FOR ALMOST FOUR YEARS AND recently decided to go on medication because my T-cells dropped to 334 (they're now back up to 456 with an undetectable viral load).

Since starting my meds a few months ago (Truvada and Isentress), my total white blood cell count went from 6.4A (last September) to 2.8A now, and my neutrophil absolute count went from 3.81A to 1.09A in the same period. Is a decrease in white cells and neutrophils most likely from my medications, or from something else? I am worried that if my white cells are low I might develop some kind of infection or cancer or hyper auto-immune response. Can you help me understand what is happening?

—John

Dear John,

First off, I agree with your doc that you need to be on medication to fight your HIV. In fact, I might have started you sooner. It has been well documented that patients tolerate ARV (antiretroviral) medications better when starting at a higher T-cell count, and they recover T-cells more quickly and typically more robustly when beginning therapy at an earlier stage.

You mentioned that your T-cell number dropped along with the drop in your white cell count. T-cell numbers are actually calculated from your total white blood cell (WBC) count, and so I would expect your number to be lower if your actual white cell count fell. The percentage of CD4s (T- cells) are also measured though, so that while the CD4 number fluctuates with changes in the WBC count, the percentage of CD4s often stays fairly consistent. So I would be curious as to what your percent change was, if there was any.

Neutropenia refers to a low level of a particular kind of WBC, the neutrophil. These cells are important because they help fight against bacterial infections. Severe neutropenia causes increased susceptibility to infections, usually with organisms normally found on the skin, in the nasopharynx, and as part of the intestinal flora. A worrisome value is when the absolute neutrophil count falls to less than 500 cells/mm^3. The only HIV drug that has been associated with neutropenia is AZT. Yet any of the HIV drugs can cause an idiosyncratic or hypersensitive (allergic) reaction, manifesting as a drop in neutrophils.

Isentress has been associated uncharacteristically with neutropenia. Emtricitabine, one of the components of Truvada (along with tenofovir) has also been associated with neutropenia, but these associations are questionable. I think one concern today with HIV management is that even though we have recommended everyone with HIV be considered candidates for therapy, we may be too quick to use the newer agents before their definitive safety data has been more fully established. Isentress looks quite benign, for example, but there are more and more reports of elevated CPKs (a lab finding), muscle pains, and hypersensitivity reactions. Also, the inter- and intra-patient variability with Isentress levels is higher than with any other ARV agent. So if your T-cells continue to fall along with your neutrophil count, I would speak with your doctor about possibly changing your HIV drug regimen.

Neutropenia doesn't only result from medications. Infiltration of the bone marrow with a malignant process, connective tissue disease such as lupus, or an infection of the bone marrow with a virus like CMV (cytomegalovirus) can also lead to neutropenia. Typically there would be other signs and symptoms that would lead a clinician to suspect those types of causes.

With the rapid introduction of new HIV drugs, it is advisable for you or your doctor to consult the manufacturer, a drug information center, or even a poison control center when questions arise related to whether a certain drug may be suspected as a cause of your neutropenia.

Good luck—I hope this information is helpful.

—Bruce Rashbaum, MD, AAHIVS
Capitol Medical Associates
Washington, D.C.

Submit your questions to AAHIVM@tpan.com

Due to space limitations, not all submitted questions can be answered in this column. For more information about AAHIVM, call 202-659-0699 or visit www.aahivm.org.

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SALIENT RAMBLINGS
SAL IACOPELLI

‘A dream is a wish your heart makes...’
—from the Walt Disney film *Cinderella*

IT IS SOMETIME IN THE DISTANT FUTURE, WAY BEYOND WHAT MOST of us imagine.

The concept of race has become a non-existent issue as years have melted into years. Black merged with white. White with brown. Brown with yellow. For most, the idea of race has become antiquated. In the United States, it is no longer a part of consciousness to identify as Italian or Mexican or African or Chinese or Polish or Irish or Korean or Puerto Rican. No one under the age of 20 even knows from which race they hailed. Americans simply think of and refer to themselves as Human, not of any specific distinct and separate race or creed, but as part of one inclusive family. No longer is there the outcry of inequality or bias due to skin color because there is no such injustice. There are finally equal rights in law, in mind, in spirit.

