CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Agenda Item # 10
1/29/09 ICOC Meeting

January XX, 2009

Re: Immediate Federal Financial Initiatives: Biomedical Stimulus Plan

Dear **WORKING DRAFT**

As Chair of the Governing Board of the California Institute for Regenerative Medicine, which was established by Proposition 71, the California Stem Cell Research and Cures Initiative, it is my intent to submit to the Board at our January 29-30 meeting a proposal to request federal financial assistance for five potential federal initiatives. It is important to obtain your preliminary feedback on the potential of these programs to obtain Congressional approval and/or White House support. Advice and direction on program modifications to enhance the potential for federal support would be greatly appreciated.

Below, I provide a short summary of the scope and terms of these proposals, followed by a narrative explanation of the economic strategy.

1. Biomedical Capital Infrastructure/Stimulus Program I

The capital infrastructure of medical research facilities for non-profit and academic research institutions is critically short of capacity to lead the next generation of biomedical advancements to reduce suffering from chronic disease and injury. For projects that can start within 90 days, and be completed within 24 months of receipt of federal funding, where the federal share of funding does not exceed 40% of the cost of the facility, a $750 million program should be immediately authorized, and a second $750 million would be authorized in the second year.

Investing in the capital infrastructure that is critical to developing and leveraging the strategic advantages of the intellectual capital infrastructure of the United States should be a top priority. These federal investments will yield a two-tier stimulus. First, immediate construction and equipment stimulus expenditures will generate a substantial number of jobs. Second, the construction of new biomedical research facilities will create a concurrent demand for the recruitment of scientific, medical, and technical research and clinical staff for the facilities.

The validation of the necessity for these facilities would be provided by requiring state or local government agency, research institutions, and

donor matching funds of at least 60% of project costs and state agencies must have submitted the project proposals to a peer review competition. A $1.5 billion federal program would assure a $3.75 billion federal stimulus construction program.

2. Biomedical Intellectual Capital Infrastructure/Stimulus Program II

Biomedical research, approved by peer review and pursuant to medical and ethical standards that follow National Academies of Science or National Institutes of Health guidelines, should be funded for established state and local government programs that can provide at least 30% of the program costs. The federal share of this program should be sized at $2.1 billion to fund research and clinical trials that can occur within a 24-month window after receipt of federal funds.

The United States cannot afford to lose its leadership position in the biomedical research field. Research capital is currently being severely cut back in the public and private sectors. Funding non-profit medical research and public/private medical research partnerships through state and local governments would support the advancement of medical therapies and help sustain America's job base in the biomedical sector. In addition, to the extent that this funding addresses interventionist medical therapies, like the Salk vaccine or cell replacement therapies, it would create a strategic opportunity to enhance the health of patients and reduce future healthcare costs. It might, for example, provide an opportunity to reduce the need for open-heart surgeries or organ transplants accompanied by lifelong immunosuppressant regimes at extraordinary costs.

The validation of the critical value of this research would be provided by the 30% state or local government match. A $3 billion stimulus program would therefore be funded by a $2.1 federal expenditure.

Leveraged Stimulus Plan Direct Funding Total For State And Local Governmental Agencies – for Stimulus Programs I & II

Under Stimulus Plan Programs I and II, federal program expenditures of $3.6 billion would result in combined federal and state stimulus program expenditures of approximately $6.75 billion [$3.75 billion Program I and $3.0 billion Program II].

An economist at the Stanford Medical School, in conjunction with a cost-benefit analysis group, has recently estimated that the direct construction multiplier effect of the expenditures proposed in Stimulus Program Plan I to be 1.80. Using this multiplier, the proposed federal expenditures, along with public and private matching funds, would result in $6.75 billion of economic activity and 51,262 job years of work.

The same economist has estimated that the multiplier effect of the direct research expenditures described in Stimulus Program Plan II to be 1.93. Using this multiplier, the proposed federal expenditures, along with public and private matching funds, would result in $5.79 billion of economic activity and 21,714 job years of work.

