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September 24, 2007

Mr. Robert Klein, Chair
ICOC, California Institute for Regenerative Medicine
210 King Street, 3rd Floor
San Francisco, California 94107

Dear Mr. Klein and ICOC Members:

Thank you for the welcome opportunity to continue our discussion about the joint California State University (CSU) - California Community College (CCC) proposal for stem cell workforce development and public outreach.

At the Independent Citizens Oversight Committee (ICOC) Meeting on August 8, 2007, we presented our comprehensive proposal crafted to address economic and workforce development. The ICOC asked us a series of questions that we promised to answer. We are pleased to present our detailed responses to the ICOC's questions (attached). We are strongly of the opinion that the answers we have provided thoroughly demonstrate that the CSU and CCC can deliver on the workforce development plan we presented in our proposal.

We recognize the remarkable convergence between the CIRM Scientific Strategic Plan (December 2006) and the CSU/CCC proposal for stem cell workforce development. Both plans outline the need for a diverse stem cell workforce comprised of educated scientists to drive fundamental research, along with a skilled set of scientists, managers and technical staff able to translate discoveries into stem cell based therapies and technologies.

Again, we appreciate the opportunity to bring our strengths to serve the aims of CIRM and strongly believe that the CSU and CCC are educational partners of choice to build California's stem cell workforce. The CSU/CCC consortium can impact and reach a geographically dispersed, diverse set of Californians in an extremely cost efficient manner. We welcome the opportunity to work with CIRM to meet the Five Year Goal for stem cell workforce development.

With kind regards,

Sincerely,

Charles B. Reed
Chancellor

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"*5-Year Goals*"
"Goal VII: CIRM will have increased the work force of stem cell researchers in California. Through its training programs and through the recruitment of scientists to California, CIRM will augment the number of basic, translational and clinical scientists, as well as the number of trained technical staff. CIRM will strive to increase the diversity of the work force at all levels." (*California Institute for Regenerative Medicine, Scientific Strategic Plan, December 2006, p. 3*

CCC/CSU Response to Questions from CIRM ICOC

Find here detailed responses to individual questions from the CIRM ICOC Meeting on August 8, 2007, after presentation of a proposal from the California State University and California Community College Partnership for the Development of the Stem Cell Workforce. A draft version of this response was presented to CIRM staff and a subcommittee of the ICOC on September 13, 2007.

A. Chiu (CIRM): "Although the details are sketchy, but I believe the speakers just prior have drawn much of their material directly from pages 59 and 60, including initiatives as well as conclusions from our Strategic Plan."

As the CSU/CCC teams reviewed the CIRM Scientific Strategic Plan (SSP, *1*) released in December 2006, we affirmed that our comprehensive proposal, originally prepared in summer of 2006, successfully addressed High Level 5-Year Goal VII:

> **"*5-Year Goals*"**
> **"Goal VII: CIRM will have increased the work force of stem cell researchers in California. Through its training programs and through the recruitment of scientists to California, CIRM will augment the number of basic, translational and clinical scientists, as well as the number of trained technical staff. CIRM will strive to increase the diversity of the work force at all levels."** (*California Institute for Regenerative Medicine, Scientific Strategic Plan, December 2006, p. 37*).

To support CIRM's mission and goals, the Scientific Strategic Plan outlines eight initiatives. Importantly, the comprehensive CSU/CCC plan proposes solutions that address *more than one* of these strategic initiatives. **Our position is that effective economic and workforce development requires activities in addition to offering existing life science curriculum to Californians.** The CIRM initiatives best addressed by our proposal are: Scientific Training and Development, Mission Driven Science, Tools/Technologies/Infrastructure, and Responsibilities to the Public. For our presentation on August 8, 2007, we included Tables that mapped proposed CSU/CCC activities and budget to these four initiatives (included here as Appendix I). Together these activities provide a comprehensive framework for workforce development and training.

Several examples of specific framing text in the CIRM SPP that directly connect to our proposed activities are presented below.

1. For example, the CIRM SPP justification for 5-Year Goal VII, includes this text from page 61 outlining ***Scientific Personnel Development***:

"In the near future, we expect that California will see a surge in the number of laboratories engaged in stem cell research in both academic institutions and biotechnology or pharmaceutical companies. The growth of this industry will require an educated and well

trained work force. CIRM will support training of technical staff with essential skills for stem cell research such as cell culture, microscopy, fluorescence-activated cell sorting and analysis, micromanipulation techniques, surgical techniques, and good laboratory practices (GLP). Training will be supported at the undergraduate and masters levels with certificate or degree programs." (*CIRM Scientific Strategic Plan, December 2006, p. 61*).

