From: James & Jun Parsons <jparsons001@san.rr.com>
Reply-To: "jparsons001@san.rr.com" <jparsons001@san.rr.com>
Date: Tuesday, May 21, 2024 at 3:30 PM
To: Claudette Mandac <cmandac@cirm.ca.gov>
Cc: "jparsons001@san.rr.com" <jparsons001@san.rr.com>, "parsons@sdrmi.org" <parsons@sdrmi.org>, "PARSONS@PLURIXCEL.COM" <PARSONS@PLURIXCEL.COM>, Vito Imbasciani <VImbasciani@cirm.ca.gov>, Maria Bonneville <mbonneville@cirm.ca.gov>, Jon Thomas <jthomas@cirm.ca.gov>, "djensen@californiastemcellreport.com" <djensen@californiastemcellreport.com>, "david293@substack.com" <david293@substack.com>
Subject: [EXT] Public Comments to CIRM Application Review Subcommittee Meeting on May 30

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Dear CIRM ARS,

Thanks for the meeting notice and thank you for this opportunity to present my Public Comment.

Lack of a scalable human cardiac stem cell source with adequate heart muscle regeneration potential remains a major setback for heart replacement, and fabricating a human heart is still beyond reach. San Diego Regenerative Medicine Institute (SDRMI) PluriXcel-SMI-Heart Platform enables direct conversion of pluripotent human embryonic stem cells (hESC) uniformly into a large supply of human cardiac stem or precursor cells for heart replacement or bio-fabrication [patent: USPTO# 9,428,731], providing a practical scalable solution for heart regeneration. More about the innovative hESC technology platforms that have overcome some major bottlenecks or hurdles in the regenerative medicine market can be found on our websites https://www.sdrmi.org & https://www.plurixcel.com.

Could you please explain to the diverse California and the world why our application TRAN4-16090 “Defined hESC Platform Enabling Large Scale Manufacturing of Clinical-Grade Cardiomyocytes for Heart Regenerative Therapy and Biofabrication” is not even eligible for applying for CIRM TRANS even though it is translational by nature, urgently needed stem cell technology to address major bottleneck in regenerative medicine, completely meets CIRM TRAN4 eligibility criteria, and aligns with CIRM’s mission “to accelerate world-class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and the world” (Please also see my previous comments at ICOC meeting on our websites https://www.sdrmi.org & https://www.plurixcel.com), and why those projects to neither deliver transformative regenerative medicine treatments nor do it in an equitable

manner to a diverse California and the world actually made to the top list of CIRM awards, just because they do have a lot of conflict of interests (COI) to tout for them, including Harvard professors and former ISSCR presidents, as demonstrated by a flood of Letters to the Board. Could you please explain to the diverse California and the world why CIRM, a California stem cell agency, would not support hESC medical innovations to reach patients who urgently need them, keep letting such crucial innovations of EDWO small business get triaged by COI of CIRM against CIRM's commitment to DEI and inclusive excellence, instead let taxpayer dollars to fuel adult stem cell scams, like iPSC Ponzi scheme of skin cells reprogrammed with oncogenes, spread all over the diverse California and the world (Please see below: Aspen Neuroscience and Ryne Bio/Kenai Therapeutics used plagiarized preclinical animal safety and efficacy data of the hESC products to obtain FDA approval and CIRM awards for iPSC products). More about the manufacturing process of the scarlet "Red" iPSC Ponzi scheme of the Bush Administration and those behind it who colluded to profit from government funding and private investment can be found on our websites https://www.sdrmi.org & https://www.plurixcel.com.

One of the fatal flaws of immunotherapy that none of the immuno-oncology companies would tell the public is that immunotherapy is extremely ineffective, only kills < 1% of cancer cells, and cancers are well known for reoccurrence if only one cancer cell is not killed. Irving Weissman, the Stem Cell Center Director of Stanford University, of course knows that, and of course he also knows the basic scientific facts that CD47 – the "do not eat me" signal -- is a common cell surface ligand expressed on both healthy and cancer cells, and CD47 antibody attacks not only cancer cells, but also stem cells of vital organs, making it highly toxic to patients. However, he still had CIRM former President back his Company Forty Seven with $15 million of taxpayer money, which allowed him to sell Forty Seven to Gilead Sciences for $4.9 billion that had generated $67 million for Stanford and $191 million for himself in March 2020. In July 2023, Gilead Sciences had to eat the loss of $4.9 billion and end Phase 3 trial of the CD47 antibody of Forty Seven since it is unlikely to improve survival, after multiple clinical holds for over a year, which have raised some serious questions about how Forty Seven could even pass Phase 1 safety trial with the $15 million from CIRM if they did not falsify or fabricate data in CIRM-funded research and clinical trials, after previous $40 million from CIRM to Irving Weissman's other Company Stem Cell without any competition had produced absolutely nothing. Of course, the public would not hear anything even slightly mentioned about such failed clinical trials that CIRM has pumped into hundreds of millions of taxpayer dollars in CIRM press releases, and CA taxpayers end up having to eat the losses too. Who have actually profited from the loss of taxpayer dollars, profited from deliberately harming patients, profited from intentionally defrauding the investing public in the staggering amounts of hundreds of millions, even billions? Could you please explain to the diverse California and the world why Irving Weissman's scam projects of his Company Stem Cells and Forty Seven and TRAN4-16091 of purifying HSC

that neither deliver transformative regenerative medicine treatments nor do it in an equitable manner to a diverse California and the world could actually make to the top list of CIRM awards again and again to make the investors and CA taxpayers have to eat billions of losses, while he and Stanford University have indeed profited millions?

