

FDA-Compliance-Enforcement-Letter-SENT-1-23-2018

----- Original Message -----

Subject: RegeneXX Case 1:10-cv-01327-RMC "Advisory panel" and "Clinical Trials" COMPLIANCE ENFORCEMENT
Date: 2018-01-23 20:06
From: Susan [Cassady] - Neuhart
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Reply-To: http://hansandcassady.org/contact_form/index.html < CONTACT FORM

[BEGINNING OF DOCUMENT]

TO: USA FDA Commissioner Dr. Scott Gottlieb, M.D. (and, FDA "CBER" Ombudsman's office agents) ALSO: Manufacturer's Assist., Product Deviations, CBER(Peter Marks, M.D.- Ph.D.), Product Surveillance (CBER), DIRECTOR-OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY – CBER

FROM: USA Citizen – Susan Marie [Cassady] – Neuhart

Subject: RegeneXX Case 1:10-cv-01327-RMC "Advisory panel" and "Clinical Trials" COMPLIANCE ENFORCEMENT

Date: 1-23-2018

Dear USA FDA Commissioner Dr. Scott Gottlieb, M.D. (and, FDA "CBER" Ombudsman's office agents: Ms. Sheryl Lard-Whiteford, Ph.D. and Mr. Howard S. Balick, J.D.), (CBER Compliance Director: Ms. Mary Anne Malarkey) et al

Thank you! for your recent statement regarding (the) "*FDA's comprehensive new policy approach to facilitating the development of innovative regenerative medicine products to improve human health*" AND *cell-based therapies and their use in regenerative medicine.*" (made January 16, 2018 - [Reference 1](#))

Sir, I read your "comprehensive new policy" announcement with great interest. As, I am exactly the person that you were referring to in your January 16, 2018 announcement. I am very hopeful of the success of "regenerative therapies"! And,

I would like to contribute – to their successful implementation and offering to the American public – if I can.

You see, I have been recently diagnosed – by a MRI procedure (performed 10-23-2017) – that I have a “*Supraspinatus Tendon Tear*” in my right shoulder. The MRI files and the radiologist’s report which documents this “tear” can be accessed & downloaded through my personal web site ([Reference 2](#)) PLEASE NOTE: I DO NOT SELL ANYTHING UTILIZING MY “PERSONAL” WEB SITE. Rather, its sole purpose is to facilitate communications – with professionals – in the USA Government, my large family – and, my acquaintances. In fact, to review my personal medical documents, you will require a password and a username – which, I will gladly supply (these) – to your FDA agents. Please REPLY email your request to me – OR, use my personal web site CONTACT form. In fact, to produce these important medical documents, the US Government (and I) paid over \$5,000 US dollars to the identified “radiologist” – who also (BTW) identifies himself as an M. D. – on his company web site. ([Reference 5](#))

My “Google Research” performed thus far ([Reference 6](#)) indicates that a “conventional surgical repair” – of this tendon tear – will require the “sacrifice” of my right shoulder’s Deltoid muscle – so that a conventional orthopedic surgeon may gain access to the underlying tendon area of interest – to perform surgery. Then, I must endure a 4 to 6-week period of an “immobilized” right arm.

This stated, my reasons for contacting you today are varied (totaling four items):

First, a SW Ohio “Medical Doctor” – states (on his web site) – that he is a “licensed representative” for a product called “RegeneXX”. This seem odd – as, (in fact) the FDA did file and win a Court action related to this very product in 2012 and 2014. [Case 1:10-cv-01327-RMC Document 47 Filed 07/23/12] FDA vs REGENERATIVE SCIENCES, LLC, REgeneXX Procedure]. ([Reference 12](#) – Results & COMPLAINT) The legal results (as I understand them) was full “enjoinment” [PROHIBITION] of the sale of the product “RegeneXX” & ALL related medical services– to the American public. This was (then) “upheld” – in a later & higher USA Court [2014]. ([Reference 15](#)) Now, just in case – this “*unscrupulous actor*” ([Reference 1](#)) reacts to my inquiries (already made directly to his company) by removing the “advertisements” – that I did see, I have posted his “WWW statements”- for your convenient viewing - onto my personal web site. ([Reference 3](#)) Or, you can just go (directly) to his web site: ([Reference 4](#)) This

person's full name and Medical License number are: Henry Stiene, M.D. Medical License #1063402949