The CSU/CCC plan includes several proposed activities to address these workforce needs, including stem cell laboratory and course development, industry responsive curriculum offerings and certificates, and professional development for CCC and CSU faculty leading training program development. The CIRM SSP's recognition of the need for undergraduate and masters' level instruction clearly reflects the stem cell sector's requirement for a broad range of skills and educational preparation levels, most of which are not at the doctoral level.

Together the CSU and CCC serve close to 3 million of California's citizens. The CSU confers 44 percent of California's life science and health professions bachelor's degrees, 65 percent of California's bachelor's degrees in business, about 50 percent of its bachelor's degrees in engineering, and about 41% of the state's health care and life sciences degree holders at the graduate level. Thus, the CSU and CCC are primary state resources for the technical workforce that will staff the stem cell industry.

2. The CIRM SPP also includes justification for an initiative titled ***Responsibility to the Public:***

"California population's is remarkably diverse – a source of its cultural strength and variety. CIRM will strive to reflect that variety in its activities. For complex reasons, the diversity of California is not adequately reflected in the scientific community and CIRM will need to make special efforts to encourage the training and education of minority scientists. CIRM will also need to make special efforts to ensure that clinical trials of therapies resulting from stem cell research include minority populations. Finally, CIRM will make special efforts to maintain communication with its diverse public constituency." (*CIRM, Scientific Strategic Plan, December 2006, p. 54*).

Yearly, the CSU and CCC serve close to 3 million of California's citizens. The majority of those enrolled in the CSU and CCC are students of color, and many are economically disadvantaged, first in their family to participate in higher education, and/or come from groups historically underrepresented in Science, Technology, Engineering, and Mathematics (STEM) disciplines. Many speak languages other than English, and are culturally competent in a variety of settings.

The CSU confers more undergraduate degrees to African-American, Latino, and American Indian students than all other public and private institutions in the state of California combined. For the 2001-2002 academic year, the CSU conferred 58% of the bachelor's degrees awarded to Latino students; 53% of bachelor's degrees to American Indian students, and 52% of bachelor's degrees to African-American students.

The notable diversity, accessibility, and affordability of the CSU and CCC provide CIRM with avenues to communicate with and engage segments of California's population not served by other public or private higher education institutions. The CSU and CCC's flexibility of instructional sites, degree and certificate formats, and schedules, coupled with the geographic distribution of campuses throughout the state, ensure that multiple educational pathways to careers to the emerging stem cell sectors are available to California's citizens.

The CSU/CCC plan includes several proposed activities to address these needs including expansion of the CCC Bridges to Biotechnology program, dissemination of stem cell curriculum system(s)-wide, and access to materials and methods unique to stem cell technologies to prepare an industry-ready workforce.

3. Furthermore, the CIRM SPP includes initiatives aimed at ***Public Outreach*****.**

"To an unusual degree, stem cell research is in the public eye.… Most importantly, patients and their families feel a deep involvement in stem cell research. The engagement, support and interest of this broad constituency are a great strength for CIRM. It also confers a responsibility for the Institute to communicate and interpret the results of stem cell research in many venues and be aware of its broad impact on society; effective communication that fosters awareness is an imperative for CIRM."(*CIRM, Scientific Strategic Plan, December 2006, p. 92*)

The CSU/CCC plan includes several proposed activities to address public outreach needs, including development of stem cell research focused course content and instructional modules, that can be embedded in undergraduate general education life sciences courses. All undergraduate degree programs within California's public higher education system must include a life science course as part of the general education curriculum. Development and wide dissemination of stem cell course materials throughout the CSU and CCC systems will ensure that a broad segment of California citizens have accurate and up-to-date information about stem cell advances, technologies and products.

The CSU and CCC students educated in general education life science courses include a significant fraction of California's future K-12 teachers, social services providers, and civil servants. Thus, CIRM's investment in the CSU/CCC partnership is highly leveraged and has a multiplier effect: those students educated in the CSU and CCC as science teachers, social workers, public policy developers, and administrators provide the linkages between California's communities and the stem cell industry. Without those linkages, California's community will be less aware of the importance of innovative stem cell based technologies and advances in their own lives, a key to ongoing public support.

