

PUBLIC SAFETY NOTICE

FDA Device Allegations Complaint/CDC Public Health Warning

Against:

BodyBalance System (Ovation/SlimSculpt Products)
8840 W. Russell Rd., Suite 245
Las Vegas, NV 89148
888.954.2980

Micheal Londo (Owner): 407.529.9920
Dan Lier (Sales Dir): 702.807.1769
Kaitlyn Bivers (Sales): 702.613.8394
Ally Jordan (Bus. Mgr): 855.886.3604

“In my decades of medical and therapeutic device design and evaluation (450+ devices over my career), I have never witnessed such a profoundly flawed and criminally negligent health industry product. My Team verbally presented a list of concerning issues directly to Micheal Londo (owner) and his Sales Staff, Dan Lier and Kaitlyn Bivers, after a 4 week Ovation Zero Gravity bed evaluation. We later provided a written report for the most critical of the public safety issues in an attempt to motivate them to revisit and radically revise their device design. A dozen additional conversations on the issues had no impact on their product rollout.” (Steve Frazer)

Per Mr. Frazer’s experience formally evaluating over two hundred medical and therapeutic devices, a single “disqualifying design issue” presenting a user safety issue was common. To identify 2 “disqualifying design issues” from the same device was very rare. Mr. Frazer has no recollection of any single device presenting 3 “disqualifying design issues”. **The Ovation device has 6 “disqualifying design issues” ... and all impact user and public safety. There are no modifications to this device that would render it safe. The device requires radical re-engineering by someone with far more health and safety awareness than Londo.**

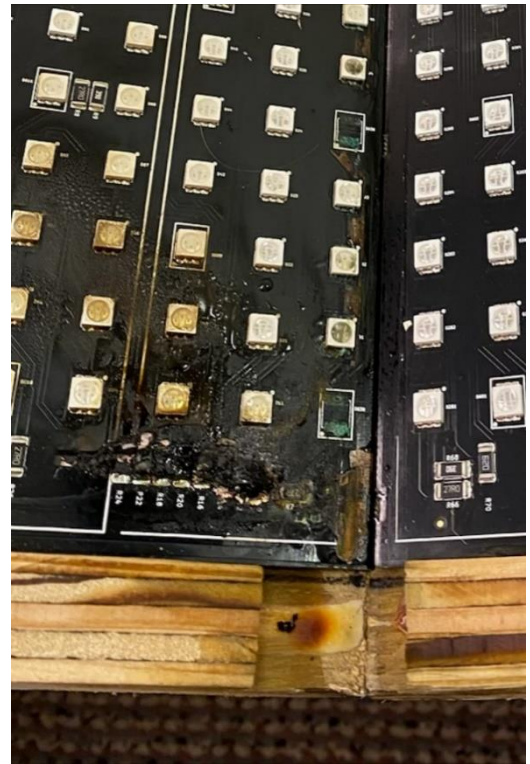
When we discovered there had been no modifications made and the company had manufactured and delivered hundreds of these devices, we took the time to contact a few of the commercial facilities that had purchased the devices (spas, chiropractors, etc.) and discovered many had already experienced a list of failures and had exposed their respective clients and staff to this device resulting in many injuries. In fact, several of the customers listed on the BodyBalance

System website (<https://bodybalancesystem.com>), will deny ever having had an Ovation device in their office/clinic/spa in a litigation mitigation effort. While most of the business owners returned the Ovation devices quickly due to the failures, many others found themselves financing a failing device fighting “no warranty” and “no returns” policies. If the business had already paid for the



device, no-return was allowed, if the business had not yet paid for the device, the BBS staff came in without warning and removed the device aggressively.

