Urgent News Alert From Juventix: Foreign Platelet-Rich Plasma (PRP) Company Spreading Misinformation

To Deceive Physicians and Consumers - Smear Their Competitors - and Limit Access to Affordable Care - Leading Regenerative Medical Company – Juventix - Sets the Record Straight with Verifiable Evidence

Tampa, Mar 16, 2020 (Issuewire.com**)** - Regenerative Medicine is defined by the *American Association of Blood Banks®* as *"the process of replacing or regenerating human cells, tissues or organs to restore or establish normal function".1* Within the field of regenerative medicine there are potential treatments that are harvested from a patient's own body, called *autologous therapies*, which are *"(of cells or tissues) obtained from the same individual"*. Autologous therapies are renowned for the fact that they are safe, effective, relatively easy to perform, and affordable options to risky and often costly alternatives such as surgery.

One such autologous therapy is Platelet-Rich Plasma, or PRP for short. This therapy works by harvesting whole blood from the patient and processing it to extract the blood platelets, growth factors, plasma and other naturally occurring components utilized by the body to respond to injury and repair tissue damage. PRP has been extensively studied by the medical community and has proven to effectively treat a variety of conditions ranging from degenerative musculoskeletal conditions, such as, Osteoarthritis of the knee, to aesthetic concerns such as androgenetic alopecia, which is also known as "male pattern baldness". In fact, PRP therapy is so safe and effective that over 11,632 clinical research studies have been published in the *US National Library of Medicine* by *The National Institutes of Health* without a single adverse event or serious side-effect ever reported!2

To properly harvest and prepare Platelet-Rich Plasma, a licensed healthcare provider often uses a medical device called a "PRP Kit" to aide in this process. While there are many types of PRP Kits offered for sale to healthcare providers both domestically and abroad, not all of these medical devices are created equal. Many manufacturers, distributors, and marketing companies the world over present often complex "solutions" in the form of their PRP kits to healthcare providers under the guise that their device is in some way superior to other products available in the marketplace. While this is true to a degree, some companies have produced adulterated "scientific research", falsified lab reports, flashy sales collateral or websites and other misinformation to confuse and mislead both healthcare providers and the general public as it relates to the field of autologous regenerative medicine, and more

specifically to PRP Kits themselves.

One such company that has resorted to predatory and deceptive tactics such as this, is Regen Lab™. In a February 12th, 2020 email-blast titled *“RegenLab USA LLC, a growing company with a new facility and new organization!”,* many false claims and attacks were levied against various competitors. This email, that was in all reality a thinly vailed “hit piece”, attacked various other manufacturers as being *“non-conforming”*, or manufactured outside of the USA. The irony of this deceptive promotional email distributed to various healthcare providers in the United States is that Regen Lab itself is a foreign-based corporation that does not yet make its own products in the USA, as self-admitted within the email itself.

One of the companies attacked in the above-referenced email is Estar Medical™, an Israel based company that markets a competitive product labeled Tropocells® PRP Kits. These companies have a history of the conflict as evidenced by a 2019 legal ruling; *“UK High Court Refuses to Grant Regen Lab Permission to Appeal the PRP Patent Revocation Judgement and Orders Regen Lab to Pay Hundreds of Thousands of Pounds to Estar Medical”.*3 One can assume this email to be purposefully misleading, especially considering it was sent from Antoine Turzi, founder and CEO of RegenLab SA, who was cited by the UK Patent’s court as being quote: *"not a reliable witness".*

To further unravel this piece of “Fake News”, numerous other “bombshell” claims are levied against more competitors of RegenLab™, such as Healeon Medical and their HD PRP™ system. They claim that *“there was a recall of products reported to the US-FDA”*, including the HD PRP™ kit and other products. But a quick search of the 1,224 medical device product recalls previously and currently issued by the US Food and Drug Administration4 reveals there was *never* a recall issued of this device or brand. A further search for the other brand names listed within the predatory and deceptive email as having USFDA recalls issued against them including “*Juventix Medical PRP Kit, Suneva Medical HD PRP, Integrity PRP kit, Medshift PRP, Prizmah PRP and CellTherapy PRP kit*” also all come back without any previous, current, or pending recalls issued by the FDA.

In further effort to sow dissent, misinformation, and chaos to damage the business interests of their competitors Regen Lab™ distributed another predatory email on Tuesday, March 3rd, 2020 entitled *“Non-Conforming Chinese Medical Devices Are Placing Consumers & Patients At Considerable Risk”.* They attacked a host of their competitors, again referencing an article disguised as “news” which was a paid press-release distribution by a for-hire company. They even included a picture designed to make it appear as if there was a safety recall issued against their competitors headlined *“The Medical Community Should Avoid If They Come Across These Products: There Is An Urgent Alert On These Items ----- Confiscate & Notify Authorities:”*

So why does the deceptive behavior of one “bad actor” in the regenerative medical community matter to physicians, to consumers, and to those of you reading this article? Because misinformation such as this is a danger to competition, to the development of advanced technology and more efficient solutions, and above all behavior like this puts at risk access to care offered by affordable, safe, and effective medical devices and solutions.

One such medical device company that was unscrupulously attacked by these false claims levied against it is Juventix Regenerative Medical, LLC. Unlike Regen Labs™, Juventix is actually a US-based corporation, owned and operated by US citizens and that pays taxes and contribute to their local community. Additionally, Juventix Regenerative Medical, LLC is registered with the US Food and Drug Administration holding the registration number 3015942805, which is confirmed by the FDA through their public online “Establishment Registration & Device Listing” database.5

Additionally, Regen Labs™ incorrectly claims that Juventix line of PRP Kits is manufactured by a Chinese based company that *“has been shut down by the Chinese CFDA”.* Not only is that claim false, the Juventix Medical PRP Kits have been issued an FDA 510(K) clearance under the Premarket Submission Number: BK170136, which verifies that their products *“demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.”* The same degree of registration and clearance afforded to other reputable Class II medical devices in the USA.

This series of email and “bought-and-paid-for” press releases appear to be an effort by Regen Labs™ to unfairly compete with their peers that produce safe, effective, and above all affordable devices made available to US physicians and by extension, their patients.

For complete information on Juventix, visit: www.Juventix.com

1. http://www.aabb.org/aabbcct/therapyfacts/Pages/regenerative.aspx
2. https://www.ncbi.nlm.nih.gov/pubmed?term=platelet%20rich%20plasma
3. https://www.biospace.com/article/releases/uk-high-court-refuses-to-grant-regen-lab-permission-to-appeal-the-prp-patent-revocation-judgement-and-orders-regen-lab-to-pay-hundreds-of-thousands-of-pounds-to-estar-medical/
4. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
5. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=234461

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