Additionally, the CSU system provides bachelor's degrees to teachers and education staff (87 percent), social workers (87 percent) and public administrators (82 percent). Altogether, about half the bachelor's degrees and a third of the master's degrees awarded each year in California are from the CSU, including close to 2000 teaching

credentials in the life sciences. Close to sixty percent of the teachers credentialed in California (and ten percent of the nation's teachers) each year are prepared by the CSU.

As one example that addresses both *Public Outreach* and *Responsibility to the Public*, please consider the enrollment aspect of clinical trials management. The success of clinical trials rests on a team approach, involving physicians, nurse coordinators, statistical experts, ethicists, patient advocates, and social workers, among other specialists. To enroll diverse populations for clinical trials, effective participant recruitment strategies and culturally competent communications are key factors. Recruitment is often aided by health care and social work professionals who are actively working in the communities from which participants would be drawn. Most of these professionals in California are educated at the CSU and CCC.

B. Pizzo (Stanford): "And I think that there's an opportunity for other kinds of partnerships to be constructed that would allow that to take place. And here I'm talking about the whole array of health professionals who are going to be critical to this effort going forward….. And it seems to me that this would again afford another venue for facilitating science literacy, not only at the undergraduate and graduate levels, but also moving into the high school level as well. And I would hope that you would, in addition to the creative processes already in play, think about these venues as well."

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1. Students enrolled in nursing, health sciences and allied health programs at the CSU and CCC take a core curriculum of biology and chemistry coursework, so these students will be reached as part of our plan to introduce stem cell course materials into both general studies and life sciences curriculum. **We also see great opportunity for increasing outreach amongst this student population so as to recruit students into translational and clinical research career tracks.**

The CSU graduates the majority of the state's workforce in nursing, health sciences, and allied health programs. Certain specialties within the life/health sciences are disproportionately supported by the CSU: 64 percent of the state's nursing graduates; 92% of health professionals and related scientists (mostly allied health); and 100% of gerontology graduates receive their degrees from the CSU.

2. **Future high school teachers will be reached as part of general education course materials at the CSU. Current high school teachers also enroll in courses and workshops offered by the CCC and CSU as part of their ongoing professional development.** One good example is the Summer Life Sciences Institute in San Diego, sponsored by a Department of Labor Grant, BIOCOM, the San Diego Workforce Partnership and hosted at the Miramar College campus.

Pasadena City College is just completing a new cell culture facility and is currently holding their third course in stem cell culture, held midday three times a week. Additional courses can be offered at night or in the summer so teachers can attend

and incumbent workers have greater access. Workshops proposed for CCC and CSU faculty professional development offer another cost effective way to reach out to this population, in addition to existing stem cell courses offered by the CCC.

C. Reed (Burnham): "One of the questions I had was the statistics cited for the need for workers in the associate, Bachelor's, and even master's degree scientific degrees at those levels is based on U.S. statistics. I wondered what the statistics are for California."

At our presentation August 8, 2007, we cited a U.S. Department of Labor prediction that by 2012, more than 80% of biotechnology workers will have an education at or below the master's level.

To refine this prediction, we can refer to figures from a report, "Under the Microscope: Biotechnology Jobs in California," from the California Employment Development Division (*2*). In this report, the authors define biotechnology as an emerging field that "uses living organisms and their components to make products." Based on this definition, the conclusions in the report are probably applicable to the emerging stem cell sector in California also.

Importantly, the report summarized figures and predictions for biotechnology companies from several domains, including agriculture and pharmaceuticals. While not all these product segments are germane to the emerging stem cell industry, the only job title probably *not* applicable to stem cell companies at this time is "Plant Breeders."

The remainder of the job titles (see Appendix 2) include assay analysts, technicians, research associates, customer service representatives, process development associates; jobs that are all needed for stem cell product development. Subtracting predictions associated with plant breeders, the report provides data that says **the California biotechnology workforce involved in Research and Testing is already 84% non-PhD and that percentage is predicted to stay the same through 2010.** The report predicts over 40% growth (~34,500 new California research and testing jobs) in biotechnology jobs by 2010; we predict that roughly 80% of those jobs will be at the associate, bachelor's and master's levels. Furthermore, industry sources reviewed the 2007 Radford Biotechnology Benchmark Survey and report that out of roughly 200 research and development job titles, only ~15% require doctoral or medical degrees at entry. Anecdotally, a recent *Investor's Business Daily* article (*3*) reported that 180 of 1750 employees at Amylin, a California biotechnology company, have doctoral degrees roughly reflecting these figures.

