



PoWeR Health Solutions

First Issue

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Dear Supporter

We are sending you our first issue of our newsletter. Our goal is to disseminate information difficult to find in other sources. We will strive not to have overlapping information with popular health newsletters out there!



I am concentrating on lipodystrophy in this first issue. I hope you enjoy this newsletter and find it valuable. If you do not find this information valuable to you, please unsubscribe using the link at the bottom of this newsletter.

If you like it and think it can help others, forward it to them using the link at the bottom!

In health,

Nelson Vergel
 Director
 Program for Wellness Restoration
 A 501 (c) 3 non profit all volunteer organization
PoWeRUSA.org
nelsonvergel@yahoo.com

The Biggest Lipodystrophy Survey in the Community- See results to date and participate

TO VIEW RESULTS TO DATE : [lipodystrophy survey results- click here](#)

TO PARTICIPATE IN THE SURVEY:

[Lipodystrophy survey- take part- click here](#)

SURVEY SUMMARY

- Mostly white men, over 45 y.o, more than 15 years of infection
 - Taking meds for over 10 years, most currently taking HAART
 - 96% self reported changes in body shape, : mostly facial and buttock wasting, veiny extremities, and abdominal fat increase
 - Depression and thoughts of suicide in the past were reported by 90% and 23.4% of survey participants, respectively
 - 41 % reported having stopped HIV treatment due to fears of worsening body shape in the past
 - Decreased sexual activity, isolation, and changed clothing style were the most reported changes in behavior
 - Exercise and diet changes were the most reported options used to try to reverse body changes
 - 67% had to pay for interventions out-of-pocket
 - Switching from Zerit to Abacavir or Tenofovir, using Sculptra, and "doing nothing" were the most common options used to manage facial lipoatrophy
 - 91 % reported high lipids now or in the past
 - 33% reported high glucose levels now or in the past
 - 87% believed that HIV meds cause increases in belly fat, and 92 % believed that HIV meds can cause fat loss under the skin
- Many had great comments about where lipodystrophy research should be headed

Are Protease Inhibitors Not the Bad Guys We Thought They Were for Lipodystrophy?

More and more studies are showing the effect of starting naive patients on protease inhibitors plus Viread+Epivir or Emtriva and following those patients up for any body composition changes. A recent study presented at the Lipodystrophy and Adverse Events Conference in Sydney on July 2007 by Dr Andrew Carr comparing Aptivus (Tipravavir) boosted with Norvir versus Kaletra (both arms also on Truvada) found people's **subcutaneous fat did not decrease and, more surprisingly, their visceral (belly) fat did not increase in 48 weeks**. We have known for a few years that thymidine analogs like Zerit (D4T) and AZT be risks factors for lipoatrophy (fat loss under the skin)

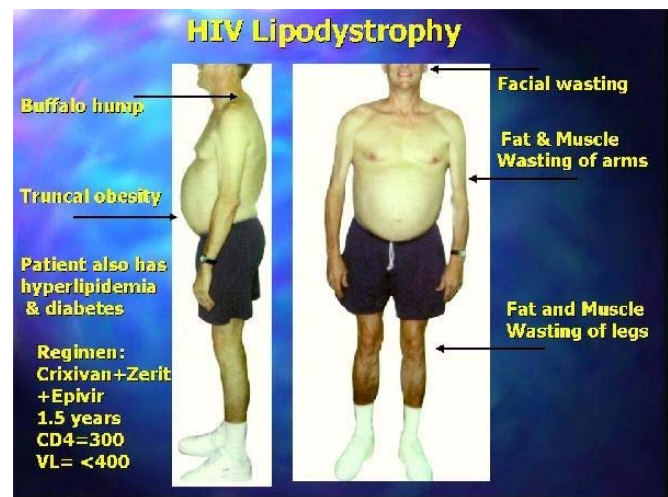
but this is the first study to actually show what happens when we start naive patients on protease inhibitor combinations that do not include these two nucleosides. Are thymidine analogs also responsible for fat gain in the visceral area? Insulin resistance and glucose intolerance was not observed in either arm, although lipids increased in both (with more increases in the Tipranavir arm.)

