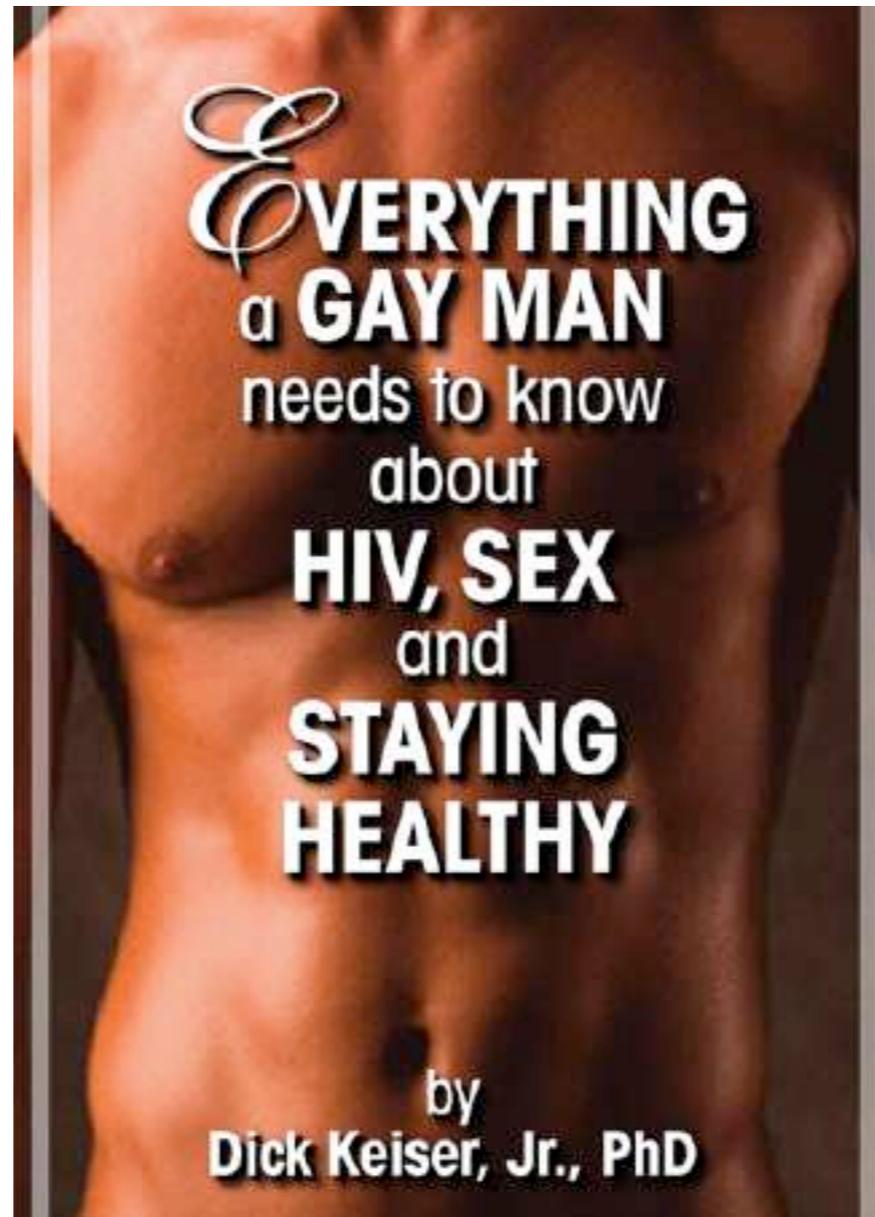
