From: James & Jun Parsons <jparsons001@san.rr.com>
Reply-To: "jparsons001@san.rr.com" <jparsons001@san.rr.com>
Date: Wednesday, May 22, 2024 at 1:33 PM
To: Claudette Mandac <cmandac@cirm.ca.gov>
Cc: "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>, "jparsons001@san.rr.com" <jparsons001@san.rr.com>
Subject: [EXT] Public Comments to CIRM Governance Subcommittee Meeting on May 30.

Public Comments to CIRM Governance Subcommittee Meeting on May 30.

Xuejun Parsons, PhD
CEO/President, San Diego Regenerative Medicine Institute, http://www.sdrmi.org
Founder/CEO, Xcelthera, https://www.plurixcel.com

Dear CIRM Governance subcommittee,

Thanks for the meeting notice and thank you for this opportunity to present my Public Comment. I'd like to make a public comment about "Evaluation of CIRM ICOC Chair and Vice-Chair".

In CIRM PAs, on CIRM website, CIRM, a California State Agency and a California Stem Cell Agency, clearly states that "The mission of California Institute for Regenerative Medicine (CIRM) is to accelerate world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world". Since CIRM ICOC Chair and Vice Chair are not scientists, I know very little or almost nothing about them. However, from those CIRM awards that neither align with CIRM's mission nor deliver transformative regenerative medicine treatments nor do it in an equitable manner to a diverse California and the world, most of those CIRM awards are even scientifically-flawed or fraudulent, but actually made to the top list of CIRM awards; from those embarrassing false or scientifically-flawed or fraudulent statements in CIRM PAs, application packages, slide shows, meetings, press releases; we, the public, could clearly see they haven't provided the vision and leadership in regenerative medicine essential to CIRM's mission, nor do they have the knowledge and integrity to uphold the scientific credibility of CIRM awards, to restore public confidence in CIRM, to gain both the public and the State of California support for bond financing, to help gain voter support for future Proposition, to avoid frauds and wastes of taxpayer money and negative public perception of CIRM; to

uphold the DEI and inclusive excellence principle and commitment of CIRM; to ensure the transparence and accountability of the entire CIRM funding process, from grants selection, review, to ICOC award; to ensure California taxpayer money to be ethically used to deliver life-saving treatments and cures for patients, not to be unethically and unaccountably distributed to profit only those who have ties to CIRM and/or ICOC; to ensure CIRM comply with the Federal and State laws, including the conflict-of-interest (COI) law the State of California about its employees; to uphold the scientific integrity, research standards, scientific credibility, openness, and fairness in CIRM grants selections, reviews, and awards; to ensure that CIRM grants selections and reviews are based on scientific merits, but not on close-ties; to ensure no double standards in CIRM funding process, from eligibility criteria, grants selections, reviews, to ICOC awards; to ensure no such anti-science, biased, discriminative/marginalizing, anti-California Stem Cell Research and Cures Act, anti-CIRM's mission, flawed, and COI eligibility criteria, terms, languages, guidelines, and instructions specifically written for stem cell scams in CIRM program announcements and application packages, from Discovery to Clinical programs to CIRM Training/Infrastructure programs; to ensure the presentations, summaries, reviews, public statements, press releases, and awards presented to ICOC in public are scientifically sound and contain no embarrassing scientifically false or fraudulent statements; to ensure the most promising stem cell research projects that would bring enormous benefit to CA diverse population to be reviewed and funded; to ensure the highest quality stem cell-based projects to be awarded; to ensure CIRM to deliver the promise of the California Stem Cell Research and Cures Act for California voters. We, the Public, are appalled by how much CIRM ICOC Vice Chair Maria Bonneville likes to display her COI and ties to CIRM awards in public again and again by floating her scientifically fraudulent awards to the top lists of CIRM awards, including CLIN1-14770 Autologous Gene Corrected Sinus Basal Cells to Treat Serious Cystic Fibrosis Sinus Disease at the cost of taxpayer dollars, instead of doing her job to fulfill the mission of CIRM that is "to accelerate world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world" and to deliver the promise of the California Stem Cell Research and Cures Act for California voters.

Due to lack of a scalable human neuron source, the need to restore vital tissue and function for a wide range of neurological diseases remains a daunting challenge to conventional drug development. San Diego Regenerative Medicine Institute (SDRMI) PluriXcel-SMI-Neuron Platform enables direct conversion of pluripotent hESC into a large supply of human neurons for neuron circuitry repair and nerve tissue bio-fabrication [patent: USPTO# 8,716,017], providing a practical scalable therapeutic solution for CNS regeneration. 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. SDRMI PluriXcel-SMI-Heart Platform enables direct conversion of pluripotent human embryonic

stem cells (hESC) **uniformly i**nto 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 therapeutic 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) in the staggering amount of >$300 million, even let tens of millions of taxpayer dollars waste on scientifically flawed or fraudulent CIRM CLIN awards directly linked to CIRM ICOC Vice Chair Maria Bonneville. 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 Cell 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 hundreds of 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?