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About Me:



Dr. William Rassman, Medical Director and Founder of the [New Hair Institute](#).

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Archived Entry:

Post Date:

Oct 30, 2008 at 11:32 am PT

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FDA Warns Gaunitz About the Hair Laser They Market

October 30 2008, 11:32 am PT | Posted in: [Hair Products](#)

Just a couple weeks ago, the FDA published a warning letter sent to the makers of the LaserComb (see [here](#)). Now, a reader sent in a new find on the FDA website — a warning letter to another laser company that shows they are selling a product or service that is in violation of the law. [The letter](#) starts off...



Dear Mr. Gaunitz :

The Food and Drug Administration (FDA) has learned that your firm is marketing the THL-1™ Handheld Laser in the United States (U.S.) without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Another laser, another violation. Read the entire document at the FDA site — [here](#) .

Tags: [laser](#) , [fda](#) , [gaunitz](#) , [thl-1](#) , [thl1](#) , [erchonia](#) , [handheld laser](#) , [hairloss](#) , [hair loss](#) , [warning](#)

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Balding Forum

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16 Comments

1. [Daniel Knepshield](#) - October 30th, 2008 at 12:40 pm

I am still trying to remain open-minded about the potential of these devices to aid hair regrowth or, at least, slow down its progression.

This Gaunitz device; however, is the biggest scam in the market. The device sells for \$2,499.95!!! That's right, the price is not a misprint! The sad thing is the device contains only ONE laser diode that you can buy from any electronics supply-house for about ten dollars! One measly laser, that's all you get with this piece of junk. For anybody that can't appreciate the gravity of what I just pointed out, consider the fact that the HairMax sells for about \$500.00 dollars and has nine laser diodes. Most people consider the HairMax seriously overpriced. The Gaunitz has one diode (of the same power and class) and sells for two thousand dollars more!!!! Truly unconscionable...

The really sad thing is a certain well known transplant doctor (not Dr. Rassman, btw) sells this thing on his web site. I think his fellow doctors should shame him into stopping.

2. [William Gaunitz](#) - October 31st, 2008 at 9:27 am

If you knew anything about laser diodes, you'd know that the laser diode is only as good as the module the runs it. Laser modules can not just be purchased at Radio Shack. A diode can be purchased for \$.50, but a good module will go for \$350. The laser module in the Erchonia THL-1 laser is specially designed for Erchonia's medical applications and is used in almost all of their FDA medical devices.

Erchonia Medical, who created the device, sells a 2 diode line generated beam medical device globally to medical practitioners for \$16,000. That device, the PL5000, is the same wavelength and intensity as the THL-1 Handheld Laser. The PL5000 was used by Lance Armstrong during his final Tour De France to expedite wound healing and cellular recovery. This function is the same for the hair follicles.

The Erchonia Medical was the first Medical Device Manufacturer to have any Low Laser Therapy Device FDA approved for effectiveness. They are the cutting edge of the medical low level laser therapy industry. <http://www.erchonia.com/default.asp?contentID=51>
Try it, before you bash it.

3. [LAZERFISH](#) - November 1st, 2008 at 4:20 am

Mr. Gaunitz. I do know something about Laser diodes. It seems that you don't.

A 5mw laser, especially one that is Line Focused is too weak to even reach the hair follicle. Your laserComb uses lasers in the 635nm range. The accepted frequency for hairloss is 650nm. I could care less if you say Lance Armstrong used an Erchonia laser or not. For your information, the standard frequency for deep wound healing and deep pain relief are lasers in the 780nm and above range, approaching infrared.

Most physicans don't know squat about laser therapy so they are willing to drop 16K for 10 mw of power. The saying is definitely true that A Fool is Born Every Minute!!

ONE 5mw laser is about as effective as a screen door on a submarine.

You know something, you and other lasercomb makers should be ASHAMED of yourselves for selling your laser devices at such an outrageous price for such a scrawny amount of power. You are taking advantage of balding men's weakness to try anything to grow hair.



I have checked out your 5 step program too! Basically useless except for the Propecia and Minoxidil and the laser hood (not your handheld). You are charging an outrageous price for things that a man can pick up at their nearest pharmacy for a fraction of the cost. Your site even talks about financing as if your buying a house or something..LOL!

2500USD for a 5mw Laser Comb!!!! Shame, shame, shame on you sir!

Mike
LAZERFISH LLLT.

4. [Gary](#) - November 3rd, 2008 at 9:48 am

Mike,

I have gone through the Gaunitz process and have regrown 90% of my hair and am sick of hearing all this back and forth about cost and laser this and that, I did my research, I went through the program, I use the handheld daily...it works! The company has been around for years, they have two clinics in Arizona, everyone loves what they can do for us balding people. Its not a scam, I'd never spend \$2500 on something if it didn't work, you only use it for 4 minutes a day and its not a laser comb..please try it first and then form your radical opinions on your competition.