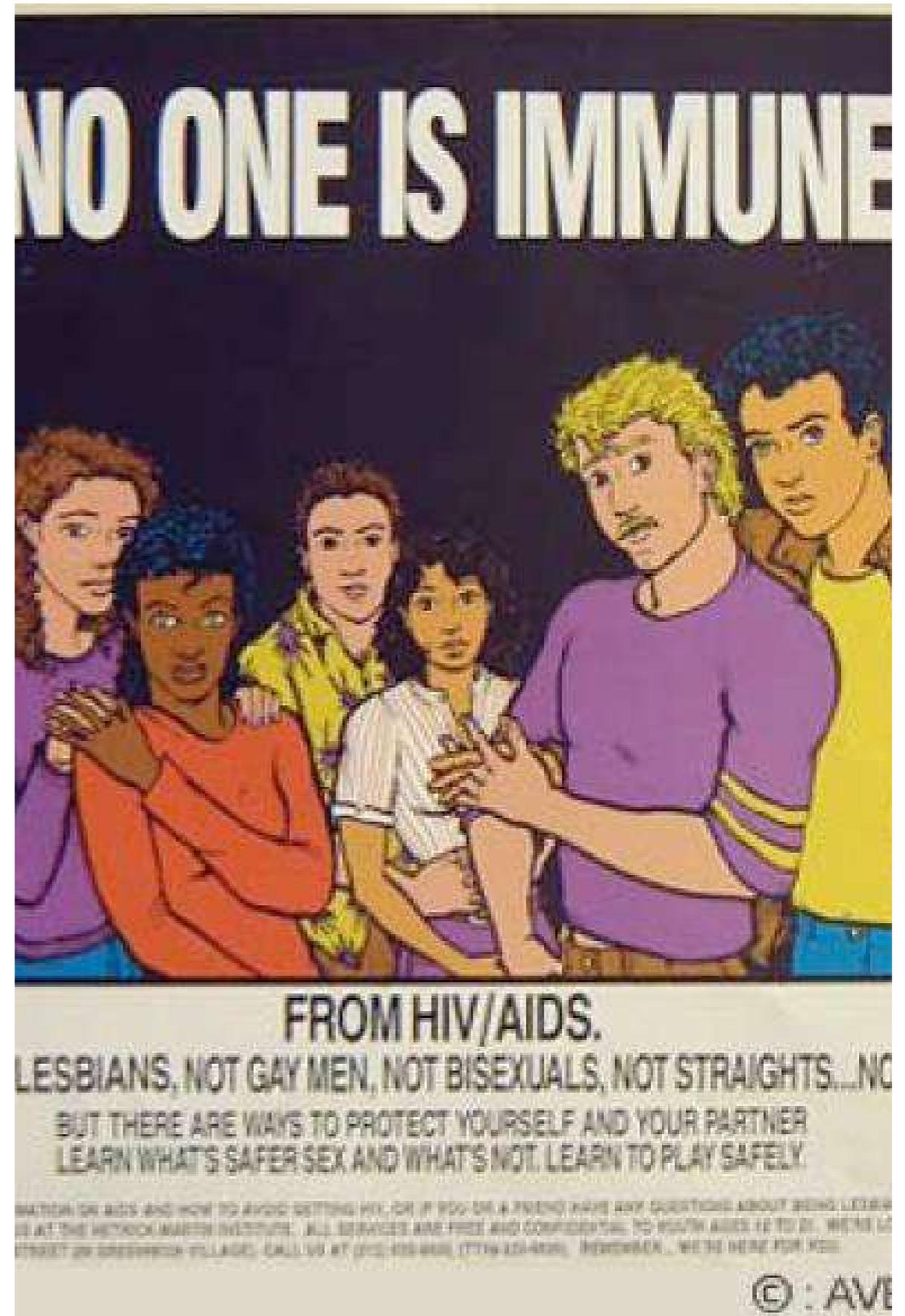