Each of these Ovation devices are servicing dozens ... plausibly 60 unique individuals each day and based on the typical spa business model, 1,000-2,000 unique individuals each month. A treatment session on this device generates intense heat – far higher temperatures in comparison to other Photobiomodulation devices tested - so it stimulates an extreme detox response. This results in a flow of sweat, oils and every pathogen/antigen from their pores and from the older, incontinent clients, waste secretions. Individuals with greater than average body mass can sweat out over 1 liter during the session. The sloped design of the table collects this “proverbial, primordial soup” into the lower elevation “gutter” which overflows the inadequate seals on either side of the bed’s surface onto/into the untreated plywood which is the structural base material for the entire device.



This plywood biomass then takes on a new role as host for the evolution of all the pathogens/antigens deposited by all these people. It was interesting to discover that in a treatment room where the temp is generally 74F, the temperature of the device (directly under the LED circuit boards) remained between 88F-98F throughout the treatment day from the combined heat of the LED’s and circuit boards, the heat rising from the electronics in the base of the unit and the clients’ body heat.

The plywood - particularly in drier climates – also splinters onto the floor and numerous clients have reported suffering wood splinters in their feet. Consider the exposed plywood is not limited to the contained apron of the base of the device, but rather extends beyond the base such that new splinters from the plywood are actively falling onto the floor as each new client flexes the wooden bed for their session.

The bed’s surface sheet of acrylic (measured with a lab digital micrometer at .8mm) is in direct physical contact with the LED chips on the bed. In commercial use, this sheet quickly becomes brittle and begins to present micro-cracks from the heat of the LED chips and pressure from the weight of the clients. Reports from the spa businesses document acrylic sheet failure within 60 days of delivery of the device.

These micro-cracks act as vents for the clients' sweat and oils to seep directly onto the circuit boards below while the hot air from the LED chips escape through the micro-cracks as a hot gas jet which then causes blisters and open wounds on the bare skin of the device user. The surface of the bed measures at 110F-120F (under client body mass) with these gas jets measuring at 120F-130F during a session (20 mins). Note the LED chips operate at a still higher surface temperature per the direct contact with the acrylic sheet and client body mass holding the heat of the LED chips. Understand these micro-cracks require a magnifying device to observe so may be present for weeks or months before facility staff deem that a new acrylic sheet be installed. Once a few of the micro-cracks exist, the degradation of the acrylic sheet actually slows as they provide better heat dissipation.

Per our minimal inquiries to various spas, we were told of 3 dozen injuries with several requiring professional medical attention. Extrapolating our collected data set and considering the number of devices sold, there are likely over 100,000 victims with a few thousand requiring medical attention including severe burns, blisters and infected wounds. We spoke with an irate high school football player whose poor performance due to a 2nd degree thermal burn and severe blister caused by this device resulted in a game loss and a negative stat against his college scholarship goal. Men and women report 1st and 2nd degree thermal burns - many resulting in blisters. These blisters commonly became infected and simply would not heal for weeks or in some cases several months. A few reported blister scars that have never cleared.