The California Healthcare Institute's 2006 report (*4*) provides extensive documentation of the ongoing workforce development needs for biomedical/biotechnology related fields. In addition to documenting examples of the close coordination between life science businesses and the CCC and CSU (*4*, see pages 12-14), the 2006 report includes the following observation, which effectively describes the transition companies experience from an initial research focus to development and commercialization:

> "In the biomedical industry's formative years, collaborations between start-up companies and local universities focused primarily on the technical skills of biologists, chemists, geneticists and engineers. As companies progressed from research to development and commercialization though, their hiring and partnering expanded to include process development, manufacturing, packaging, marketing, distribution and many other new job functions." (*CHI, 2006*)

We maintain that it is the efficiency of this transition within the emerging stem cell industry sector that will be a predictor of the rate that safe and effective cures become available to Californians. The numbers and analyses in these reports reinforce our findings that workforce development aimed at providing skilled scientists, engineers, and technicians, at all degree levels, with particular focus on research translation and product development, is vital to supporting the emerging stem cell industry in California.

D. Reed (Burnham): "And so a question for me was to what extent is the lack of persons educated in the relevant areas a bottleneck now and obstacle to our progress with respect to stem cell goals?"

The CIRM Scientific Strategic Plan (SPP, *1*) aims to turn "stem cells into cures." Specifically, the SPP includes goals associated with product development, or mission directed science, including translational research and clinical investigations (*1,* p. 76 – 81). Turning discoveries into cures (products) that are safe and effective in patients requires translation of fundamental discoveries and preclinical findings into definitive clinical outcomes. This is a well-documented (*5*) bottleneck for all biomedical product development, unrelated to enabling, fundamental technologies like stem cells.

However, there is a growing knowledge base in industry and academia surrounding issues faced in developing stem cell based therapies (*6*). Story Landis, Ph.D, director of the National Institutes of Health (NIH) National Institute of Neurological Disorders and Stroke (NINDS), and chair of the NIH Stem Cell Task Force recently "discussed the need for funding of programs that will bring novel discoveries to market…" (*7*)**.** Dr. Landis described recent difficulties faced in translating many early stage stem cell discoveries to the clinic – a process she characterized as a "valley of death."

Training and culture issues contribute to Dr. Landis' concerns. A very recent article from *HealthDay News* (*8*) features insight from Dr. Richard Schilsky, associate dean of clinical research at the University of Chicago who calls "the overabundance of dead-end phase II trials [in cancer research, specifically] 'a tough academic and cultural issue... As an academic community, we have to develop a better reward system for people who play important roles in developing these large, multi-center [phase III] trials.' Companies and academic centers need not only physicians, but also skilled and experienced regulatory experts, biostatisticians and trial designers, clinical trials managers and project leaders to move stem cell therapies as efficiently as possible

through clinical trials. As noted earlier, nurses, social workers, and allied health professionals are also key team members.

The National Institutes of Health are also well aware of the obstacles facing translational medicine and have linked the issue to scientific training and workforce development, specifically citing difficulties in recruiting and retaining sufficient numbers of clinical and translational researchers (*9*). The NIH Roadmap (*10*) includes the acknowledgement that "our nation's ability to fully explore the ever-expanding opportunities for medical advances are limited only by our resources, the most important of which is the scientific workforce."

E. Reed (Burnham): "In the U.S. bureau of statistics there are cited chemists, engineers, computer scientists, people working in environmental Ag and food industries. I think we can argue that none of those require special programs in stem cell programs, only biology requires a special program. So, again, it's a point of what is the deficit in terms of biologists trained at those levels that we really need to help move these things forward?"

If the aim in moving things forward involves product development of stem cell based technologies, we respectfully submit that interdisciplinary teams are required. **Not only students in biology, but also engineering, education, allied health and even business can benefit from stem cell course materials.** We propose that increased exposure and understanding of stem cell advances, biology, and technologies will set future product development teams up for success, whether they gain hands-on experience in a stem cell laboratory, take a course at a workforce training center, or learn about the excitement and promise around stem cell research as part of their general education.