Only 1-2 Pills a day?  
Excerpt from Book



# The New HIV Epidemic and What It Means to You

- AIDS is over HIV lives on
- Polls show most Americans no longer consider AIDS a major problem (2009-2010).
- Social Challenges: Isolation, Rejection, and Depression
- Can you afford to be HIV+? 25K to 40K a year!



# Glossy HIV Drug Ads Mask HIV Reality

Note: These Direct-To-Consumer ads (for all pharmaceutical products) are banned in virtually every country in the world except for the US as being mis-leading!

## ONLY 1-2 PILLS A DAY?

1. Three pages of potential side effects
2. Additional pills and/or treatments to counter the side effects
3. Cost of HIV meds. Can you afford to be HIV+?
4. The most commonly used HIV regime in the US costs between \$14,000 and \$18,000 per year.
5. These are rated as Tier 5 drugs when you look at your insurance copay -- and your copay can be 33% of list cost!
6. HIV is manageable, but presently you must take the drugs for life. Can you comply with taking daily medications and afford this regime?

## Only 1-2 pills a day?

Let's take a look at the reality.



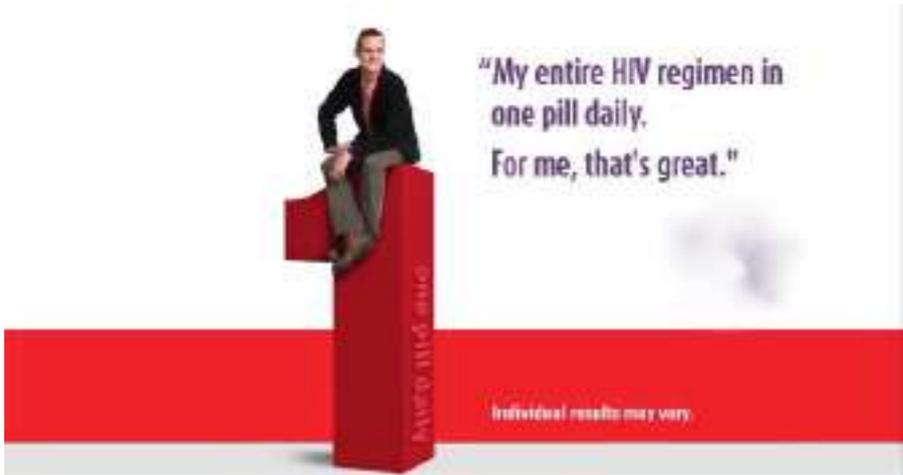
First of all, this is not like taking an aspirin for a headache one time until it is over. It is DAILY MEDICATION FOR LIFE!

By combining 3 HIV medicines into 1 pill taken just once a day, **COMPLERA** reduces the number of pills you may need to take for HIV.



These ads generally show young, fit individuals relaxed and matter-of-factly stating: "My regime is one (or two) pills daily".

And basically imply there is no reason not to be on the meds.



It is interesting that the FDA in 2001 censured the HIV drug companies for misleading advertising. (The Center for Disease Control and

other authors followed up with a progress report published in 2007: Health Aff (Millwood). 2007 Sep-Oct;26(5):1392-8 Direct-to-consumer advertisements for HIV antiretroviral medications: a progress report. Kallen A, Woloshin S, Shu J, Juhl E, Schwartz)

The questions raised in this review are:

- Do the ads accurately portray the treatment regime (is it really only ONE PILL?)
- Do they point out clearly side effects
- What about efficacy (or effectiveness)? Why should I take this pill over another one.
- Do the individuals portrayed in the ads represent the general population? (Virtually all of the ads portray 'paid models' all of whom are young, happy and ripped)

- Do the ads, by their happy-go-lucky approach, trivialize any risk-reduction, undermine safe sex lessons, and thereby encourage more unprotected sex and more infections.
- Are they helpful to the consumer? <Your physical makeup, not the glossy ads, determine which, if any of these drugs, you can take for HIV)
- Do they mention cost?
- Some question whether the ads should be allowed to run at all since the drugs are so new, no long term side effects are known! (or at least wait for a year after they have been out in the general public)

## Side Effects to the Medication

Side effects initially occur as the body gets accustomed to these drugs: generally from 3-weeks to 3 months.

Common side effects:

- Nausea
- High LDL
- Low Testosterone
- Bone density loss
- High Blood Pressure

The endless potential side effects are listed in the 3 pages accompanying each ad, but who reads them? And all the side effects are in fine print.

Lets get a reality check, because I can assure you with only 28% compliance in the US, these pills are not easy to take on a regular basis -- nor do most guys feel "great" that they are these medications for life!