Gary

5. LAZERFISH - November 3rd, 2008 at 4:27 pm

You've grown back 90% of your hair eh?? What were you, a Norwood 1 to 2, LOL??? Sorry to burst your bubble but NO TREATMENT PROGRAM on the planet can grow back 90% of a bald man's hair.

I don't believe you. Using a 5mw laser comb for only 4 minutes WILL NOT deliver the required amount of laser Energy for the bio photo stimulation to take effect.

ONE 5 mw laser whether a 2USD or 2500USD (LOL) one delivers NO MORE than 5mw of laser power...TOTALLY USELESS!

If you grew some hair back, you could have gotten the same results for a fraction of the cost just getting things from a pharmacy yourself and building your own laser Unit. I think it's time to bring this debate to the forums. See you at <http://www.regrowth.com>

Lest I repeat myself, Shame, shame, shame on you Gaunitz for selling a 2500USD 5MW Laser Comb!!

6. [OverMachoGrande](#) - November 3rd, 2008 at 5:50 pm

I wholeheartedly agree with Lazerfish. It is absolutely shameful to sell a device that is so underpowered/overpriced like a ONE DIODE laser brush for \$2,500. And before you start... yeah, I know QUITE A BIT about diodes myself, too.

...And if you have MBP (and not some chemical/medical issue), you don't grow back 90% of your hair with ANYTHING if you've been balding for any significant amount of time. PERIOD.

So, the "hair loss industry" is truly in a crisis state -as it has been for years- and the laser aspect is no different. That is a true shame since this is a treatment that shows so much promise. The true problem here is that on one side, you have "doctors" like certain un-named hair transplant surgeons that make bogus videos based on junk science entitled "Why LLLT Can't Work". On the other side, you have companies selling an almost criminally overpriced product that won't deliver anything close to the 3-6 joules range that you need, or laser clinic "doctors" that charge thousands and thousands of dollars for treatments that should be a couple of hundred at the most.

So who wins in this scenario?? NOT THE CONSUMER, that's for sure. The consumer gets misinformed completely and gets hosed out of hard earned money. At least with a laser clinic, yes, you are spending too much money... but it's on something that WORKS, unlike a one 5mW diode laser brush. I really can't even believe that I'm having to make a post like this since this concept is SO RIDICULOUS.

The only people that win here are the people that have taken the time to educate themselves about what it takes to get results from lasers, and what that should cost. THANK GOODNESS that more and more people are educating themselves so they don't fall victim to either one of the LLLT industry's sharks.

Thanks for the warning about this. Indeed.. this *is* something that needs to be brought to as many people's attention as possible. The forums shall be informed.

-O.M.G.

7. Nidhogge - November 4th, 2008 at 8:19 am

To achieve the biostimulation necessary for positive hair results, 10 to 30 minutes of treatment time with 650nm diodes is required. This will provide three to six joules of energy, which is the scientifically accepted range for biostimulatory results.

The Gaunitz device has an insane markup value, and is an attempt to capitalize on the desperation of a balding man. I suggest folks visit OverMachoGrande.com, a not-for-profit site that teaches you how to build your own laser helmets with the same diodes that are used in the clinical devices, except at a fraction of the price. Everything that you could possibly want to know about lasering and hairloss can be found on that resourceful site.

Don't buy into Mr. Gaunitz propaganda. I don't have a commercial interest—he does.

8. Ace - November 4th, 2008 at 12:10 pm

I purchased the hand held laser for \$2000 at The Scottsdale Gaunitz hair growth center at the beginning of the year. I was actually stupid enough to finance it through care credit, paying \$50 per month. So because Gaunitz violated fda laws in marketing this, do I have a chance of receiving a refund?

9. [LAZERFISH](#) - November 4th, 2008 at 4:45 pm

Ace, I feel for you brother. You should contact Gaunitz and demand a refund. Good Luck! Gaunitz has the chance right here to prove that they are a reputable company by offering you a refund on a product that they knowingly sold to you under false pretenses. Keep in contact!

Mike

LAZERFISH LLLT

10. [gary](#) - November 7th, 2008 at 10:34 am

Again, you guys can go and state what you want in regards to lasers and how much better your product is. I grew most of my hair back and no I wasn't Type 1 or 2...I was type 3 vertex going on 4. It doesn't really bother me what any of you say can or cannot be done, I'm living proof. I'm just here to give my opinion on a product that I've tried. I'm not here to sell my own product like some other people on this post. I'm just here to give the honest truth about the THL-1. It works..period. If you don't have the money, don't buy it...simple!

Gary

11. Daniel Knepshield - November 7th, 2008 at 1:51 pm

Gary,

Nobody is here trying to sell anything, except those promoting the Gaunitz laser. Even in your previous post, you encouraged people go out and try it. The post from Mr. Gaunitz reads like a piece of ad copy. You either sound like someone who works for the company or someone desperate to justify their decision to spent \$2,500.00 on a glorified laser pointer.

The only reason Mike from LazerFish even posted here, was not to promote his product, but because I asked him to post here.