Second, Sir, your announcement ([Reference 1](#)) makes it clear – that you are trying to implement an “innovative policy” – related to “regenerative scientific products and services.” Thus, I realize, that it is possible that Mr. Stiene – has obtained the necessary “special standing” with the FDA (via your announced procedures) to administer the “RegeneXX procedure” – to SW-Ohio persons. [that is, he may have a “**RMAT designation**” ([Reference 8](#))] However, the public presentation – at his web site (that I saw) – does not seem appropriate for a FDA “Clinical Trial” paradigm – with “fully divulged” patient scientific risk involved. Rather, he poses the “trial” product & service (to me) – as the “unscrupulous actor” you anticipate in your announcement ([Reference 1](#)). That is (to me), I perceive (the) *huckster* element of “*hurry & See If You Qualify*” to an unsuspecting public; Then, Mr. Stiene (M.D.) also attempts to obtain personal medical information – from potential clients ([via a web form](#) OHSAA link) and, further infers (all on his web site) that he will accept referrals – from other USA Medical Doctors – in the SW Ohio area. ([References 43 & 3](#))

Third, I want to congratulate you on your FDA employee “Pat H.”. She took my call – at the CBER toll-free number (1 800 835-4709) circa 1-18-2018. She answered my questions – with thoroughness and patience. She directed me to portions – of the FDA web site – that were useful and related. And, Pat also suggested a role, that I may wish (to play) – in the safe implementation of “regenerative technology”- to the greater American public. That is, after we discussed (briefly) my formal education, work experience and knowledge of molecular genetics – Pat stated, how this knowledge & experience *may* make me a possible “candidate” – to serve on an FDA “Advisory panel”. ([References 17-21](#))

In short, I told Pat: “... (that) my private company [[Hans and Cassady, Inc.](#), Westerville, Ohio – operating 1985-1996] was the first studio (in America, circa 1986) to provide “digital” textbook art services to College Textbook publishers. The text book titles - which H&C provided “digital art programs” for – included, [Klug Genetics](#), [Weaver-Hedrick Genetics](#), [Tamarin Genetics](#), [Zubay Biochemistry](#), [Fishbane Physics](#), etc. That is, typically based on a PhD author's input [to us] of *scribbles* and *stick figure* drawings – we worked with a reputable publisher's team of textbook developers, to create scientific and medical illustrations (to accompany the educational text) including all phases of genetic material [DNA] inheritance & replication, gene expression and protein synthesis. In fact, updated versions of these text books are still used in colleges and

universities throughout the world today (1-23-2018)...” My husband (of 35+ years) Mr. Hans Neuhart – is a Medical and Scientific artist.” ([Reference 9](#)).

The details of my formal education and professional experience appears on my personal web site ([Reference 13](#)). In brief, I formally studied the (then) very new field of molecular genetics (in an inter-disciplinary environment) – at the University of Wisconsin [during the 1970s]. I was intensely interested in answering the question(then): **HOW can a lizard regrow his lost tail?** My time (at UWGB) coincided with “Geneticist” Dr. Charles irhke, “Microbiologist” Dr. Alice Goldsby, “Environmental Scientists” Dr. Keith White & Dr. Joe Moran, “Physicist” Dr. Nancy Sell – and, many other important and early contributors – to the fields of Molecular Biology/Physics/Chemistry and, Environmental Science. ([Reference 14](#)).