## Is It Really Just One (or Two) Pills a Day?

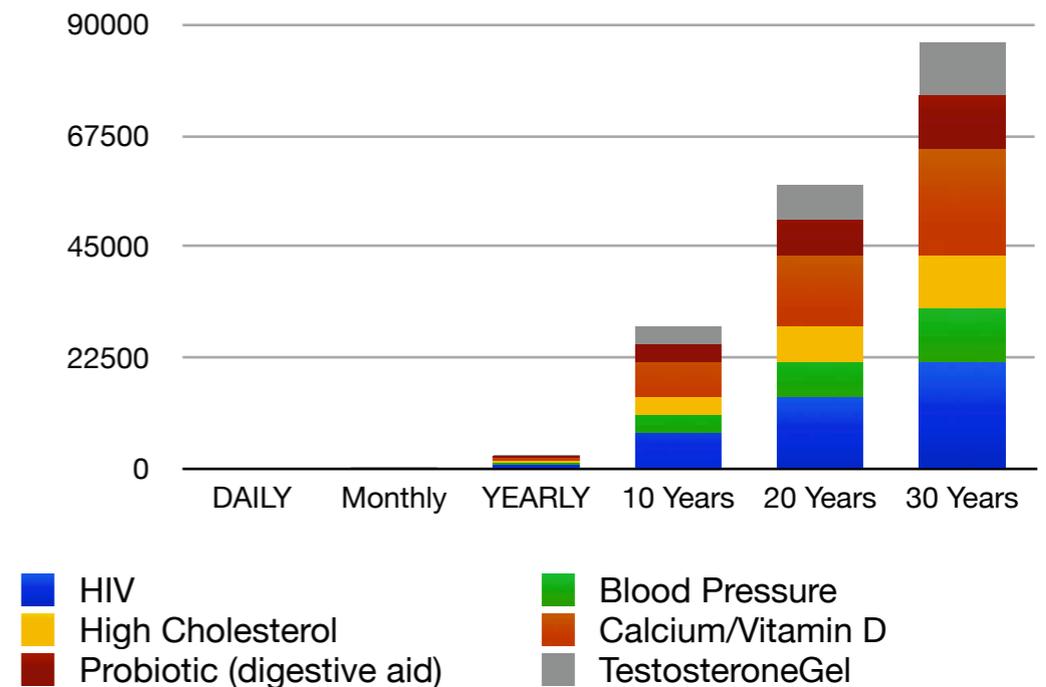
So a more realistic way to look at this is number of pills per year and per decade for HIV and the other medications to counteract the side effects.

Side Effects noted on the Pharmacy scripts for my HIV meds (Truvada + Viramune)

- High Blood Sugar
- Anxiety
- Cough
- Fever
- Generalized pain
- Numbness or tingling in hands and feet
- Peripheral neuritis
- Headache
- Nausea
- Decreased Appetite
- Muscle pain

Note: I personally experience NONE of these noted side effects.

Estimated # of Pills for HIV Therapy and Side Effects



Over 30 years, almost 90,000 pills. Do you want to begin this?

## Cost of HIV Medication - Can You Afford to be HIV+?

Now lets look at cost. Atripla or a similar regime of Truvada + Viramune cost approximately \$18,000 per year. To this add the cost of probiotics (for nausea and upset stomach), medications to counteract high LDL (the bad cholesterol), Testosterone creams or weekly injections, calcium and vitamin D to counteract bone density loss, and medication to counter high blood pressure. And there are other side effects.