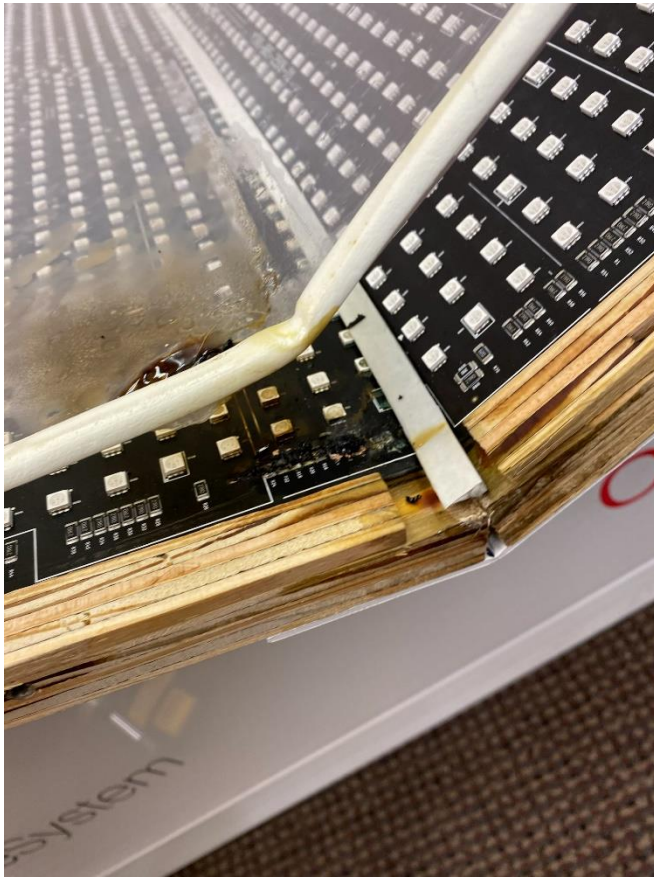
These micro-cracks provide a pathway for sweat and oils to seep down onto the LED circuit boards below and this results in the short circuiting of the circuit board. Reports of "a small fireworks display", smoke-filled treatment room, a melted hole in the acrylic sheet and the subsequent failure of circuit boards have been echoed by 4 spas from the 10 we contacted. This failure actually creates yet another issue as the circuits of this bed are not resistor load-balanced such that if 1 circuit board ceases to draw current, that leg of the power supply provides a higher level of energy to the



remaining LED circuit boards. A properly designed circuit would not suffer this issue, but this device has no such safety measure. The remaining circuit boards connected to that same power supply leg present a higher temperature which cannot be normalized across the entire surface to the discomfort and potential heat injury of the subsequent device users.

Yet, the spa owners will continue to use the device as they have made a \$50,000 investment and there is no product warranty so no repair nor refund.

The design of the Ovation Zero Gravity bed places the weight of the client directly on the circuit boards with the .8mm acrylic sheet in direct contact with the LED chips. Ponder the LED chips themselves are used as structural vertical spacers supporting the acrylic sheet. The rocking motion of mounting, dismounting and any client movement while on the device along with their body weight stresses and ultimately severs



the LED chip solder joints. This results in new and more serious issues.

The power leads of the now destroyed LED chip are still live with electric power. When the LED chip's solder joints have broken and the LED chip (vertical spacer) is physically removed from the circuit, the acrylic sheet is punctured by the vertical power lead prongs by the pressure of the weight of the user. In some cases, once the LED chip has broken off from its soldered power leads, both power lead prongs puncture the acrylic sheet and the client is being shocked by the device's power supply then using the user's tissue as the electrical conductor. Clients complain of a pinch or a tingle while they are actually being intermittently shocked throughout their treatment session. Within a few months of use, spas are counting several dozen if not over 100 missing LED chips.

Please understand the scale and count of the LED chips and power leads; thousands of LED

chips and the .8mm thickness of the acrylic sheet make observing this failure difficult for a trained engineer to recognize let alone a spa attendant. One might think seeing an unlit LED chip would be obvious, but the install pattern of the human-visible frequency range of Red Light vs. the human-invisible light of the IR LED chips makes this far more challenging.

To repeat for clarity ... sweat, oils, waste secretions containing all the pathogens/antigens from each client drip down and puddle on either end of the center gutter and through the micro-cracks in the acrylic sheet onto the circuit boards below. As the sweat, oils and pathogens/antigens of hundreds of clients continue to build up on the circuit boards and on/in the plywood below, this system is literally hosting and evolving new mutated life forms. The space directly under the circuit boards per this design is the perfect temperature for an incubator (yet not so hot as to "pasteurize" the "evolving life forms"). To compound this calamity, some portion of these "evolving life forms" are being propelled by system fans and rising hot air under the acrylic sheet and inhaled by subsequent clients and facility staff. One spa



reported a puddle under the device that was tracked through the spa by bare feet that caused numerous clients foot tissue reactions.

As time goes on, more and more LED chips are broken off the circuit boards and the LED chip power prongs puncture the acrylic sheet causing many more micro-cracks in the surface. The cracks scratch the bare skin tissue of the clients in part caused by the roughness of the acrylic sheet and in part from being scratched directly by the prongs of the circuit board protruding through the acrylic sheet.