Another study presented (AGTG 5142) showed that **those who started Sustiva+D4t or AZT had higher incidence of lipoatrophy** than those who started Kaletra plus D4T or AZT. Although we are all familiar with the CNS related side effects of Sustiva, these lipoatrophy data were a surprise to most. More research is being done to try to find out why Sustiva worsens the negative effect of thymidine analogs like D4T and AZT. Does Sustiva increase intracellular levels of those nucleosides? Does Sustiva increase the mitochondrial toxicity induced by AZT and Zerit (D4T)? We will find out eventually.

Lipodystrophy Treatments

by Nelson Vergel

Some HIV+ people experience unwanted body shape changes and metabolic problems. These problems are often grouped together and referred to as [lipodystrophy](#). However, when talking about treatments for lipodystrophy, it is better to look at these problems individually.



The body changes that have been seen in HIV+ people can include:

- Fat gain (lipohypertrophy) in the stomach, breasts, or back of the neck ("buffalo hump"); women are more likely to experience fat gain in the breasts
- Fat loss (lipoatrophy) in the arms, legs, butt, or face (sunken cheeks)

The metabolic problems that have been seen in HIV+ people can include:

- An inability to handle sugar properly (insulin resistance or [diabetes](#))
- High levels of fat (lipids), like cholesterol and triglycerides, in the blood

Some treatments can help with certain aspects of lipodystrophy, but nothing has been proven to resolve all the problems.

More here: [lipodystrophy treatments](#)



After years of research, no lipodystrophy approval for Serostim (made by Serono)

The FDA did not think that the benefits in decreasing visceral fat in HIV positive people outweigh the risks of diabetes, joint pains and hyperglycemia. However, I know this drug works very effectively to decrease belly fat. The problem is that the fat returns when you get off the drug. It is expensive and Serono has made horrible mistakes in the past that have probably costed the company any goodwill they needed for this approval.

Another company going for the same indication (Theratechnologies) should be concerned. Too bad they have done very little to develop community relations in case of any future advocacy needs. More on Theratechnologies' Tesamorelin (TH9507), a stabilized analogue of the growth hormone-releasing factor (GRF) that induces growth hormone (GH) in a specific and physiological manner here: [Theratechnologies](#)

More on the Serostim story here:
[No Lipodystrophy Approval for Serostim](#)

Although I can understand the reasons behind the FDA's decision, it is unfortunate that Serostim did not get approved for HIV related fat accumulation. As you can see by the photos kindly provided by Dr Jon Kaiser in SanFrancisco, this hormone is highly effective at burning fat depots.



Facial Lipoatrophy- Resources

Commonly Used Options for HIV-related Facial Lipoatrophy

PRODUCT	TYPE/SESSIONS	APPROVED?	COST
Sculptra (New Fill-PolyLactic Acid)	Non-permanent 3-7 sessions needed	FDA approved	Patient Assistance for Product only (under \$40,000 a year income). Labor cost avg. \$400 per session. Full price: \$1100 per session for product
Radiesse Calcium hydroxylapatite (CaHA) microspheres	Non- permanent 2-3 sessions needed	FDA approved	Patient Assistance Available \$75/vial- 6-9 vials needed Full Price: \$1200 per session
Silikon 1000 Microdroplets	Permanent- 4-6 sessions needed	Off label use- FDA approved for Intraocular injections to treat CMV- related retinal detachment	No Patient Assistance- \$800 per session
Bioalcamid Poly-akyl-imide gel	Permanent- 1-2 sessions needed	Not FDA approved- Europe, Canada, Mexico, others	\$4,500 avg total
PMMA- polymethylmethacrylate	Permanent- 1-2 sessions needed	Not FDA approved- Mexico, Brazil	\$1200 avg total cost

HERE IS A LIST OF RESOURCES (THERE ARE MANY MORE; THESE ARE JUST THE ONES THAT POWER KNOWS BEST)

Silikon 1000 : [Derek Jones MD](#) or www.resderm.com or <http://www.orentreich.com/> (used off label in the US)