I was the person who wrote the first comment. When Mr. Gaunitz responded, I knew that I did not know enough about lasers myself to engage into a debate, so I asked Mike from LazerFish to come here and lend his expertise. Mike hasn't once promoted his product, nor has he even mentioned it....to me, that shows a lot of class. OverMachoGrande also has a website promoting lasers, but he does not sell anything. His site is non-commercial. The only thing he "sells" are the benefits of laser therapy. A quick review of all the comments easily shows that nobody is here promoting anything except the Gaunitz people. Your accusation appears to be an attempt at misdirecting people away from the real issue and the result is a FAIL.

I am not convinced that lasers for hair regrowth have been conclusively proven to have any benefit. That being said, I am open-minded in regards to their alleged benefits and use a handheld device myself. The Gaunitz device, however, just cannot possibly provide any benefit. The Gaunitz handheld laser has the unique distinction of being the most expensive handheld device in the entire industry (about 3 times more expensive than the second most expensive) and also being the LEAST powerful!!! It is, in terms of power, the equivalent of a ten dollar laser pointer dressed up in fancy housing with a few bells and whistles and being sold for an unconscionable amount. The effect of its power on the scalp to provide any sort of bio-stimulation is null. The Gaunitz does not even use the correct laser frequency that is recommended by the overwhelming majority of laser advocates. Bottom line: The device does not deliver on any level...power, frequency or value.

As far as your claims about your hair regrowth...I do not believe you either. You say that you grew back

90% of your hair. 90% of what? It is misleading and meaningless to quote percentages without giving the numbers that the percentages are derived from. For example: A seller of a sham diet pill could say his product caused people to lose 500% more weight than a placebo. Sounds very impressive, huh? Well, what if you closely examined the actual study numbers and it was revealed that the study participants only lost 5 lbs and those on the placebo lost 1 pound in comparison? Losing only 5 pounds does not sound very impressive, but it is still true that, mathematically, it was 500% more. So, instead of giving actual numbers, the seller gives percentages because they sound more impressive. This is how percentages can be used to mislead, so just quoting percentages is totally meaningless.

Are your results subjective? Did you look in the mirror and say "gee, it looks like I have about 90% of my hair back" or did someone actually measure it for you? Did you have a baseline study done and have it compared to your status after treatment? Was the study done by someone impartial, and not a person at the Gaunitz center who would have motivation to see results that weren't really there? Are you on any medications for your hairloss? How do you know you can attribute your success to the Gaunitz laser and not to the other modalities used by the center? We don't have answers to any of these questions, but yet you are willing to give all the credit to the Gaunitz laser, even though you admitted to being on their program which includes other treatments. Even if you did grow back that much hair (which I don't believe) you cannot attribute it to the Gaunitz laser. In summary: Your results, if any, are either overstated, fabricated or attributable to other treatments you received.

12. [LAZERFISH](#) - November 7th, 2008 at 7:38 pm

Gary, if you grew hair, it was probably from using his Minoxidil and Propecia therapies, part of his 5 step program I believe, and totally overpriced compared to what you can get from your local pharmacy. Both of those drugs work well on the vertex.

I don't like your statement where you said,

If you don't have the money, don't buy it.

Does that mean hair regrowth at Gaunitz is only for the rich??? And those with little cash are basically screwed???

That is the problem with the hairloss business today. Lot's of businesses screwing over patients by charging ridiculous prices. Totally makes my stomach turn over.

Hate to sound like a broken record, but ONE 5MW LASERCOMB will do ABSOLUTELY NOTHING TO GROW HAIR.

Oh, and please give my regards to Mr. Gaunitz when you go to work on Monday! LOL!

Mike

LAZERFISH LLLT.

13. [.gary](#) - November 10th, 2008 at 3:17 pm

Blogs are here to express peoples opinions and mine will not change. If you must know, I'm just a satisfied customer who is a Commercial Lending Officer at a well know bank here in Scottsdale with a full head of hair. Most likely you will post again, but this is my last entry. Good luck with your hair regrowth journey.

Gary

14. [jj mclure](#) - January 29th, 2009 at 11:49 am

it's not shameful to sell anything in america. that's capitalism. it's only shameful to the person who buys it and knows it's a scam or is blind to the truth. there are plenty of shameful products for sale out there. don't be one of the suckers that are supposidely born every minute. and hey, if the person buys it and feels good about his purchase then it's not a shameful or sucker buy. i could call the guy next door that bought a chevy a sucker for buying a lemon. right?

15. [Dr.Snir](#) - July 24th, 2010 at 1:56 am

What's the verdict on the X5 laser?

16. [Nadav](#) - July 29th, 2010 at 1:24 pm

William Gaunitz is certainly not a crook.

Infact, i believe he is one of the very few individuals that actually knows pretty much everything about hairloss, especially lasers.

I Suggest you try and do some digging about the THL-1 and the X5 laser, because they have been

PROVEN effective.

Everybody is trying to make money in life, no one will sell you a device in a losing price.

Go to amazon/other laser clinics and you will see the price is pretty much the same.

By the way - the price is 1,995\$

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