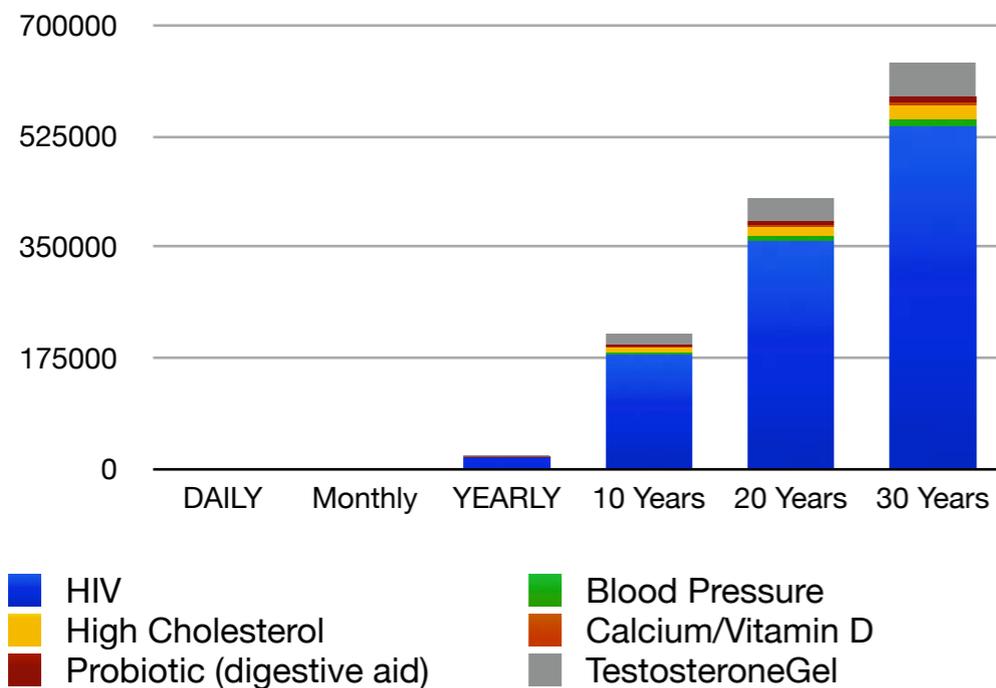
## There are major financial reasons for individuals not to become HIV+!

My first 30 days of Truvada was free. When I went to get it refilled along with Viramune, my copay was over \$600.00 for one month!

I called my doctor's office and said: "I can't afford to live!"

They found a plan that would accept me.

Estimated \$ Cost of HIV Drug Therapy



Over 30 years, the drugs alone will cost over \$600,000. Who will pay?

## Total Cost of Treatment for HIV

HIV treatment is still largely experimental. You must be closely monitored to ensure that the medication is keeping the virus under control.

Monitoring includes:

- Quarterly lab workouts
- Quarterly physicals

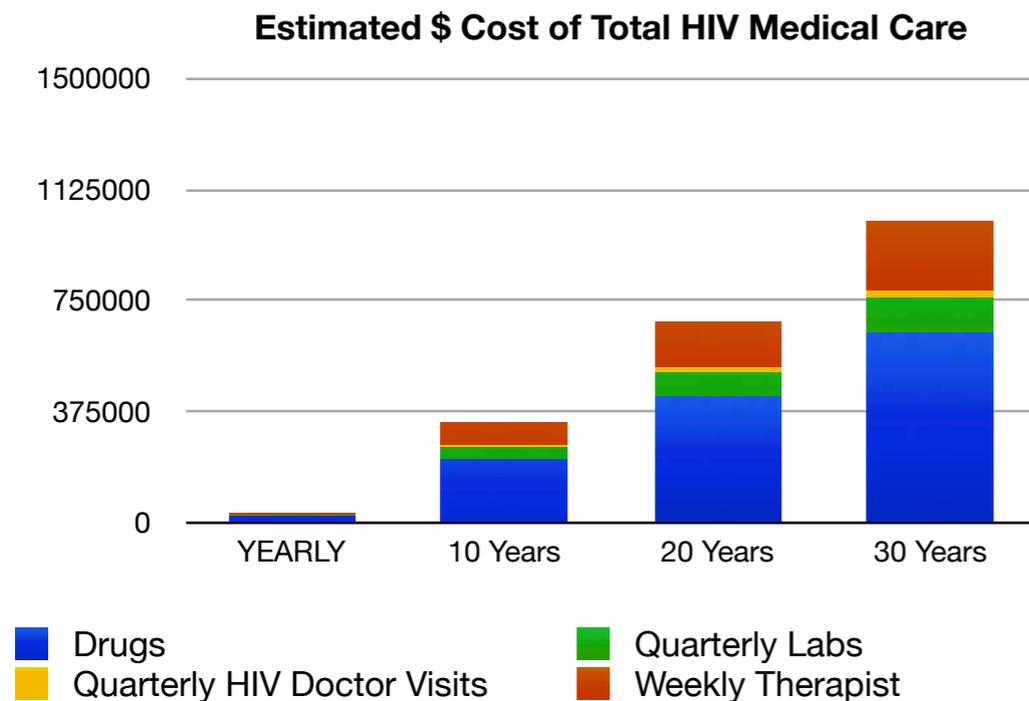
These are **not** inexpensive.