If the emerging stem cell industry tracks its projected growth with the rest of the biotechnology industry, **we'll see ~40% growth rate in employees needed by 2010** (*2*). We are not able to gather data on how many are already employed by the California stem cell sector in order to calculate a predicted stem cell specific deficit. Arguably, the emerging stem cell industry sector faces unique challenges as it develops clinical best practices for new cell-based product manufacturing, testing, formulation, and delivery. Not only does the sector need physicians interested in clinical research, but also project managers, statisticians, engineers, computer scientists, preclinical researchers and regulatory experts, among others, to fill jobs and surmount the challenges of translating discoveries into cures. The CSU/CCC is uniquely positioned to deliver this high-level workforce to assist in ground-breaking research efforts and bring them to commercialization.

F. Reed (Burnham): "Another issue related to that is what training do they need? And at this point stem cell research is something that mostly requires a general, well- grounded, basic education in biology."

We respectfully submit that a skilled workforce is needed not only for fundamental stem cell research, but also for translational studies and product development. The CCC/CSU team outlined learning outcomes in biology curriculum, based on a foundation of fundamental life sciences curriculum and good tissue culture training in our original August 2006 proposal. Based on experience gained since last summer within the CCC, preparation of a student to work in a stem cell culture lab requires one course in mammalian cell culture and one in stem cell culture. **Hands-on building of specialized laboratory skills is essential to the success of the stem cell workforce. Intellectual understanding of stem cell biology is not sufficient.**

In response to the CIRM Scientific Strategic Plan goals for workforce development, we also see the need for industry-responsive curriculum. For example, workforce training centers can focus on GMP issues associated with stem cell manufacturing and scale up, in addition to regulatory issues and quality assurance and control. Existing Professional Science Masters programs in clinical trials management can be augmented with emerging clinical practice surrounding stem cell based product development.

As with any advance in science, additional funding is requested to support innovation and new facilities and infrastructure to accommodate new directions. CIRM is funding add on capabilities and facilities for stem cell research in California to support the sector. Our proposal to layer stem cell content and experiences, including human embryonic stem cells, into California's workforce training and education is similar in its motivation.

G. Reed (Burnham): "I think another point for which I wanted clarification was to have a better understanding of really what percent increase in the workforce would this represent incrementally above what we already do in terms of generating well-trained biologists who would be prepared to go into laboratories and to take on the task of stem cell research."

The answer to this question fundamentally relates to the premise by which Proposition 71 was funded: that the state's investment of $3B would lead to both cures and economic growth. Prior to the passage of Proposition 71, various researchers,hypothesized that the California Stem Cell Research and Cures Act would create jobs. Baker and Deal (*11*) predicted creation of 22,000 jobs. Whether this figure is realistic or not, the question here for CIRM might boil down to the definition of workforce development. Are future stem cell jobs created all related to human embryonic stem cell (hESC) research jobs in the nonprofit sector - or - are they also jobs in clinical product development within industrial settings and the ancillary service sector?

In 2005 CIRM made training awards to about 170 scholars in doctoral and clinical programs throughout the state. We are not aware of awards to students not training in doctoral or post-doctoral programs. **Our position is that there is still the need to train workforce at undergraduate and masters level to meet CIRM's 5-Year Goal VII,**

especially for stem cell related jobs addressing translational, clinical and product development projects. If CIRM determines that the workforce required for stem cell research consists only of well-trained biologists, the CSU graduates 44 percent of California's life science and health professions bachelor's degrees – a significant percentage of California's future workforce, unsupported by CIRM sponsored training or resources to date.

This academic year the CCC and CSU together will prepare approximately 150 students in hands-on stem cell laboratory courses at Pasadena City College, City College San Francisco, and six different CSU campuses. At San Diego State University alone, 23 students at bachelors, masters and doctoral level are involved in faculty led stem cell research projects. Our proposal predicts that together the CSU and CCC will train ~4000 students (~4X over current capacity) over five years, if funded. Likewise, 49 CSU students participate in independent study involving stem cells as undergraduate and graduate researchers in faculty labs system-wide. This proposal aims to provide 250 internships to students statewide, a 5X increase.