The clients then have open wounds which are susceptible to infection from the jets of hot gases through the micro-cracks from the circuit board containing the “evolved life forms”.

Spa and chiropractor staff (the device target market) are unlikely able to disassemble and reassemble this device for proper sterilization. Even if their skills were up to the task, proper sterilization protocol should be conducted for every client session and is a 2 hour task based on the fastener count and components that must be removed, sterilized and reassembled. And this sterilization process would expose the facility staff to serious biohazards likely beyond their training and tools.

When a new acrylic sheet is installed (by a BodyBalance System staff or a handy man), the missing LED chips are not replaced so the power lead prongs pierce the new sheet within only a few uses and the cycle continues. Repairing the broken-off LED's in the field is cost prohibitive.

The BodyBalance System company owner, Londo, and staff are now operating in a calculated criminal mode ... far beyond criminal negligence ... in their total disregard for public health and safety. In multiple conversations, Londo and Bivers stated clearly that they had received numerous complaints. **The potential for pathogen/antigen mutation/evolution in this Ovation device (which presents as an efficient incubator) must be recognized by all Public Health agencies. Seriously, any of these devices – just one of hundreds in the field today - has the potential to be “Ground Zero” for the never-before-seen mutated pathogen/antigen that expands to pandemic status. The CDC has also been alerted with the sincere concern that current or future COVID variants already have/will evolve on this BodyBalance System Ovation device.**

We implore the FDA, CDC and all Public Health agencies with jurisdiction to declare a Recall and Mandated Shutdown on this product in the interest of Public Health.

And per our testing, the Ovation Zero Gravity device has no significant efficacy. In a 20 client test group with before/after (8-16 sessions) ATP blood panel tests, there was no measurable ATP increase where every other Photobiomodulation device we tested showed at least some measurable ATP increase. We are working with a leading university physics department that specializes in Biophotonics and mitochondrial processing of red light photons and they were at a loss to explain why this was the lowest performing device we tested (no measurable health benefits beyond detox and slightly better circulation from the uncharacteristic heat). The LED chips used on this device are within the research-supported nm frequency for mitochondrial stimulation, yet they do not stimulate tissue rejuvenation consistent with other LED's in the same nm frequency range and mW/cm² power level. We suspect that since these LED chips have a very poor energy conversion from electricity to light (they, in this configuration, generate far more heat than other

LED's tested), this factor is also resulting in the poor efficacy ratings. This low-cost LED is in-line with the low-end technology selection of the rest of the device's components. The Ovation LED's present the highest failure rate of any Photobiomodulation device tested.

Also, while the sales staff of BodyBalance Systems are touting the Ovation device achieves rapid fat loss via lipolysis, our tests (comparing data points from devices that do achieve lipolysis in university clinical trials) proved their claims to be false. At only 74mW/cm², the LED's from this device are far below the needed energy threshold and no ETC client or staff reported any discernable fat loss from using the Ovation device. Devices that achieve true lipolysis (Photobiomodulation devices) measure at over 145mW/cm² by our spectrometers. This one false marketing claim by BBS Sales Reps is sufficient to argue the refund of every device sold over the past 15 months. Why only this period of time? Because no one at BBS was aware of what lipolysis was until Mr. Frazer presented the concept in October of 2022 ... then magically in November of 2022, Dan Lier launched a new marketing campaign claiming the Ovation device achieved lipolysis. The text volleys between Lier and Frazer are both concerning and amusing. These people have no integrity.