You may also be prescribed weekly therapy visits to adjust to being HIV positive and the associated social stigma that HIV + men experience everyday and possibly be prescribed anti-depressants.

Once you add all of this to the drug costs, life time cost of HIV treatment will easily exceed over \$1,000,000 per individual! If your co-pay is a modest 10%, that calculates to \$100,000!

Recently when I was examining health insurance options under "Open Enrollment", I found that my HIV drugs were Tier 5 drugs which meant, for this new company, my drug copay would be 33% of list or at least \$6,000 a year!

A global survey of HIV + people in 2010 showed that around 40% often felt alone and isolated because they have the virus. (FS Magazine. Listen without prejudice. Issue 124:14-18.)



## Cost of HIV to the US Economy.

This is not the end of the cost of HIV to the US Economy. In 2002, an independent group included lost productivity as a cost and estimated direct and indirect cost for that year alone to be **>\$34 Billion!** (Journal of Acquired Immune Deficiency Syndromes (JAIDS) - Emory University Health Sciences Center).

A more recent study by the CDC in 2009 looked at total lifetime treatment cost per state and calculated over \$16 Billion costs for just infections occurring in 2009. (CDC HIV Cost Effectiveness). The emphasis in the article was that because of these huge costs, it is cost-justifiable to spend more money for early detection. In fact, they estimated that increasing program costs for diagnosis of HIV from \$500,000 to \$37,000,000 actually was cost effective.

Another factor in the total cost of HIV treatment is the increased life expectancy of individuals diagnosed with HIV. From 1996 to 2005, average life expectancy has increased from 10.5 to 22.5 years. (CDC web site: [www.cd.gov/hiv/topics/surveillance/resources/reports/index.htm](http://www.cd.gov/hiv/topics/surveillance/resources/reports/index.htm))

Today, appearance-wise, there is virtually no physical/outward difference between a newly diagnosed HIV + individual and a comparable HIV- individual. However, HIV + individual's medical costs, as we have seen, are not inconsequential. The HIV Epidemic is putting a huge burden on the US health care system.

## Who Is Paying for These Drugs and Treatments?

A large part of the HIV Treatment is covered by US Government programs. Even so, the numbers just do not add up to the estimates presented earlier of total costs. Especially if you realize that the rate of infection has continued at 50,000 individuals a year for the past twelve years.

From an article "Treatment and Care for HIV & AIDS in the United States of America" ([www.avert.org/aids-treatment-america.htm](http://www.avert.org/aids-treatment-america.htm)), come the following information.

In 2008, Medicare paid \$7.5 billion dollars, making it the USA's largest source of public funding for HIV/AIDS. In the US, 1:5 individuals receiving HIV care are 65 and over.

In 2010, the US Department of Health and Human Services released a total of \$4.14 Billion to the Ryan White HIV/AIDS Treatment Extension Act.

The remainder costs are paid for by private insurance companies, somehow absorbed by the various HIV/AIDS organizations, subsidized by the drug manufacturers themselves, or paid for by the individuals themselves.

## How to I Get Help in Paying for My Medications?

### Drug Company Assistance Programs

**Abbott** - Positive Partner PLUS Card

**Boehringer Ingelheim** - Viramue Co-pay Savings Card

**Bristol-Myers Squibb**, another HIV manufacture has a similar program. In 2011, they helped over 250,000 patients with free Bristol-Myers Squibb prescription medicines valued at over \$450 million through donations to the Bristol-Myers Squibb Patient Assistance Foundation as well as other programs.