We are currently unable to gather figures associated with statewide stem cell course enrollment or budgets at other public and private institutes and colleges in California so as to estimate potential CSU/CCC contribution to overall workforce training, however that is defined.

H. Reed (Burnham): "And I think the last point for which I wanted clarification and something for the board to think about is the one of getting at the reason why proposition was initiated in the first place. And it was really a reaction to restoring funding that had been withdrawn by the federal government for original research on human embryonic stem cells. There is no federal prohibition against training either of a didactic nature or of a practical nature in terms of working in laboratories because the training can be done even with approved human embryonic stem cell lines and can also be done with mouse cells, such as mouse blastocysts, for purposes of training."

While we acknowledge that there is no prohibition on stem cell training based on approved cell lines, there are very few federal agency resources to support comprehensive, focused workforce training or curriculum development programs for associate or undergraduate level scientific or technical training. Several CSU faculty have already applied to NSF's Course, Curriculum and Laboratory Improvement program for support at individual campuses; while dissemination is the long-term goal of these programs, support for state-wide dissemination and implementation is usually beyond a typical award budget. In addition, there is very little federal support available for industry-responsive curriculum, such as regulatory affairs or clinical trials management. Likewise, while workforce training resources are available at the state level and through the Department of Labor, the award budgets are not sufficient to implement a state-wide program with the capacity to address CIRM's 5-year workforce goal.

CIRM has placed value on preparing a diverse workforce to support research, and perhaps development and manufacturing of medical therapeutics based on human embroyonic stem cell technologies. **In order to fulfill this commitment to California taxpayers, the higher education systems and existing biotechnology sector need to be engaged at deep, systemic levels.** Workforce training is an essential part of the state's economic engine and CSU/CCC are uniquely positioned to provide that training to support future economic development.

I. Cunningham (for Susan Bryant, UC Irvine): "Will they have the same fundamental training in biology, for example, in cell biology and biochemistry that other students in biology have so that this is something that's added onto the top?"

Yes, the laboratory and course materials development, expansion and implementation proposed here aims to layer new content, methods and techniques onto existing curricular frameworks. For example, CSU Fullerton added a stem cell laboratory course elective (BIOL429) to their biology bachelor's degree program. CSU Channel Islands implemented a stem cell technologies course as part of the existing Masters in Biotechnology and Bioinformatics degree program. Notably, CSU Stanislaus and Merced College faculty are collaborating to develop a unit on stem cell techniques for a Cell Culture and Advanced Biotechnology course to be offered in the winter term at Stanislaus. As mentioned earlier, Pasadena City College and City College of San Francisco have already implemented stem cell techniques coursework within the CCC biotechnology program offerings. CSU Fresno will offer a stem cell certificate to post-baccalaureate and already-employed workers through the Extended Studies division.

Each of these existing course materials can be replicated or modified and disseminated state-wide, with additional support. However, despite attempts to pool available resources within and even between the systems, the CSU and CCC currently do not have resources to offer stem cell related curriculum widely across the systems within the 5-year timeframe that CIRM is proposing to address workforce development.

J. Penhoet (Gordon and Betty Moore Foundation): "So if this matures, it would be nice to get some indication of an assessment of how successful your existing programs are as a way of evaluating, so to speak, how likely you are to be successful with a broader base program."

Measures of success or impact of existing CSU and CCC programs can be based somewhat on workforce statistics. We know that California businesses rely on the CSU and CCC to provide the bulk of their workforce, regardless of technical area. To supply that business need, the CSU confers 44 percent of California's life science and health professions bachelor's degrees, 65 percent of California's bachelor's degrees in business, and about 50 percent of its bachelor's degrees in engineering.

In addition to capacity and capability data, an indicator of the quality of general, basic science education received by students progressing through the CCC/CSU systems

might be based on tracking how many students enter doctoral programs. **As evidence of our effectiveness, the National Science Foundation has consistently identified the CSU as a top baccalaureate institution of origin for STEM doctorate recipients.** For example, a recent published study (*12*) identified five CSU campuses among the top 50 undergraduate institutions of origin of Hispanic doctoral recipients. 10% of life science doctoral students admitted to the Universities of California are CSU graduates.