3. Federal Loan Guarantee Program for State/Local Government-Funded Biomedical Research – Stimulus Program III

A $3 billion program of federal loan guarantees for 5 to 10 years would also provide an extraordinary and critical stimulus to the economy. Beyond the traditional grant model for funding biomedical research, state and local governments have developed loan programs for public and private companies conducting biomedical research and clinical trials that have been selected through peer review and that conform to the medical and ethical guidelines of the National Academies of Science, the National Institutes of Health, the Institute of Medicine, and/or other state and federal regulatory authorities. Federal dollars can be further leveraged by supporting these loan programs through guarantees of a percentage of the loan and retaining the economic discipline for state and local governments by requiring them to take the top loss responsibility. Conservatively, with the federal guarantees of the bottom 50% of portfolio loss, the federal financial risk can be insulated or mitigated and the federal credit impact can result in a 200% economic stimulus as compared to the federal credit exposure.

To the extent that these loan guarantees address the period from initial proof of concept, through the preclinical studies that precede a phase I human trial approval and continue through to phase IIA or B of FDA-approved human trials, a critical gap in funding that is vital to advance therapies to patients can be addressed. This funding period has been labeled the "valley of death." Venture capital and venture lending in this phase of therapy development has virtually disappeared during the current credit crisis. Approximately 50% of small public biotech companies have less than six months working capital and an equal or greater number of small private biotech companies have less than six months working capital. For the development of therapies through to the demonstration of human efficacy, it is critical that these private companies have the ability to partner with non-profit and academic research institutions to carry the development of therapies through Phase I and II human trials. In the absence of such funding, critical advances in mitigating chronic disease and injury will be abandoned at the very time the proof of concept has been validated by scientific and medical studies.

The validation of these peer-reviewed biomedical loans would be assured by state and local government funding covering the top 50% of risk. Because state and local governments would assume the top 50% of the risk, patient advocacy organizations, private civic donors, research institutions and/or parties may be recruited by state and local government for risk sharing of the state and local government contribution. These risk-sharing syndicates would further diversify the risk and provide additional layers of validation.

A $3 billion federal guarantee program could therefore provide $6 billion in federal stimulus expenditures. All loans under this program would need to be originated within 24 months of federal allocation of funds, with 50% originated in the first 12 months; and, the disbursements under the loan program would need to be made within 48 months of origination. The predictability of a 48-month funding program could provide the assurance to the private capital markets and to joint ventures between research institutions and private biotech companies that is essential to begin a Phase I or II human clinical trial. Without a four-year predictable and reliable commitment of funding, these critical processes in the therapy development cycle cannot proceed.

Loan Guarantee Stimulus Program Impact for Stimulus Program III

Under Stimulus Program III, the Biomedical State Agency and Local Government Loan Guarantee Program, the federal guarantees would result in combined federal and state stimulus generated biomedical research and clinical trial

funding of $6 billion. Using the economic models of the economist of the Stanford Medical School, also used by the state of California, these research and clinical* trial expenditures would have a direct multiplier of 1.93, resulting in $11.58 billion in economic stimulus activity and 43,428 job years spread over the four-year fund disbursement schedule.

4. Permitting Biotech Firms to Sell R&D Tax Credits to Fund Research and/or Clinical Trials – Stimulus Program IV

Biomedical research companies should be authorized to sell R&D tax credits when the proceeds are required to fund additional research under the research or clinical trial program for which the qualifying expenditures were made. This permitted sale of tax credits would be limited to biotech companies that were below a specified asset size and that have less than a specified level of annual net revenue. Historically, tax credits have been used by large biotech and pharma companies that are relatively unimpaired by the capital crisis. Conversely, small biotech companies have not been able to use R&D credits, in general, because they have not yet developed a profitable income stream. There is therefore a misalignment of federal subsidies – which must be rationed during this time of crisis – wherein large companies that do not need the subsidies are receiving them whereas small companies for whom these subsides are essential cannot access them. In the next couple of years, there is an opportunity to set aside a large amount of these tax credits for small companies, including small companies in joint public private partnerships. These companies would be authorized to sell the tax credits to fund additional research or clinical trials where the expenditures of the companies and their non-profit partners gave rise to the tax credits themselves.

