

Frank Litvack M.D., FACC
3550 Wilshire Blvd., Suite 840
Los Angeles CA 90010

May 5, 2011

Constitutional Officers
California Institute for Regenerative Medicine (CIRM)

Re: CIRM Chair Position

Dear Sir or Madame:

After careful consideration I am writing to convey my interest in the Chair position of CIRM. It would be an honor to contribute in a leadership capacity to this remarkable Institute.

My decision is based on the following considerations. First, I believe in the great potential of stem cell technology. To be on the frontline, in what well may be the transitional medical technology of this half-century, is nothing short of exhilarating. Second, my thirty-year career as a Clinician, Researcher and Entrepreneur has been dedicated to caring for patients and to providing solutions for unmet clinical needs. My prior experience makes me confident that I am well qualified for this position. Finally, I believe in Public Service. I am in position to dedicate a significant amount of my time and energies in this regard.

It may be worthwhile to provide my views on CIRM as well as the philosophy that I would pursue if selected as the Chair. CIRM belongs to the people of California. Indeed, I view CIRM as a remarkable example of democracy at work. When politics in Washington were impeding science, the People of this state voted to fund a sanctuary for stem cell

research. It is imperative that this resource is effectively managed so as to assure the optimal use of each dollar. As the Institute belongs to the citizenry, they have both the right and the expectation of complete transparency.

The bond funding that supports CIRM must be viewed as an investment, the principal return on which ought to be new therapies and cures. The investment should further assure that California is the world's epicenter of stem cell research with the ensuing dividend of high quality jobs, new enterprises and incremental tax revenue.

The primary responsibility of the Chair is to provide oversight in conjunction with the Board so as assure the viability, functionality and effectiveness of CIRM. I maintain a variety of other activities and the part-time nature of this position is attractive. I view the Chairman's role as leading those areas that fall outside of the President's statutory responsibility including aspects of finance related to Agency funding and philanthropy, public communications as well as optimizing relationships with industry and international collaborators. I believe that the Chair and the Board must, in consort with the President, coordinate high-level strategies. The Board is composed of accomplished persons with a broad variety of skills. If selected, I would call upon its members for advice, counsel and leadership in specific areas. My management style is that of a consensus builder. I work to afford both a voice and respect to all stakeholders. On those occasions when consensus cannot be met or should performance fall short, I will not hesitate to make specific recommendations.

I now turn my attention to a brief review of my qualifications:

Early Life - I was born in Montreal Canada. Both of my parents were immigrants and my father had a small, struggling grocery business that afforded our family a middle-class lifestyle. I immigrated to the United States in 1982 and have been a naturalized American citizen for more than twenty years.

Education - I received my undergraduate and medical education at McGill University in Montreal Canada. I completed a three-year Residency in Internal Medicine at that institution. From 1982-1985 I was a Fellow in Cardiology at Cedars Sinai Medical Center in Los Angeles. I am Board certified in both Internal Medicine and

Cardiovascular Diseases. I had a third Board certification in Interventional Cardiology, which recently expired and I have not renewed, as I do not presently practice.

Medical Practitioner – I completed my formal Cardiology training in 1985. That year I joined the full-time faculty at Cedars Sinai. From 1986 until 2000, I was Co-Director of the Cardiovascular Intervention Center at that institution. During that time, with my Co-Director Dr. Neal Eigler, we built an internationally recognized program in Interventional Cardiology. I became one of the busiest practitioners of the specialty in Southern California. *We were involved in numerous clinical trials including those under IDE and designed for FDA approval of novel products. I enjoyed at various times the role of local or national Principal Investigator. In my capacity as Investigator I had interaction with FDA related to product approvals. I presented data at an FDA Advisory Committee related to approval of a cardiovascular device.* I received clinical referrals not only from around the state but from elsewhere in the country and abroad. We performed many firsts including the world's first cases with excimer laser angioplasty in humans. Dr Eigler and I performed and published one of the first series describing the benefit of coronary angioplasty during acute cardiogenic shock. Of all the activities that I have been involved with, the one that has been the most fulfilling and that I personally most identify with, is as clinician.

Academic Career- *During my tenure as faculty at Cedars Sinai I was continually active in research with a focus on 'bench to bedside' or translational research. I received my first 5 year NIH grant, a Young Investigators Award, in 1984 at the age of twenty-nine. I subsequently was Co-Investigator on an NIH SCOR as well as RO1 grants. I further received several grants from industry and philanthropy. I published extensively in peer-reviewed journals on a variety of related subjects and acted as referee for many of the leading cardiology journals. I lectured extensively around the world. We were the first to use coronary angioscopy to delineate the morphologic nature of what is now described as vulnerable plaque in living patients. Our group, in collaboration with the Jet Propulsion Laboratory, pioneered the development of the excimer laser for medical application-an early example of translational research. We were the first to publish detailed pre-clinical pharmacokinetic data of a lipophilic drug delivered off a*

coronary stent—heralding the era of medicated stents. Our team published extensively on the clinical applications and limitations of coronary stents and other interventional procedures. My academic curriculum vitae are attached.