Vocational training is legislated into the mission of the CCC. One-third of the 110 CCCs offer hands-on certificate classes in biotechnician training in response to regional need for an operational workforce. One of the outstanding examples of the CCCs engagement in biotechnology workforce training is its central place in the National Science Foundation Advanced Technology Education effort titled "Bio-Link" (http://www.bio-link.org) hosted at City College San Francisco. Partly based on efforts through this national center, the high-quality and successful biotechnology workforce training of the CCCs is well-known throughout the nation.

The CSU is also focused on development of lab skills and has been successful in making sure that all graduates get hands-on training. For instance, CSU Fullerton biology majors graduate with at least 75-80 hours of lab experience — more if they do independent research, which 50% do. 100% of the Fullerton chemistry majors carry out independent research. The CSUPERB program sponsors student-faculty research projects, dispersing $1,291,836 in grants between 2003 and 2005. Subsequently, CSUPERB investigators were able to garner $9,397,600 of federal funding, a 7:1 return on investment that reflects the nationally competitive quality of applied research projects within the CSU.

One of the best indicators that CSU and CCC can work together successfully to achieve goals for CIRM is that we have developed shared processes for curriculum development and review over a number of years. On a local and regional level, faculty from both systems are working effectively together on issues such as as teacher preparation.

K. Concluding Statement

We wanted to address two major attributes of our proposal that are distinctive, but that were questioned by the public after the August 2007 presentation to the ICOC. First, we are proposing a *systemic* approach to our educational processes, rather than a “campus by campus” engagement. Second, we are proactively proposing a comprehensive set of programs and activities, rather than awaiting a formal workforce development RFP from CIRM.

With regard to the first point, the biotechnology educational programs across the CSU and CCC have historically been approached as system efforts. **Both systems have found that efficiencies are gained by disseminating resources and sharing materials system-wide. Importantly, system-wide dissemination assures access can be provided to excellent curriculum and resources in communities *statewide*.**

Culturally, biotechnology faculty in both systems have learned over the years to reach out to each other to keep pace with technologies and emerging practice. In practice co-located, interdisciplinary faculty in both systems have collaborated and cooperated to gain "critical mass" and to bring innovations to the two systems, many times in creatively ingenious ways that bring along great efficiencies, including management of instrument donations and co-development of new module and course material development. For instance, the CCC and CSU have partnered with SoCalBIO and the Pasadena Bioscience Collaborative on the C-LAB project, aimed at cooperatively providing biotechnology industry responsive curriculum in the Los Angeles region. Coordination on this scale is administered by program staff rather than burdening individual faculty with already heavy teaching loads or deans at individual campuses. Another recent example of system-wide administration is the CSU system's support and coordination of the system-wide Alfred P. Sloan Foundation grant for development of Professional Science Masters (http://www.calstate.edu/pa/news/2006/sloan.shtml). We might compare this comprehensive funding approach for workforce training to mechanisms increasingly used by federal agencies such as large, multidisciplinary NIH awards that may have "huge potential payoff." (*13*)

For the CSU, the CSUPERB (www.calstate.edu/csuperb/) system-wide initiative in biotechnology has successfully functioned as evolving communities of interest, learning and practice for well over a decade. Advisory and peer review committees drawn from CSU faculty, dean and presidents, along with system administration oversight, provide deep engagement and ownership on the part of individual CSU campuses in the overall CSUPERB effort. Yearly the program engages several hundred life sciences, engineering, and business faculty at 22 of the 23 campuses in the CSU. Over 700 students and faculty from across the system attend the annual CSU Biotechnology Symposium to learn about emerging science, network with each other, CCC faculty and industry representatives, share new curriculum, and present student-faculty research. Importantly, faculty from across the system formed a stem cell taskforce in 2005 that has been coordinated by CSUPERB and supported by CSUPERB funding to provide a hands-on stem cell workshop and an ethics roundtable associated with the 2007 CSU Biotechnology symposium.

The CCC has established six regional hubs, sited at individual community college campuses, together forming the network of the California Applied Biotechnology Centers (CalABC). Systemwide coordination of these centers is provided by the CCC central office. The CCC Economic and Workforce Development Program CalABC provides connections, via the six regional directors, to faculty members at the colleges who run courses such as biotechnology, histology, chemical technology, stem cell technology, nanotechnology and bioinformatics.