Sunday morning, a bright, clear, azure sky. The warm, smooth scent of fresh Venusian coffee and the comforting buzz of sweet voices lures me from my bedroom into the kitchen. I hug my daughter Sofia and kiss the foreheads of her twin son and daughter. My husband of 51 years, Yamil, rises ponderously, enveloping me in his hairy, heavily muscled arms, tickling my neck with his thick salt-and-pepper beard (mostly salt now) and whispers, “I love you more than stoning Hatanists. More than ridiculing Dogmacrats and voting Humanist.” “And I love you more than mid-20th Century modern furniture, which never goes out of style,” I reply. I sink into a padded wire Eames dining chair with a tall cup of coffee while Yamil flips on the wall tele-screen. President RuPaul IV’s majestic image pops into focus. She is being interviewed by HNN (Human News Network) and is discussing last month’s 100th anniversary of the celebrated HIV eradication mega-pill. ...”what I find astounding,” drones the android reporter-BOT, “is that the cure was actually discovered 10 years earlier and it consists mostly of seaweed and Earl Grey tea leaves.”

“Oh, yes, girlBOTfriend, but the greedy pharmaceutical giants refused to push through testing and approval because it would drastically cut their all-important, soul-crushing profits,” replied our FABulous president.

My granddaughter Max, who is working on her PhD in extinct communicable diseases, couldn’t resist. “100 years ago, what were then referred to as ‘communities of color’ accounted for 65% of the over 50,000 new HIV infections occurring in the United States each year. In females, African American women had a prevalence rate that was 20 times that of non-Hispanic whites. Women accounted for more than one-quarter of new HIV cases while Latina and African American women made up 79 percent of all women with HIV.”

Sofia, who is a Civics and New Government professor, chimed in, “The then lethargic, fragmented, and unaccountable U.S. response to the epidemic, which was a direct result of a non-existent national plan, was largely to blame. Thankfully, that was addressed by President Barack Obama’s visionary leadership and the establishment of his Office of National AIDS Policy.”

I interrupted Sofia and Max, “What is ‘Latina?’ What the hell do you mean, ‘non-Hispanic whites?’ If you insist on speaking in a dead language about dead diseases this early on a Sunday, I’ll need more caffeine.” I turned to my grandson Yaap, “Babe, tune to a different TV station, HIV is so last century.”

An olfactory discussion panel show popped on the screen. The panel hostess (wearing vermillion silk with a fashionably shaved and tattooed head) was discussing the abolishment of the Republican and Democratic parties in September of 2025 with her guests. (The scent of jasmine emanated from the tele-screen.) “That September day truly made this a nation of freedom. Not one month later, world leaders spontaneously disarmed and, for the first time in recorded history, we had global peace.”

A panelist commented, “The savings the U.S. realized amounted to over 650 billion dollars each year. Our Humanistic leaders funneled those billions into services and support people so sorely needed.” (The tele-screen pumped out the sweet smell of freshly mown grass).

“Indeed,” commented another panelist, “and education was given the utmost priority and the system was completely overhauled.”

“And let’s not forget,” chimed another panelist, “that same-sex marriage rights were voted into law, finally becoming part of the Constitution.”

“Have faith in your dreams and someday, someday, your rainbow will come smiling through.”

beepbeepbeep...

... WHOA—well, that’s cool—my penis miraculously grew two inches...

... beepbeepBEEP...

...and each of my ex-boyfriends gained 30 pounds and grew nose warts...

...BEEPBEEPBEEPBEEP...

... and it was discovered that smoking cigarettes is good for you...

BEEPBEEPBEEPBEEP...

... zzzsnort.

I roll over, turn off my alarm, sigh, and get up to face the day.

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