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Project: SoftWaves to prevent opioid addiction and to help addicts in their recovery.

SoftWaves are electro hydraulically generated acoustic waves delivered “unfocused” into a patient via a parabolic lens. The first shockwave patient was treated over 30 years ago for the first FDA approved indication, kidney stones. The technology has evolved considerably and is now used for a myriad of clinical conditions not requiring any analgesia and it can be performed in any doctor’s office or health center. The risks are nearly nonexistent and the proven mechanisms of SoftWaves in medicine are well understood. The mechanisms of action that are of interests in our discussion regarding opioid and other pharmaceutical addictions are as follows:

1. SoftWaves immediately modulate inflammation, pain, and swelling and cause an immediate increase in the blood supply in the targeted area. This will immediately reduce pain and inflammation in most patients. The basic science is documented and includes certain cellular receptors (TLR3), an increased permeability of cellular surfaces, and the release of exosomes containing proteins and RNA that trigger a biologic cascade.
2. A permanent increase in blood supply beginning as soon as 4 weeks after treatment and continuing to improve up to a period 12 weeks after treatment. It is proven in animal models that there is a 300% increase in small, medium, and large blood vessels in the targeted ischemic or pathologic tissue.
3. SoftWaves have been proven in animal models to recruit, activate, and cause endogenous stem cells to differentiate. This biologic cascade described is identical to the cascade that results after a patient is injured. The mechanism is **self-healing**. In the vast majority of instances when a patient is injured, regardless of whether it is a wound, trauma, fracture or sports injury, a body will heal itself sufficiently within a maximum of 12 weeks. In those cases where a chronic injury or trauma persists after 12 weeks, and the body’s own healing effort has ceased, a SoftWave therapy

will make the body react as if a fresh injury has occurred and initiate another 12 week healing cycle.

The benefits of these 3 mechanisms of actions (and others to a lesser extent) can be utilized in several ways to support the reduction of opioid addiction. The first group of patients that would benefit from Softwave therapy are those patients that become addicts as a result of surgery, post-surgical complications, or just by taking the prescription pain meds as prescribed by the surgeon. Examples of the proven benefits are as follows:

It is estimated that 2 million opioid addicts are created annually as a result of elective surgeries alone. Plastic surgery is a large percentage of these cases. This number grows dramatically when you include all surgeries. In randomized controlled clinical trials, it was proven that when Softwaves are applied to a patient's surgical incision during surgery (after it is closed), the post surgery recovery time is reduced, there are fewer complications, and most importantly pain is reduced post-surgery requiring less medication and fewer prescription medications.

Most plastic surgery (elective) patients return to their doctor's office shortly after surgery, in severe pain, demanding prescription pain medications. Historically, doctors prescribed these meds for an extended period of time. Studies have shown (what studies?) that even a few days of these prescription medicines can lead to long term addiction. In a recent small clinical trial (where, who, when, can you send to me?), plastic surgery patients who returned to their doctor for their first examination demanding prescription pain medications were offered a SoftWave treatment at the surgical site before a prescription was written. 75% of these patients obtained immediate pain relief such that they no longer required prescription pain meds.

It is reasonably believed (and easily proven) that the combination of a SoftWave treatment during surgery, and one or two additional treatments post-surgery could reduce the number of pain medicine prescriptions by at least 50%. There are additional benefits as well: shorter recovery time, reduced scarring, fewer complications, and an improved appearance of the scar. Conservatively, the therapy could reduce the number of addicts created as a result of post-surgery pain medicines by at least 50%. If this therapy is available to surgeons and a reasonable reimbursement established, the number of new addicts created post

operatively each year are likely to be dramatically reduced. Even though many surgeons know this works, or even believe it may work, they will not offer this technology if they are not paid to do so. The average cost of this therapy in the US is less than \$500 including the technician. This cost is often less than the cost of prescription meds that it is replacing.

It is also understood that a huge percentage of addicts become addicted as a result of an accident, trauma, or injury that created chronic pain such that they required prescription pain meds to treat the chronic pain. For lack of technology, insurance, and numerous other factors many of these patient's progress to opioid use and addiction to manage the chronic pain.

SoftWave therapy has a record of being one of the best technologies in the world to manage acute and chronic pain. Every day it is utilized to successfully treat the highest level professional athletes. Over 200 NBA players have been successfully treated for chronic pain including the biggest names in the league. SoftWave is regularly flown to the Emirates to treat Royal family members. There are 10,000 shock wave devices in use worldwide for acute and chronic pain. SoftWaves are safe, relatively painless, non-pharmaceutical, and can be delivered quickly and inexpensively.

In the recovery center setting, SoftWaves can be added to the standard of care to support the recovering addict. If an addict's chronic pain is not addressed during rehabilitation, a patient's is very likely to return to addiction after the program is completed.

It is also understood that acute pain often presents during the detoxification and rehab process. This pain can also be managed.

Additionally, a patent pending process of targeting a patient's reflexology points on the hands and feet during recovery may greatly reduce the side effects felt by the patient during the withdrawal period. Generally, the patient's feel much more calm and relaxed after these treatments. This is a very exciting discovery but the results are very preliminary. In the 20 plus cases that I have witnessed the outcomes most often produce amazing tearful responses. Again, this can be quickly and safely proven or not.

And, it is understood by the doctors and therapist dealing with addiction that a huge percentage of males suffering from opioid addiction suffer from erectile

dysfunction. This ED causes depression and prevents an obstacle to recovery. SoftWaves (electrohydraulic unfocused ESWT) therapy is the new patented standard of care for the treatment of ED with over 50,000 patients successfully treated last year.

Finally, based on our related research, we believe that we will have a strong benefit when we treat the teeth and gums of meth addicts. We are supporting the first such trial and will apply for an IRB within 90 days to treat the first patient's. Any improvement that we can make to the teeth, gums, and mouth of these patients would lead to an increased self-esteem and surely benefit in their recovery. A 2008 study published in The Journal of Dental Research demonstrated that, in-vitro, low-energy ESWT is capable of disaggregating the Gram-positive and Gram-negative bacteria that are important in biofilm formation, and of selectively killing two of the primary pathogens associated with oral and systemic infections.

Our final grand plan to support this horribly afflicted section of our society is to create thousands of outstanding jobs for the recovered addicts. Jobs offer hope, and hope is the key to prevent a recovered addict from relapsing. After this program is launched on a national level, thousands of jobs will be created to identify, recruit, and treat the millions of addicts and to train the technicians to provide this therapy. I would hope that we try to fill these new positions with as many recovered addicts as possible. The application of this technology is safe and simple. With some limited job training post recovery (critical part of the program), recovered addicts would make ideal SoftWave technicians and trainers. Who better to recruit, treat and support other addicts through the process than somebody who has already completed the journey?

Most readers of this summary will want to attack individual claims and find reasons not to believe. The most frequent one I hear is it is too good to be true. Every once in a while, it is not too good to be true.

The most exciting thing is that every claim is easily proven. The pain benefits are almost immediate. Patients get off the pain meds immediately. Any plastic surgeon can prove these claims very quickly. Even if we are only successful in half of the cases this would be an astounding clinical, social, and historic success.