Per our interactions with Micheal Londo and Dan Lier, they have displayed a total disrespect for Public Safety, government oversight and compliance and they have shown no empathy for their victims. From our direct experience, they also have a well-established track record for blatant disregard for contract terms and fair and ethical business practices. As a strong suggestion, secure their bank records to identify who has purchased these devices as they will not otherwise provide comprehensive records. Ally Jordan is the BodyBalance System Business Manager and we observed that she too operates without empathy and her arguments are completely focused on profits. When we sent 2 of our staff to meet with her, she blindly denied every issue, while Londo screamed and cussed at our staff until they left the building. In an early conversation, Londo admitted to receiving complaints from a list of his clients and Kaitlyn Bivers (Sales Rep) once explained that there were only 44 Ovation Zero Gravity devices manufactured that represented the first 147 sales, as many units were returned by the customers and then resold ... multiple times. In speaking with high-end Las Vegas resorts, we understand BodyBalance System is swapping out the Ovation devices regularly – as often as every month or two - so they enjoy a no-failure experience to leverage the brand of the resort for other, lower-profile Ovation device sales. BBS has engaged the support of social media professionals who scrub the bad user reports on every platform.

We calculate the sales from these devices have grossed well over \$10 million dollars so even a \$500,000 fine will have little impact on their business. With an FDA Recall and/or a CDC Shutdown ... state, county and metro level public health agencies are far better empowered to go to their respective Attorneys General and Secretaries of State to shut down the business (BodyBalance System is a Florida LLC and their manufacturing facility is in Nevada) and criminally prosecute Londo and staff. Be advised that BodyBalance System's newest product, SlimSculpt uses a flat surface, but still suffers from the majority of the design and public health issues detailed above and still poses a significant public safety threat.

From discussions with other Photobiomodulation manufacturers, we understand this is the 4th therapeutic product Micheal Londo has produced and all resulted in litigation, customer injury and similar device failure timeline (within a few months). You may wish to contact Karl Rothschild

(310.403.3890), CEO of multiple companies in the market space. Karl will echo similar experiences and litigations with Londo and previous failed products.

Ponder BBS is selling these Ovation devices with no warranty. Seriously, a \$50,000 device with no warranty (this fact is buried in the fine print of the sales contract and may also be found on their websites: <https://bodybalancesystem.com> and <https://ledlightscontour.com>). When the Ovation device begins to fail and calls are made for repair, small spa owners are blind-sided as they have operated with reasonable, responsible new equipment warranties for years and then discover that the BodyBalance System company will provide no support even when device failures occur within weeks of delivery.

Motivated from speaking with select spa owners, we have consulted with a Nevada law firm to initiate a Class Action litigation against Londo, Lier, Bivers and Jordan to help recover the loss of their Ovation device costs. This Class Action may cascade to a spa client Class Action where victims come forward seeking restitution for their injuries. **The most significant injuries that present in near real-time are the 2nd degree thermal burn blisters and resulting scars, however, particularly the staff of the various commercial clinics/spas who received dozens if not hundreds of treatments on the device and experienced repeated 2nd degree thermal burns will suffer a breakdown in skin cell telomere integrity resulting in mutated cell clusters progressing into various types of skin and tissue cancers. Skin cancers induced by repeated 2nd degree thermal burns are well documented in medical case files and medical research. Long-term clinic/spa clients using the Ovation device are at risk of experiencing the same.**

Please consider in Las Vegas alone (highest geo-area concentration of the Ovation devices installed), tens of thousands of women make a living based on their physical appearance so blister scars and cancer showing up years later will certainly impact high-income performance and service careers (100 victims losing 5 years of income at \$100K/year = \$50M). **Londo and BodyBalance System must be required to create a substantial "Health Fund" to cover these victims' medical costs and lost income.** Consider the high school football player who suffered the 2nd degree thermal burn and severe blisters from a treatment on an Ovation device. His performance in the following game was poor ... inconsistent with his previous record. He knew there were college scouts in the stands and if overlooked for recruitment, the economic impact to this young man can be conservatively calculated in the tens of millions as opportunities for the support of a university athletic scholarship, university education and the potential of an NFL contract were taken from him by a device that should have never been allowed on the market.