Aspen Neuroscience and Ryne Bio/Kenai Therapeutics used plagiarized preclinical animal safety and efficacy data of the human embryonic stem cell (hESC) products to obtain FDA approval and CIRM awards for induced pluripotent adult/stem cell (iPSC) products.

My former mentor Jean Loring and her Company Aspen Neuroscience have used their plagiarized primate animal study data generated from the hESC products of our Company (see https://www.plurixcel.com or https://www.sdrmi.org), which we hold patent, to obtain IND from FDA for their iPSC product ANPD001, and millions of California Institute for Regenerative Medicine (CIRM) grants, and ~$250 million of private investment, even though Jean Loring/Aspen have absolutely no data no protocol no publication to show they could turn iPSC into DA neurons, even though Jean Loring/Aspen have no data no protocol no publication to show they have any iPSC-derived DA progenitor or product that is Nurr1 positive and could generate those primate study data they used for FDA approval for their iPSC product ANPD001 and in CIRM CLIN2-15547, titled “Phase 1/2a Dose Escalation Study of Autologous Neuron Replacement in Sporadic Parkinson Disease”.

In addition, Jean Loring’s student and cofounder of Aspen Neuroscience and Jeffrey Kordower have also used their plagiarized monkey study data from the hESC products of my proposals to obtain ~$4 million of CIRM CLIN1-14300 award, titled “Allogeneic iPSC derived Dopaminergic [DA] Drug Product for Parkinson's disease [PD]”, and $82 million of private investment for their Company Ryne Bio’s iPSC product or Kenai Therapeutics iPSC product RNDP-001, even though they have absolutely no data no protocol no publication to show they could turn iPSC into DA neurons, even though they have no data no protocol no publication to show they have any iPSC-derived DA progenitor or product that is Nurr1 positive and could generate those primate study data they used for FDA approval for their iPSC product RNDP-001 and in CIRM CLIN2-14300. And Aspen Neurosciences and Ryne Bio/Kenai Therapeutics have identical iPSC products with different names. Jeffrey Kordower/Lorene Studer/Bluerock Therapeutic has been eyeing our hESC therapeutic product for years, even published our large primate PD model study data in their Nature paper without our knowing and permission (see Kirks et al., Nature 2011;480:547-551) for their DA01 until they retracted those data later on to avoid the consequence of scientific misconduct. The neuronal lineage specific transcription factor Nurr-1 is essential for maintenance of maturing and adult midbrain DA neurons, or an essential marker for DA progenitor cells or DA neurons. The DA01 of Bluerock Therapeutic does not even have

nuclear-localized Nurr-1 (see Piao et al., Cell Stem Cell 2021;28:217-229), suggesting DA01 of Bluerock Therapeutics with connections to UCI/UCLA/Salk/UCSD and big Pharms, like Bayer, is actually not a DA progenitor, will certainly fail in their clinical trial.

Over 15 years ago, the rogue scientist Shinya Yamanaka put 4 oncogenes – the genes to cause cancers -- into skin cells like all those hundreds and thousands of scientists or researchers had been doing genetic manipulations before him for over 30 years. The difference is that everyone before him had made cancer cells, but he suddenly made stem cells with no proof no data, which he called "induced pluripotent adult cells" and sent that paper to the top scientific Journal Cell for review. Cell editor Emilie Marcus, who was bidding for CIRM chair, changed the name to "induced pluripotent stem cells (iPSC)" upon publication without any scientific evidence or data in order to gain political fame during the Bush Administration. And more shockingly, Shinya Yamanaka even won Noble Prize for it in 2012. The dean of Harvard Medical School George Daley even went to testify in Congress that iPSC are identical to hESC, lying straight to the face of Congress. Who said this? "The only thing needed for the evil to triumph is for the good people to do nothing", how true. You could find more about the manufacturing process of the scarlet "Red" iPSC Ponzi scheme of the Bush Administration and those behind it who colluded to profit from government funding and private investment on my website https://www.sdrmi.org.

One well-known scientific fact about cancers is that cancer cells have lost their ability to differentiate. hESC technologies and differentiation protocols do not work for iPSC because iPSC are cancer cells, none responsive to spatial temporal sensitive developmental signals. iPSC derived neurons do not even look like neurons in all those CIRM iPSC awards, including in CIRM CLIN2-15547 of Aspen Neurosciences, in CIRM CLIN2-14300 Of Ryne Bio, and in DISC0-15654 of Al Alam Denise in Lundquist Institute this round, which just shows how low the scientific standards of all the CIRM awards are or all the CIRM awards have little or no scientific merits at all, no idea how they got selected by CIRM VPs and General Counsels.

It is undeniable scientific fact that all induced pluripotent adult/stem cell (iPSC) products contain oncogenes, and FDA has strict regulations regarding any product harboring oncogenes, no matter how they lied and cheated to FDA to get their iPSC products approved for clinical trials. There are serious safety concerns to implant iPSC or cancer products into patients. Implanting the iPSC products of Aspen Neuroscience and Ryne Bio/Kenai Therapeutics in PD patients would cause brain tumors or cancers, seriously harming patients. Previously, FDA approved the CIRM funded clinical trial of Irving Weissman's Company Forty-Seven to use anti-CD47 attacking both stem cells and cancer cells that were highly toxic to patients without any concerns for patient safety. Now CIRM and FDA want to put tumors or cancers into patients

also without any concerns for patient safety. Even giving $2.5 million of taxpayer dollars to EVERSANA to lie and cheat more patients into CIRM's harmful clinical trials approved by FDA. Where are the scientific integrity and moral fiber of those at CIRM/ICOC and FDA who are only interested in their own profits?