**Gilead's U.S. Advancing Access® program** provides assistance to patients in the United States who do not have insurance or who need financial assistance. Gilead's U.S. Advancing Access® program provides assistance to patients in the United States who do not have insurance or who need financial assistance.

**Merck & Co.** Isentress Patient Savings Coupong Program

**Tibotec** - Tibotech Therapeutics Patient Savings PProgram

**ViiV** Healthcare - MySupportCard

**ADAP.** AIDS Drug Assistance Programs are a set of programs in all 50-states in the United States that provide Food and Drug Administration-approved HIV treatment drugs to low income patients in the U.S.

The programs are administered by each state with funds distributed by the United States government. They are also administered under state-specific guidelines. As part of the recent health insurance bill, the older language that allows the states to require and AIDS diagnosis (T-cell count <200) before allowing one to enroll in this program persists. Because of this, you are at risk if you live in states with this requirement--primarily the Southern US States..

**The Partnership for Prescription Assistance (PPA) program** is designed to help uninsured Americans get the prescription medicines they need at no or low cost. To find out if you qualify, here's all you need to do:

Call toll-free 1-888-4PPA-NOW (1-888-477-2669).

Know the names of the medicines you take.

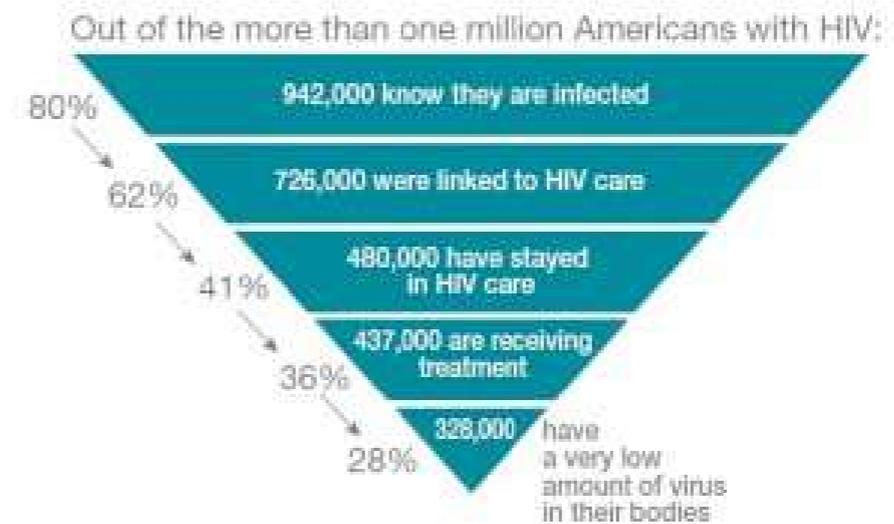
A trained specialist will answer your questions and help you apply. The call center accepts calls in English, Spanish and approximately 150 other languages. You can also visit the Web site at [www.pparx.org](http://www.pparx.org).

**Government programs.** If you do not have insurance, help may be available through:

[The National AIDS Hotline, 1-800-232-4636](https://www.hiv.gov/nahotline)

[Medicare & Medicaid, 1-877-267-2323](https://www.medicare.gov)

[Veterans Affairs \(VA\), 1-877-222-8387](https://www.va.gov)



## Adherence

Current medications do **not** kill the virus. They prevent it from replicating and destroying T-cells. The only thing that is keeping it at bay is the daily medical regime. Unfortunately, in the US, only 28% of HIV positive individuals are following the prescribed routine.

This model was first described by Dr. Edward Gardner and colleagues, who reviewed current HIV/AIDS research and developed estimates of how many individuals with HIV in the U.S. are engaged at various steps in the continuum of care from diagnosis through viral suppression. Their analysis, published in the March 2011 edition of the journal *Clinical Infectious Diseases*, found that along each step of the cascade, a significant number of people living with HIV in the U.S. “fall off”, and only a minority of persons with HIV actually achieve suppression of their viral infection.