I am retired – at this time – mostly related to a stroke – that I suffered – in 2012: (SAH at my MCA). Initially, I was completely paralyzed – from the stroke event; But – today (now 5 years later) - I perform (27+) YOGA poses daily (at the YMCA) and I am constructing a personal web site ([Reference 3](#)) – (all) at the suggestion – of my Medical Doctors. I take one hyaluronic acid capsule (200 mg) daily. Finding out – only recently – that HA is being investigated ([Reference 41](#))– relative to its role in mammal “nerve”- and, green lizard appendage and organ regeneration. This is a happy coincidence (only)! – In fact, I began taking HA – after reading about the success of YOGA + HA – in helping USA Veterans – suffering from chronic aging symptoms – such as arthritis. ([Reference 42](#)) In fact, my current Orthopedic Surgeon (Jennifer Jerele M.D.), has cautioned me (recently) – that, daily “Yoga poses” are not likely to fully “heal” my torn (and painful) supraspinatus tendon tear – without surgical intervention. However, trying to remain optimistic [**and, hoping to be included in a safe “clinical trial”** – under the auspices of the FDA] – I am delaying (this) surgery – despite my discomfort.

Fourth – and finally: **A)** My formal education and experiences – in the employ of the USA military (through GE), scientific writing and software systems development may be useful - if applied to (the) research, investigation, package tracking, protocol development - and, enforcement method documents needed- for FDA CBER/public health inspector implemented protocols - insofar as the *extraction, packaging, shipment and tracking* of human genetic materials-related to regenerative products and services. **B)** As my personal resume’ ([Reference 13](#)) shows, I created reporting and training systems (such as this) for the USA-Simulations Systems Division of General Electric and Battelle Memorial Institute – under the auspices of (their) USA Military Contracts. **C)** Thus, unlike

many of the “clinical trial” participants, you can “assume”, (that) I would have an “informed opinion” about the experimental protocols and documentation – that I (personally) would want to see utilized – in my treatment. **D)** In fact, it may be very helpful- to other participating Americans (that) I am (still) very detail oriented. In fact, this aspect (of my personality) assisted Dr. [PhD] Jiayuan Fang (of Sigrity Software) – to realize 83 million US dollars- on the sale of his EDA software tools – to USA Cadence EDA Software. In small part (this USA technology “sale”) was a result of the Speed 2000 End User’s Manual – that I created – in partnership with my co-workers – from China, Pakistan, India and Mexico ([Reference 45](#)). **E)** I paid for 100% of my college education; AND, earned much of my USA “Work-Study Program” award, through “coding software & reporting systems”– for the Professors of UWGB _ and their National Science Foundation grants ([Reference 14](#)). Thus, I would be wary and circumspect of “college students” -earning their college “Work – Study” Award Program proceeds – in perhaps “filthy labs”, at Colorado State University – day-to-day handling the materials – related to my biologic stem cell therapy treatment. That is, as a UWGB student, I worked day-after-day in just such a minimal, practical & necessary laboratory environment (under the auspices of the National Science Foundation) – related to sewage waste-water treatment experiments (to recover hydrogen gas). And so, I can appreciate the areas of “Lab Protocol” – that may need “special attention”. [See the district court judge’s comments – related to the Regenerative Sciences case. ([Reference 12 – page 2](#))] **F)** As I told Pat, “...there would be no charge for any small contributions - that I could make- to your good FDA work efforts.” That is, I am “legally disabled” – and, I am pleased to collect my (well-earned) Social Security benefits – which, (I fear) would be put at risk – if you paid me. **G)** Moreover, although I am doing relatively well – in my daily rehabilitation program – I am (I admit) very deliberate (*slow*) in my actions. That is, I become confused - if hurried. I also surrendered my driver’s license after my stroke event. Thus, I could not commit to an aggressive daily work-schedule. **H)** On the other hand, I am (obviously) – a passionate writer – **and, if permitted to be a “participant” – in a clinical trial [as I would like to be!]**– I could contribute the communications abilities - that I still have (to suggest and complain – when necessary) – by written means. **I)** My recent brain scans (MRI & angiogram – with dye) are clear – no concerns noted. I am reasonably certain, that my Neurologist (an M.D. and a Professor) would sign up – to my participation – in a clinical trial.

Thank you- again (Dr. Scott Gottlieb & your FDA team)– for your efforts – to keep the American public safe! I look forward to hearing from

you – or, your assigned FDA staff member – re: “**RegeneXX**” and Dr. Stiene M.D. – ([Reference 4](#)). Also, I hope to “serve” & “participate” in a “clinical trial”.