Bioalcamid in Canada (several cities) <http://www.faceforward.ca/> or Mexico (monterrey) send an email to Dr Garza at egarzaskin@yahoo.com (not FDA approved in the US yet)

PMMA in Mexico (Tijuana) email luis_casavantes@msn.com (a similar product approved in the US for cosmetic use, not HIV lipoatrophy: Artefill, but very expensive!)[Dr Luis Casavante's web site](#)

Metracryl in Rio De Janeiro (not approved in the US): Dr. Marcio Serra drmarcio@clinicamarcioserra.com.br and web site <http://www.clinicamarcioserra.com.br/>

Sculptra : <http://sculptra.com/US/Index.jsp> (FDA approved for HIV lipoatrophy). Patient assistance available (free product for those under \$40,000 a year income), ask a doctor in your area by finding him/her in the Sculptra web site using your zip code. Dr Doug Mest (DrMest@aol.com) in Hermosa Beach, CA and Dr Gervias Frechette (GERVAISFRECHETTE@aol.com) in NYC and San Francisco, have a lot of experience and have trained many of the US doctors for Dermik over the past two

years with over 1600 patients.

Radiesse: radiesse.com (FDA approved for HIV lipoatrophy). Partial patient assistance available. Email nelsonvergel@yahoo.com for more details on the program.

More information on these products in [FACIAL WASTING](#), one of our web sites

For buttock wasting reconstruction photos: [Buttock Reconstruction](#)

Share Your Experiences With Others- Help us to create a provider's list

We are trying to generate a list of providers who have a good track record treating HIV facial wasting, performing buffalo hump/neck liposuction, and other procedures that may help improve body changes in HIV.

Please help us by filling out this quick form

[EXPERIENCES WITH LIPODYSTROPHY PROVIDERS- CLICK HERE](#)

We will make this list public in our web site facialwasting.org and our 2600 people [pozhealth at yahoogroups.com](http://pozhealth@yahoo.com)

Thank you to all who participate!

Watson drops nandrolone (Deca Durabolin) and Savient stops helping low income patients on Oxandrin. But other source options have emerged...

By Nelson Vergel, Program for Wellness Restoration

The current terrain for wasting patients in the era of HAART

On March 20, 2007, Watson Laboratories stopped the production of nandrolone decanoate (old brand name: Deca Durabolin), a low-cost injectable anabolic steroid used for HIV wasting, citing the lack of raw-material suppliers for the product. Patients found out when they went to their pharmacies for a prescription a week later.

For more on the story:

http://www.gmhc.org/health/treatment/ti/ti21_1.html

For more information or to find out how to get involved, please [VISIT THIS LINK](#)

More info about this and about other sources of nandrolone in the US can be found at <http://savehivwastingmeds.blogspot.com/>

Compounding Pharmacies making nandrolone for those with a prescription:

Name	Address	Phone number	Web	Cost per ml of Nandrolone (200 mg/ml)
Applied Pharmacy Services	3207 International Drive Mobile, AL 36606	877-729-1015	www.appliedpharmacyrx.com	\$9.50 per ml in a 10 ml multi dose vial or \$9.75 per ml for a 4 ml multi dose vial or \$10.00 per ml in a 1 ml vial
The Compounding Shop	4000 Park St. N St Petersburg Florida 33709	866-792-6731	www.gotocompoundingshop.com	\$12.00 per ml in 10 ml multi dose vial
Collage Pharmacy	3505 Austin Bluffs Parkway, Suite 101 Colorado Springs, CO 80918	800-888-9358	http://collegepharmacy.com	only available as a 10 ml multi dose vial for \$94.75 this is for 200 mg/ml, this compounder also offers 100 mg/ml
Kronos Compounding Pharmacy Now sold to AnazaoHealth	3675 S. Rainbow Blvd. Suite #103 Las Vegas, NV 89103-1059	800-723-7455	www.anazaohealth.com	\$26.50 per ml for a 10 ML vial

Patients who fail Androgel and Testim reach adequate testosterone blood levels with cheaper gels

Androgel and Testim are 1 % testosterone gels approved by the FDA for the treatment of hypogonadism in men (testosterone deficiency). However, a substantial number of men using these products do not reach the desired total testosterone blood levels of 500 nanograms or more required for best quality of life and libido. Many of these patients have tried 10 % gels manufactured by compounding pharmacies for under \$50 a month. Testim and Androgel cost more than \$600 a month. Contact the pharmacies listed above for more details.