The validation of the necessity for these tax credits would be provided by the requirement that the companies to expend their own dollars to give rise to the credits in the first instance. Given that the R&D tax credits already exist under federal law, this proposal amounts to a realignment of these subsidies to generate and sustain expenditures that would not occur in the absence of these subsidies, particularly in the current credit crisis. Arguably, big biotech and pharma companies will be able to access credit without the benefit of the R&D credits. Furthermore, borrowing costs for major companies with high credit have declined and these reduced borrowing costs should offset the loss of R&D credits for these major corporations. Given the limited market for R&D credits during this period, companies should be permitted to "bank" these credits and sell them two or three years later. The existence of the tax credits would create collateral that could entice private lenders or venture capital to provide interim financing while the companies wait for the tax credit market to recover.

This program – Stimulus Program IV – has not yet been sized. Additionally, specific assumptions must be documented as to the partial displacement or deferral of large pharma research expenditures, given the partial allocation of R&D tax credit authority to small biotech firms. These assumptions have not yet been developed and vetted.

5. Funding of NIH Research Expansion- Intellectual Capital Backbone of the Country – Stimulus Program V

For all of the arguments previously stated, the expansion of NIH biomedical research funding is critical to sustain the strategic intellectual capital leadership of the U.S. in biomedical research. Of primary importance, it is extraordinarily

* Clinical model adjustments need to be made.

central to the commitment of the U.S. government to reducing the pain and suffering of patients and their families from chronic disease and injury. Whether from an economic or a humanitarian perspective, NIH funding must be expanded with an immediate early release of a component of that funding in the stimulus program for 2009. Private donor capital is radically declining for biomedical research across the country because of economic conditions and state funding has fallen off precipitously due to drops in state government revenue. The NIH budget has been relatively flat for five years resulting in a decline in real buying power. It would be critical to immediately create a "Federal Bridge Stimulus" to fill this gap in biomedical research funding for non-profit and academic research institutions before these research institutions are precipitously forced to dismantle their biomedical research programs. Research staff layoffs and research program disruptions could force the youngest and the brightest new faculty, post-docs, and graduate students out of this field, destroying the potential recruitment of America's best and brightest for three to five years or more. The daily devastation of patients' lives by chronic disease and injury does not morally permit us to allow this tragic and potentially immediate impact on the biomedical intellectual future of this country.

If an immediate commitment to increase NIH funding were made of $3 billion per year for two years, an immediate, higher floor could be assumed by U.S. research non-profits – permitting them to sustain and increase their research staff commitments. This early commitment could later be optimized, long term, in a comprehensive NIH funding bill that might be approved late in 2009 for fiscal 2009-2010 funding.

"Federal Bridge Funding" Stimulus for the NIH – for Stimulus Program V

Even an initial sizing of this suggested program would require input from a broad array of scientific and medical research constituencies. For discussion purposes, if this Program V Stimulus were approximately $3 billion a year for each of two years, totaling $6 billion, the economic stimulus impact would be roughly $11.58 billion, generating approximately 43, 428 job years over a two-year period.

Your Guidance and Input is Requested

We will provide economic data to support these program proposals. We request any supporting data that the Congressional staff may already possess. We particularly request and would appreciate critical input and guidance from you, members of your Committee and Committee staff.

The ideas discussed above are under consideration for possible submission to the Board of the California Institute for Regenerative Medicine at the end of January. Your guidance will have a significant and immediate impact on which of these programs are submitted to the Board and how these programs are structured.

Sincerely,

WORKING DRAFT

Robert Klein
Chairman, Governing Board of the California Institute for Regenerative Medicine