Relevant Business Career- My interest in research led me to the world of medical technologies. I have been an entrepreneur and have founded or been involved in the development of several companies in the field. Of these, major Medical companies have acquired three and one remains an independent public company after merging with a competitor. I was Chairman of Progressive Angioplasty Systems Inc. that was acquired by United States Surgical Corporation in the late 1990's. I served as Chairman of Savacor Inc., a developer of implantable pressure monitoring devices for the patients with Congestive Heart Failure that was acquired by St Jude Medical in 2005. From 2001-2007 I was Chairman and CEO of Conor Medsystems Inc. When I invested and joined the company it had less than ten employees. *During my tenure I raised \$80 million of private equity and an additional amount of approximately \$80 million in an IPO in 2004 and follow-on public offerings.* In 2002 we were valued at \$10 million. In 2007 we had 300 employees and were sold to Johnson & Johnson for more than \$1 billion. As CEO I was directly or indirectly responsible for all aspects of the company ranging from *Finance, Regulatory Affairs, Operations as well as Legal* and Sales and Marketing. In 1985 I was Co-Founder of Advanced Interventional Systems Inc.. I served as outside Director but was not involved in management. In the mid 1990's this company merged 49:51 with a competitor Spectranetics that remains independent to this day though I have had no involvement.

Presently, I am General Partner in Reprise Medical Technologies LLC, a medical device incubator in Menlo Park. I am Chairman of Entourage Medical Technologies, a cardiac device company within the incubator. I am Chairman of iHerX Pharmaceuticals, an early stage company in San Diego with a novel viral entry blocker for the treatment of hepatitis C that is in Phase Ib trials. I am partner in Litvack Knowles Group, which is endeavoring to introduce novel medical technologies into China. I also sit on the Board of Nile Therapeutics, One Lambda Corporation, Pervasis Pharmaceuticals and Recor Medical Inc. If selected to the board I would resign and divest from any company deemed to be a

conflict of interest. Below I provide a summary of my skill sets as related to management.

- 1. Recruiting and managing senior executive personnel:** I managed the cardiovascular intervention center at Cedars Sinai including nurses, technicians and physicians. More relevant, at Conor I reduced my direct reports to three- Chief Operating Officer, Chief Financial Officer and Chief Technical Officer. Each of these had the Vice Presidents reporting directly to them. I am a firm believer in hiring the best executives and then delegating responsibility but requiring accountability.
- 2. Corporate Finance:** I have raised several hundred millions of dollars for companies I have been associated with. Investors included Angels, Venture Capitalists, Hedge Funds, Mutual Funds, Public Markets and Corporate partners. I have worked with leading Investment Banks including Citi Bank, Morgan Stanley, Lehman Brothers, CIBC, Cowan and others.
- 3. Clinical and Regulatory Affairs:** *I am well versed in matters related to FDA, product approvals and clinical trials. Virtually all the companies that I have been associated have done U.S. and/or outside U.S. trials and have interacted with various regulatory agencies.*
- 4. Intellectual Property and Business Litigation:** *I have substantial experience with the creation, licensing and litigation surrounding intellectual property. The medical Device Industry is highly litigious. At Conor, we were involved in IP litigation (as plaintiff and defendant) both in the U.S. and abroad. Given the mission critical nature of these cases I took a direct role as we retained and managed the teams of IP litigators.*
- 5. Communication:** As CEO of a public company I was the primary interface with shareholders, analysts and other interested parties. I was required to speak frequently at various symposiums and Banking conferences.
- 6. Corporate Governance:** Conor conducted an IPO in 2004. At that time we had one year to become compliant with Sarbanes Oxley. We successfully became compliant and were not cited for any material violations.

7. **Cell Therapy:** *I am on the Board of Pervasis Pharmaceuticals in Cambridge MA. The company's product is an endothelial cell therapy. I joined the Board approximately three years ago and have gained significant insights into the regulatory and manufacturing challenges faced in the development of cell therapy. For two years I have been an unpaid advisor to Capricor Inc, a cardiac stem cell company. The company is based on the research of Dr. Eduardo Marban, a CIRM grant recipient. I have advised them with regards to clinical trial strategy and the shift from autologous to allogeneic stem cells.*
8. **Licensing and Business Development:** I have substantial experience in dealing with the Business Development, Licensing and Investment arms of large Device and Pharmaceutical companies.