The Ovation Zero Gravity bed that ETC evaluated failed quickly in numerous ways and was rejected. It should also be noted that 126 ETC clinic clients were provided a no-cost session on the evaluation Ovation device and none ... not a single client ... chose to use it again at a \$30/session fee. Beyond the issues detailed above, 100+ LED lights failed within 30 days on this system. Rather than to remove the bed from our offices as we expected, Londo redirected monies we had paid his firm specifically for a custom device fabrication contract to the purchase of the Ovation evaluation device we had rejected. Londo then refused to deliver our new custom device we designed and purchased. When ETC ultimately agreed to pay for both devices (10 discussions directly and via our attorneys), Londo refused any deal unless all Intellectual Property rights of the custom device were conveyed. Understand Mr. Frazer spent 3 years and 150,000+ treatment sessions evaluating 64

industry devices to collect the data to design the custom fabricated device (>\$1M in R&D). The IP was not negotiable so no deal was made. Yet Mr. Frazer's custom design is now "Londo's new product offering" the SlimSculpt device (Londo corrupted Mr. Frazer's health-safe design). So, civil litigations against Londo, staff and company include Intellectual Property infringement and Breach of Contract to establish the evidence and judicial arguments for the criminal complaints which include Conspiracy to Defraud, Grand Theft and Extorsion.

After delivery of this complaint to the FDA and the CDC, we are sending this notification document to all the BodyBalance System clients we can identify. Then we also are sending this document to every Photobiomodulation manufacturer in the U.S. with the hope they too will spread the word to protect the public ... obviously primarily motivated by one less product manufacturer in the market space, but maybe to some degree raising the bar for their own industry. We are in the process of sending this document to every metro, county, state and federal health agency in the U.S. (26K+ government offices – ETC operates 5,000 RPA Bots). We recently were made aware Londo is now selling the Ovation beds overseas.

Note that several staff of the Southern Nevada Health District (SNHD) are clients of our *Wellness, etc.* clinic. We have notified them formally; however, it is our understanding their jurisdiction includes all the spas, chiropractors, etc. that use the Ovation devices, but not the manufacturer. SNHD inspectors will go out and likely shutdown all these service facilities sorely penalizing the victims rather than the source. An FDA Recall will ensure public health by removing all these devices from the market, however, if a small spa facility financed 4 of these Ovation devices, such a financial impact may put them out of business.

We expect Londo to immediately file for bankruptcy in response to an FDA Recall and walk away with over \$10 million dollars generated via this "business model". At this point, Londo is fully aware of the results of his actions and device design ... especially after all the critical discussions we had with he and his staff and all the complaints from customers. We suspect bankruptcy was always the end-play of his business plan as he never expressed any empathy for any victim when we presented the client cases and issues.

With sincere frustration ... we heard the same statement from multiple Nevada spa owners, "*We were excited and proud to buy a U.S. manufactured device, especially from a local firm*". ETC had exactly the same motivation. Actually, there were several conversations with Londo where Mr. Frazer stated that since his Ovation device needed to be scrapped, he would award a custom fabrication project to help support Londo's business. So, while Frazer thought he was hiring a fabricator and helping to support a local Nevada business and a product "*Made in the U.S.A.*", Londo was only focused on harvesting Frazer's years of research and Intellectual Property.

While we located the BodyBalance System FDA Registration of the Zero Gravity Ovation bed, we do not find an FDA Clearance for the device. We are aware Londo hired an FDA approved engineering evaluation firm in November of 2022 to secure Ovation FDA Clearance, however, Londo refused to answer any inquires regarding their progress thereafter which suggests they rejected the device also. They likely presented a written evaluation at the time ... if only to decline to be involved with the product. Authorities should secure and review this formal evaluation document.

The human health issues from the use of the Ovation device detailed above are not speculation or potential, they all have happened ... are happening ... and every day. Research shows these Ovation devices have been sold to commercial facilities in at least 12 states.