US AIDS DRUG ASSISTANCE PROGRAMS- HORMONE AND WASTING DRUG AVAILABILITY IN THE US

State	Nandrolone	Oxandrin	Testosterone Injection	Patches /Gels	Anadrol	Serostim
Alabama	no	no	no	no	no	no
Alaska	Yes	Yes	Yes	Yes	no	no
Arizona	Yes	Yes	Yes	Yes	no	no
Arkansas	no	no	no	no	no	no
California	Yes	Yes	Yes	Yes	no	Yes
Colorado	No	No	No	No	No	No
Connecticut	no	Yes	Yes	Yes	Yes	no
Delaware	Yes	Yes	Yes	Yes	Yes	no
DC	no	Yes	no	no	no	no
Florida	Yes	Yes	Yes	Yes	no	no
Georgia	Yes	no	Yes	no	no	no
Illinois	NO	NO	NO	NO	NO	NO
Indiana	Yes	NO	NO	NO	NO	NO
Iowa	No	No	No	No	No	No
Kansas	No	Yes	No	No	No	No
Kentucky	No	No	No	No	No	No
Louisiana	No	No	No	No	No	No
Maine	No	No	No	No	No	No
Maryland	Yes	Yes	Yes	Yes	Yes	no
Massachusetts	No	No	No	No	No	YES
Michigan	No	Yes	Yes	yes	no	no
Minnesota	No	No	No	No	No	No
Mississippi	No	Yes	No	No	No	No
Missouri	No	No	No	No	No	No
Montana	No	No	No	No	No	No
Nebraska	No	No	No	No	No	No
Nevada	Yes	No	Yes	No	No	No
New Hampshire	Yes	Yes	Yes	Yes	Yes	No
New Jersey	Yes	Yes	Yes	Yes	Yes	Yes

New Mexico	No	No	No	No	No	No
New York	Yes	No	Yes	No	No	No
North Carolina	No	No	No	No	No	No
North Dakota	No	No	No	No	No	No
Ohio	No	No	No	Yes	No	No
Oklahoma	No	Yes	Yes	No	No	No
Oregon	No	No	No	No	No	No
Pennsylvania	No	No	No	No	No	No
Puerto Rico	No	No	No	No	No	No
Rhode Island	No	No	No	No	No	No
So. Carolina	No	No	No	No	No	No
So Dakota	No	No	No	No	No	No
Tennessee	No	No	No	No	No	No
Texas	No	No	No	No	No	No
Utah	No	No	No	No	No	No
Vermont	No	No	No	No	No	No
Virginia	No	No	No	No	No	No
Washington	No	No	Yes	No	No	No
West Virginia	No	No	No	No	No	No
Wisconsin	No	No	No	No	No	No
Wyoming	No	No	No	No	No	No

Since Watson stopped the production of nandrolone, the states that were providing it for free to patients with no insurance and low income will have to stop doing so. ADAPs do not work with compounding pharmacies yet. Most ADAPs will spend more money substituting Oxandrin for nandrolone at 10 times the cost.

Are most HIV+ people in the world doomed to be exposed to body changing, metabolic unfriendly nucleosides?



A new report by Médecins Sans Frontières (MSF) shows dramatic price reductions for second-line antiretroviral treatment over the last year, largely stimulated by a compulsory license issued by Thailand. But the report also identifies a worrying trend: using the newer, **less-toxic first-line combination, now recommended by the World Health Organization, raises the cost for patients by nearly 500%, from US\$99 to up to US\$487.** The report 'Untangling the Web of Price Reductions' was released by MSF at the July 2007 4th International AIDS Society Conference in Sydney

"It's encouraging to see the price of second-line regimens finally starting to come down," said Karen Day, pharmacist with MSF's Campaign for Access to Essential Medicines. "But we are worried that the lack of competition and dramatically

higher prices for the newly-recommended WHO first line could mean that people in developing countries may not be able to benefit from improved treatment that has been widely available in wealthy countries for years."