Advocacy and Philanthropy - Each day that I practiced medicine I was a patient advocate. As a clinician, I spent countless hours with the ill in intensive care units, emergency departments and the cardiac catheterization laboratory. The suffering borne by the ill is to me neither abstract nor hypothetical. I have participated, donated to and fundraised for advocacy groups. In 2011, I acted as ex-officio member to the Board of Planned Parenthood Los Angeles. This organization is the principal provider of women's healthcare and reproductive planning to the poor and uninsured in Los Angeles County. My wife is a member of the Board and we have recently hosted a fundraiser at our home that yielded more than \$250,000. In 2007, my wife and I were honorees for The Help Group. This organization is the largest organization of its kind in the United States serving children with special needs related to autism, Asperger's and other learning disabilities. We assisted in raising substantial funds for that organization. Earlier in this decade I was on the Board of Save A Heart Foundation. This organization raised funds for the training of cardiovascular specialists from abroad who would then return to their host country. In 2002 I received their Heart Saver Award and assisted in raising substantial philanthropic funds. My wife and I have raised money for other groups in Los Angeles including Aviva, a home for wayward young women and EveryChild Foundation, a group of which we are founding members and that raises nearly \$1 million per year for under-privileged children in Los Angeles.

Conclusion – I respectfully submit this letter for your consideration. I am available to meet at your convenience or to furnish any further information that you may need.

Sincerely,

A handwritten signature in cursive script, appearing to read "Frank Litvack". The signature is written in dark ink and is positioned above the printed name.

Frank Litvack M.D., FACC

Frank Litvack M.D. is a native of Montreal, Canada. He received his undergraduate and medical education at McGill University. He received his MD in 1979 at the age of twenty-three. Dr. Litvack completed his residency in Internal Medicine at McGill. In 1982 he moved to Los Angeles to begin his three-year Cardiovascular Fellowship at Cedars-Sinai. From 1986 until 2000 he was Co-Director at the Cardiovascular Intervention Center at Cedars-Sinai Medical Center in Los Angeles where he built and directed a widely renowned clinical and research program in Interventional Cardiology. Dr. Litvack was an active clinician, teacher and a practitioner of 'bench-to-bedside' research. This productive period led to a number of innovations in Interventional Cardiology.

Dr. Litvack attained the rank of Professor of Medicine at the UCLA School of Medicine and was board certified in three specialties- Internal Medicine, Cardiovascular Diseases and Interventional Cardiology. During his academic medical career he published extensively in various areas of research related to Interventional Cardiology. Dr. Litvack is the author of more than one hundred research articles and chapters. His primary focus was translational research involving novel therapies for patients with coronary artery and valvular heart disease. Dr. Litvack is the recipient of the Society of Photo-optical and Instrument Engineers (SPIE) Leon Goldman Award for Medical Excellence. He is an inductee in the United States Space Foundation Hall of Fame for "The Unique Secondary Use of NASA Technology" for his work translating Excimer laser technology from the Jet Propulsion Laboratories into the clinic. Dr. Litvack is a Fellow of the American College of Cardiology. During his academic career, he was Principal Investigator on a 5 year NIH Young Investigator Award and Co-Investigator on both NIH SCOR and RO1 grants.

Dr. Litvack has been an entrepreneur and executive in the medical technology industry having been involved in several start-up medical companies. These include;

1. Co- Founder and outside Director of Advanced Interventional Systems in 1985.
2. Co- Founder and Chairman of Progressive Angioplasty Systems Inc., the developer of the balloon delivery system for the U.S. launch of the

- Johnson & Johnson *Palmaz Schatz* stent and other medical products. This company was sold to United States Surgical Corporation in 1998.
3. Chairman of Savacor Inc., a developer of implantable monitors for the treatment of Congestive Heart Failure. Savacor was sold to St. Jude Medical in 2005.
 4. Chairman & CEO of Conor MedSystems Inc. from 2002-2007. This company was a developer of drug delivery stents. Dr Litvack led efforts that raised approximately \$80 million privately and close to \$100 million in two public offerings. In 2002 the company was valued at \$12 million. It was sold to Johnson and Johnson in 2007.
 5. Co-Founder and Chairman of iTherX pharmaceuticals. This venture-backed company is currently engaged in two, Phase 1b clinical trials with its novel viral entry-blocking molecule for Hepatitis C.
 6. Co-Founder of Reprise Medical Technologies, a Medical Device Incubator located in Menlo Park.
 7. Co-Founder and Chairman of Entourage Medical Technologies a venture backed developer of novel devices for the treatment of Structural Heart Disease.

Dr. Litvack serves on Boards of several life science companies including Entourage Medical (Structural Heart), Recor Medical (Structural Heart), Nile Therapeutics Inc (Specialty Pharmaceutical), One Lambda Inc (Molecular Diagnostics), Pervasis Therapeutics (Cell Therapy) and iTherx Pharmaceuticals (Biotechnology). He has been an Advisor to Capricor Inc., a cardiac stem cell company. Dr. Litvack serves on the Health Advisory Board of RAND Corporation.