The CDC, did a similar study, Their findings, published in CDC's Morbidity and Mortality Weekly Report (MMWR), were similar to those of Dr. Gardner and his colleagues and can be summarized as follows:

For every 100 individuals living with HIV in the United States, it is estimated that:

- 80 are aware of their HIV status.
- 62 have been linked to HIV care.
- 41 stay in HIV care.
- 36 get antiretroviral therapy (ART).
- 28 are able to adhere to their treatment and sustain undetectable viral loads.

In short, CDC estimated that only 28 percent of the more than 1 million individuals in the U.S. who are living with HIV/AIDS are getting the full benefits of the treatment they need to manage their disease and keep the virus under control. Put another way, nearly 3 out of 4 people living with HIV in the U.S. have failed to successfully navigate the treatment cascade.

[For more information on the treatment cascade, read CDC's Vital Signs brief on the treatment cascade and the related MMWR reviewing their own analysis of the proportion of Americans living with HIV at each step in the cascade.]

There are many reasons for non-adherence to medical regimens:

- Not having access to a good Doctor to guide you through adapting to this critical medical regime.
- Crystal meth and other recreational drug use in the gay community. When you are up for days, the last thing on your mind is taking medication
- Alcohol can make one less conscious of the need for medical adherence. In addition, One study found that guys who drank excessive alcohol just skipped their meds because they felt that alcohol interfered with their effectiveness and it was better to just *save* a dose for another day. One study found that 51% became intentionally non-adherent mainly because of the belief that mixing their meds with alcohol was toxic.
- Unavailability of the medications due to the present underfunding in the drug assistance programs
- Cost of the meds
- Side effects out of control. Side effects can seriously impact your motivation to adhere to your medication.
- Drug fatigue -- It is not uncommon in any manageable disease for one to just get tired of taking your meds. In HIV, this can have serious consequences. Set up reminders, manual, cell phone alerts, pill boxes so you can see that you are following your daily routine. This has to be as normal as having breakfast, brushing your teeth.

- Depression - can affect your willingness or dedication to taking your medication on a regular basis

## Short Term Side-Effects

### Lets look at common Side effects of HIV Medications.

Not everyone experiences all or even any side effects from HIV Medications and many will just disappear within a few weeks or a couple of months as your body adapts to the presence of the HIV Virus and the treatment regimen. Remember that there is more than one HIV therapy option. Talk to your Doctor to find an HIV therapy that works best for you.

Common Side Effects include:

- Nausea - Stomach upsets are common. Probiotics to restore digestive health often help.
- High LDL (the bad cholesterol). If your cholesterol rises above acceptable limits and diet change does not work to bring the levels down, you might need to take medicines to better regulate your cholesterol. High LDL is linked to heart disease and heart attacks.
- Bone loss. Recent study found that for young male youths with HIV had 5-8% lower bone density than those not living with HIV. Study concluded that “These finding suggest a short-term impact on bone at ages when people are still growing and building bone mass.”

- Neuropathy. Neuropathy usually causes pain and numbness in the hands and feet. Study found that factors most strongly associated with developing Peripheral Nerve damage were: older age, diabetes, the use of nerve-toxic NRTIs and having a CD4 count less than 200 (an AIDS diagnosis)
- Some of the HIV drugs have been found to block testosterone receptors so the body shuts down testosterone production much as clogged insulin receptors result in diabetes. The level of testosterone in the body affects energy level and sexual libido. It is important to restore your testosterone to previous levels. This is done most commonly through daily testosterone gels or weekly injections.
- Lipoatrophy. Abnormal loss of fat in the face, butt, arms and legs. This was a common side effect of the earlier HIV Medications. These effects are rare with the current medications. Treatment of this condition include the use of natural and synthetic fillers to restore fullness to your face. This treatment is often not covered by your health insurance. If early signs of lipoatrophy occur, talk to your Doctor about switching medications. Strength training can help to build muscle in areas where the fat has gone away.

The unknown long term side effects of HIV treatment is probably one of the best reasons not to become HIV+!

## Long Term Side effects

The drugs have only been available for a few years so long term effects are **unknown!**

## Notes and References

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AIDSMEDS Lessons. Peripheral Nerve Damage Remains Common Despite HIV Therapy. April 13, 2011

All about Lipoatrophy. POZ Magazine Fact Sheet.