- Very Truly, Susan Marie [Cassady]-Neuhart

Noted references AND related Links:

- 1) <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm585342.htm> (Dr. Gottlieb’s a Announcement Jan. 16, 2018)
- 2) <http://hansandcassady.org/mri-images/index.html> (Susan’s MRI files and the radiologist’s report.)
- 3) <http://hansandcassady.org/> (Susan’s personal web site “HOME” page.)
- 4) <https://www.beaconortho.com/physician/henry-stiene-m-d/insights/> (Dr. Henry Stiene’s web site URL.)
- 5) <http://www.kriview.com/about-krri/our-team.html> (Dr. Keith Bidwell, M.D. – Radiologist)
- 6) <https://orthoinfo.aaos.org/en/treatment/rotator-cuff-tears-surgical-treatment-options/> (Surgical Repair – Supraspinatus Tendon Tear)
- 7) <http://www.cnn.com/2017/08/28/health/fda-stem-cells-bn/index.html> (news article CNN. “FDA cracks down on stem cell clinics”: August 29-2017)
- 8) <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm537670.htm> (RMAT Designation Regenerative Medicine Advanced Therapy Designation)
- 9) <https://www.scientific-illustrator.com/> (Hans’ web site)
- 10) <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm106001.htm> (CONTACTS at CBER)
- 11) <https://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/default.htm> (organization chart USA-FDA)
- 12) https://www.gpo.gov/fdsys/pkg/USCOURTS-dcd-1_10-cv-01327/pdf/USCOURTS-dcd-1_10-cv-01327-0.pdf (USA v. Regenerative Sciences) Case 1:10-cv-01327-RMC <https://www.casewatch.org/fda/court/regenexx/complaint.pdf> <COMPLAINT
- 13) http://www.hansandcassady.org/Susan_Resume_Jan2017latest.pdf (Susan’s Resume’)
- 14) <https://www.uwgb.edu/cst/our-people/founders-award/> (Susan UWGB Professors)

- 15) <http://www.bipc.com/recent-case-upholds-fda%E2%80%99s-jurisdiction-over-cell-and-tissue-product-regulation> (Law Firm Presentation: Buchanan, Ingersoll & Rooney)
- 16) <https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/default.htm> (FDA Biologics License Application (BLA) – REQUEST Process information)
- 17) <https://www.fda.gov/biologicsbloodvaccines/cellulargenetherapyproduct/ucm585218.htm> (FDA 4 Final Guidance Documents)
- 18) <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/default.htm> (ADVISORY COMMITTEE Blood, Vaccines and Other Biologics)
- 19) <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/CellularTissueandGeneTherapiesAdvisoryCommittee/default.htm> (ADVISORY COMMITTEE Cellular, Tissue, and Gene Therapies Advisory Committee)
- 20) <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/AdvisoryCommitteeVacancies/default.htm> (**NEW PROCESS:** Advisory Committee Vacancies, Qualifications, and Experience)
- 21) <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm> (Advisory Committee Calendar)
- 22) <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/CellularTissueandGeneTherapiesAdvisoryCommittee/default.htm> (Cellular, Tissue, and Gene Therapies Advisory Committee)
- 23) <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/AdvisoryCommitteeVacancies/default.htm> (Blood, Vaccines, Biological Products Committee Vacancies – 1 OF 2)
- 24) <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/AdvisoryCommitteeVacancies/ucm110164.htm>(Blood, Vaccines, Biological Products Committee Vacancies - 2 OF 2)
- 25) <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> (FDA Advisory Committee Membership Application)
- 26) <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/downloadConsentForm.cfm> (cONSENT form pdf DOWNLOAD LINK)
- 27) <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/default.htm> (Cellular & Gene Therapy Products REGULATION HOME)