About Us

As the Central Service organization of a conglomerate, ETC has formally evaluated 68 of the best-in-market Photobiomodulation devices. While some pad-based products present similar issues, this Ovation bed is the only device on the market we have evaluated that has already caused severe injury, presents substantial long-term negative health impact to clients and may have already spawned extreme, wide-spread public health issues in the form of evolved pathogens.

Our Chief Medical Research Engineer, Steve Frazer, holds undergraduate degrees in Human Physiology and Computer Science and graduate and post graduate studies in Bio-mechanical Engineering, Statistical Data Modeling, Logistics, Law and Business Management. He worked as a university Human Performance Lab Technician studying mitochondria in muscle biopsy samples for several years, served as a Medical Research Scientist evaluating treatment protocols and medical equipment and ultimately managed a total of 37 university laboratories and 8 private sector labs over 18 years.

Mr. Frazer completed his medical engineering training (which has significant curriculum overlap with the medical school program, including cadaver labs) at The Ohio State University then engaged in university research, helped to develop medical research technologies and lectured to medical school students for nearly a decade. He also worked in the OSU Medical Communications Group where he developed medical school training systems, patient education presentations and real-time, surgical support visualization systems primarily for brain surgery. Other significant research in which Mr. Frazer participated - while working with Harvard Medical Research - focused on metabolism, mitochondria and the effects of diet on health. He applied his Information Science and Database skills by designing, building and managing massive medical feedback databases for risk management for nearly 700 medical conditions over 20 years for universities and Fortune 100 corporations – including 6 of the top 10 insurance firms (for perspective, each of these projects carried budgets of \$50M-\$200M).

Wellness, etc. (ETC) has established a tissue rejuvenation clinic as the Flagship location for a Central Services project for an International conglomerate with 6M employees. Our mission is to develop 5,000 clinics across the U.S. and an additional 10,000 world-wide to serve the member company employees and the general public to improve their quality of life and to reduce Worker Comp claims. The conglomerate has allocated a multi-billion-dollar budget to accomplish this goal. This project will ultimately create an estimated 180,000 new jobs and we have already awarded \$11B in LOI's and contracts to vendors. Had BodyBalance System performed on the fabrication contract, they would have received a manufacturing contract valued at over \$1B.

A significant percentage of our current clientele are Police Officers/Administrators, Fire Dept. Staff, Public Health Agency Staff and Veterans. ETC has committed to supporting government agencies across the nation so they will enjoy a Worker Comp Experience Modification Rate premium

reduction per reduced claims and higher performance of staff in parallel with our member companies' staff.

Per our current 2,000+ clients and nearly 200,000 sessions, the recorded health benefits from our tissue rejuvenation protocols have been epic. We are tracking the reduction or total elimination of symptoms of 110 medical conditions including a primary focus of eliminating osteoporosis and the need for hip and knee implants. We have successfully returned over 200 clients from a bone density/mass rating range of -2 and below to over +1 within 12 months (this represents a \$50M+ savings in implant surgical procedures to date). We hold a contract with United Health Care/Optum for this mission. We also have embraced a combination of protocols from top medical research universities that stimulate extreme stem cell production and stabilize telomeres to eliminate virtually all skin and near-surface tissue blemishes (mutated cell clusters). Our protocols have the very real potential of eliminating all skin cancer. To date, over 800 of our clients who had previously suffered skin cancer have not experienced any additional lesions after a few dozen treatments. Our non-invasive thyroid, breast, prostate and lung cancer protocols present equally consistent and promising stats. These 5 types of cancer combined represent 92% of all cancer cases in the U.S.

Our efforts are helping to return U.S. citizens to better health and provide a higher quality of life. We are engaged in conversations with the U.S. Chief Surgeon General's Office with projections approaching \$1T annually in reduced national healthcare costs when we are fully scaled. This experience with Londo and BodyBalance System set our progress back by nearly a year.

All statements in this document are true.

Stephen Frazer, Officer
Wellness, etc. (ETC)
3505 E Flamingo Rd. Ste.3
Las Vegas, NV 89121
702.430.7390