An MSF analysis of Brazil and Thailand's efforts at providing universal access to antiretroviral therapy shows that compulsory licenses have been far more effective in bringing prices down than negotiating price reductions with companies or relying on companies' differential pricing schemes.

Another concerning problem is that **Tenofovir (Viread), a more metabolic friendly nucleoside than Zerit or AZT, is registered as of June 2007 in only 25 of the 97 countries** that Gilead deems eligible for its preferential prices. Also, **Tenofovir has not been tested in children**, despite urgent needs to prevent lipodystrophy and metabolic complications in vulnerable population. For more information, please read these two links:

[Click here for full statement](#)

[Click here for Untangling The Web:10th Edition](#)

Metabolic/Body Friendly HIV Regimens? We need data!

After 11 years of HAART, we have learned a lot about the effect of different medications on body composition, insulin resistance/glucose tolerance and lipids. But we still lack data on several D4T/AZT-free combinations. We urge companies and private investigators to study the following regimens and follow up people with DEXA, MRI and/or CT scans to determine body composition changes, if any, in treatment naive patients. Also, we are lacking "switch" data from boosted protease or Efavirenz based regimens that use thymidine analog backgrounds (D4T or AZT) to regimens with more metabolic friendly nucleosides like Abacavir or Tenofovir. I certainly hope that the upcoming 5 years bring more knowledge on this important issue.

Are these "friendlier" combos to start a naive patient or switch to from "metabolically unfriendlier" combos?

- Viramune (Nevirapine) + Truvada (Tenofovir + Emtriva)
- Isentress (raltegravir) + Truvada (we have some lipid data, but no body composition)
- Boosted Reyataz+ Truvada or Epzicom (it is unclear if visceral fat increases, but people assume that Reyataz does not cause lipohypertrophy due to its lower incidence of increased lipids. This association may not be correct and we need data to confirm this)
- Kaletra (or other boosted protease inhibitors) and/or Viramune and/or Isentress and/or Maraviroc without a nucleoside background vs a Truvada or Epzicom background
- Etc

I also think the FDA should require subset data on NDA (new drug application) submission for any drug approval. Currently, most of these data are not obtained until phase IV studies. We need to be careful about assuming that because a drug may not increase lipids, it has no body changes issues.

A Testosterone injection good for 3 months to be approved soon in the US

Indevus Announces Submission Of New Drug Application

29 Aug 2007

Indevus Pharmaceuticals, Inc. (Nasdaq: IDEV) announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for NEBIDO(R) (testosterone undecanoate) intramuscular injection, a long-acting testosterone therapy intended to treat male patients with primary and secondary hypogonadism. **Each 1000 mg injection of NEBIDO would only need to be provided once every 12 weeks, as compared to the current injectable therapies which typically require an injection every two to three weeks.**

The U.S. testosterone therapy market is currently estimated to be in excess of \$550 million. Of the approximately 340,000 men currently receiving therapy, approximately 130,000 utilize the existing injectable therapies that must be given every two to three weeks.

For more on the story: [long acting testosterone](#)

Lipodystrophy Resources

Best web site about hormones, supplements, and exercise for HIV+ people : MEDIBOLICS.COM

Bring a PoWeR lecture to your city!: [Treatment education lectures](#)

Best web site that show exercise routines: EXRX.NET

Best web site about facial wasting: FACIALWASTING.ORG

Best general information about lipodystrophy: THEBODY.COM

Best Internet discussion group : send a blank email to pozhealth-subscribe@yahoogroups.com or visit their archives at [POZHEALTH ARCHIVES](#) (YOU CAN ALSO TYPE ANY TERM IN THE SEARCH BOX PROVIDED)

Best nutrition book by one of the best dietitians in HIV: [EAT UP BOOKS](#)

Nelson's Blog : [Surviving HIV](#)

PoWeR's book: [Built to Survive](#)

HIV Buyers Clubs for Nutritional Supplements:

[Houston Buyers Club](#) ,

[New York Buyers Club](#)

Atlanta: email info@aidstreatment.org

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