- 28) <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/default.htm> (Approved Cellular and Gene Therapy Products OTAT LIST)
- 29) <https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/default.htm> (Report a Problem to the Center for Biologics Evaluation & Research)
- 30) <https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/default.htm> (Biological Product Deviations)
- 31) <https://www.accessdata.fda.gov/scripts/email/cber/bpdrcontact.cfm> (Biological Product Deviation Reporting (BPDR) – Contact)
- 32) <https://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Consumers/default.htm> (Consumers (Biologics))
- 33) <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/default.htm> (About the Center for Biologics Evaluation and Research [CBER])
- 34) <https://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/HealthcareProviders/default.htm> [Healthcare Providers (Biologics)]
- 35) <https://www.fda.gov/AboutFDA/CentersOffices/ucm481936.htm> < (CBER Leader Dr. Marks)
- 36) <https://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Industry/default.htm> (Industry (Biologics))
- 37) <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm059181.htm> (Section 8000: General Information)
- 38) <https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/UCM350368.pdf> (processing of Biologics License Applications)
- 39) <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm123224.htm> (CBER Key Staff Directory)
- 40) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1129084/> (Stem cell technology)
- 41) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2853843/> (Mechanical control of tissue and organ development)
- 42) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2614414/> (Implantation of neural stem cells embedded in hyaluronic acid and collagen composite conduit promotes regeneration in a rabbit facial nerve injury model)
- 43) [http://www.ajpmonline.org/article/S0749-3797\(17\)30290-8/fulltext](http://www.ajpmonline.org/article/S0749-3797(17)30290-8/fulltext) (Yoga for Military Veterans with Chronic Low Back Pain)

- 44) <https://www.ncbi.nlm.nih.gov/pubmed/24395315>)
(Treatment of non-traumatic rotator cuff tears)
- 45) <https://www.beaconortho.com/patient-forms/> (Hiene's OHsAA
PREPARTICIPATION PHYSICAL EVALUATION-patient FORM)
- 46) <http://www.hansandcassady.org/Speed2000UsersGuide.pdf> Sigrity
Speed2000 END UsersGuide – created (1998-2002) in partnership with:
Ming Jing, Jing Ping, Raymond Chen, Ji, Sun Zhao, Parminder Devsi, Raj
Raghuram, Winston, Jaime Garcia, Jiayuan Fang, etc.
- 47) <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm123224.htm> (CBER Key Staff Directory)
- 48) <https://www.fdi.org/wp-content/uploads/2017/12/Malarkey.pdf> (15
pages - ALL about FDA-CBER Enforcement & compliance)

Related Emails & CONTACT Information:

cberombudsman@fda.hhs.gov < FDA- CBER OMBUDS-personS
:: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122881.htm>

industry.biologics@fda.hhs.gov < Manufacturers Assistance
:: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm106001.htm>

bp_deviations@fda.hhs.gov < :: <https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129804.htm>

hctp_deviations@fda.hhs.gov < <https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm134534.htm>

ocod@fda.hhs.gov < <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm106001.htm>

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USA Congressman: [Turner\(Mike\)](#)[OH-10]

Republican, <https://turner.house.gov/contact/email-me>

Ohio Senator: [Portman\(Rob\)](#) – Republican

<https://www.portman.senate.gov/public/index.cfm/contact-form>

Ohio Senator: [Brown\(Sherrod\)](#) – Democrat

<https://www.brown.senate.gov/contact/email>

President of the United States (1-22-2018)

:: <https://www.whitehouse.gov/contact/>

(from [Reference 15](#)) “... February 3, 2014, the U.S. Court of Appeals for the District of Columbia Circuit upheld the U.S. Food and Drug Administration’s (FDA’s) position that Regenerative Sciences’ “Cultured Regenexx Procedure” was a biological drug subject to FDA approval through the biologics licensing application (BLA) process. U.S. v. Regenerative Sciences, LLC, 2014 WL 393602 (D.C.Cir. 2014). **It also upheld the permanent injunction against the Company’s use of the drug without FDA approval.** The Company asserted several alternate grounds for its position that the product was not FDA-regulated, including that: **(1)** the product is really a procedure governed by state “practice of medicine” rules rather than the Federal Food, Drug, and Cosmetic Act (FFDCA); **(2)** the product was not more than minimally manipulated, and, therefore, was included under an exemption from FDA approval; and **(3)** the product was a compounded product exempt from pre-approval. **The court rejected all (of) these arguments. ...”**

[END of Document]