With regard to the second point, **the CSU and CCC proactively approached CIRM's leadership with a proposal for workforce development in the summer of 2006, due to perceived urgency of implementation after passage of the bond measure.** We also believed that no other collaboration would be able to rapidly and widely deploy the several layers of activities needed for workforce and economic development, including

stem cell scientific training, industry-responsive curriculum, and outreach initiatives, throughout California's communities.

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Table 1. Suggested CCC-CSU Activities to Address CIRM Scientific Strategic Initiatives

CIRM Scientific Strategic Plan Initiatives	Scientific Training and Development	Mission-Directed Science	Tools/Technologies and Infrastructure	Responsibility to the Public
CSU/CCC Proposed Activities				
Stem cell degree, course and laboratory development	Technical Staff training (AA, BS, MS); Scientist training (pipeline)		Access to stem cell banks (for sharing with faculty offering courses); cell culture capabilities	
Stem cell workshops and certificate programs		Bio-process engineering; clinical investigation (AA, BS, MS workforce development)	Access to stem cell banks (for sharing with faculty offering workshops and courses); cell culture production capabilities and reagents	
Student internships	Technical staff training (BS, MS); scientist internships (pipeline)	Bio-process engineering, clinical investigation (AA, BS, MS workforce development)		Economic impact (qualified workforce to grow emerging stem cell sector)
General education life science module				Public outreach, stem cell research and society
Regional workforce training centers (industry responsive curriculum focus)	Technical staff training (AA, BS, MS, incumbent and displaced workers), scientific personnel development	Bio-process engineering, preclinical product development, clinical investigation (AA, BS, MS workforce development)	Access to stem cell banks (for sharing with faculty offering workshops and courses), cell culture production capabilities and reagents	Economic impact, public outreach
CSU/CCC Bridges Program	Technical staff training (AA, BS, incumbent and displaced workers), scientific personnel development; internships	Bio-process engineering (AA workforce development)	Access to stem cell banks (for sharing with faculty offering workshops and courses), cell culture capabilities and reagents	Economic impact
CSU/CCC Career Development Program	Technical career training (AA, BS, MS), CCC/CSU faculty development (summer research appointments, internships, job shadowing, high school teacher development)			Public outreach, stem cell research and society

Table 2. Estimated Five Year Cost Projections of Proposed CCC-CSU Activities to Address CIRM Scientific Strategic Initiatives

CIRM Scientific Strategic Plan Initiatives	Scientific Training and Development	Mission-Directed Science	Tools/Technologies and Infrastructure	Responsibility to the Public	Total 5 Year Reach (students/faculty impacted statewide)	Total 5 Year Cost
CSU/CCC Proposed Activities						
Stem cell degree, course and laboratory development *(5-6 additional campuses to offer modules and courses every other year)*	$1,650,000		$1,500,000* (reagents, cell culture capabilities)		1080 students	$3,150,000
Stem cell workshops and certificate programs *(5-6 additional campuses offer certificate every other year)*		$350,000		$200,000	660 students and faculty	$550,000
Student internships *(associates, undergraduate and masters' level)*	$5,130,000		$3,965,000 (consumables and reagents)		285 students	$9,095,000
General Education life science module *(offered starting year 2)*				$775,000	>500,000 students	$775,000
Regional workforce training centers *(8-12 new industry responsive courses offered system-wide)*	$2,000,000	$3,000,000	$2,000,000* (consumables, cell production and processing capacity)	$500,000	1600 students	$7,500,000
CSU/CCC Bridges Program *(2-3 new communities)*	$1,500,000	$1,000,000 (retraining)	$500,000 (consumables and reagents)		600 students	$3,000,000
CSU/CCC Career Development Program *(20 faculty appointments/yr.)*	$5,000,000				100 faculty	$5,000,000
General Administrative (3%) and Grants Management Costs (3%)						$1,800,000
TOTAL COSTS FOR FIVE YEARS	**$15,280,000**	**$4,350,000**	**$7,975,000**	**$1,475,000**	**~4400 stem cell training; > 500,000 general education**	**$30,870,000 (~$7500/student)**

**New equipment for stem cell production and analysis will build capability and competitiveness for follow on funding*

CSU/CCC Response to CIRM ICOC (September 2007)

APPENDIX II: California Biotechnology Workforce 2000-2010[1]

Job Title	Research & Testing		Drug Manufacturing	
	2000	2010	2000	2010
HS only				
Animal Handlers	100	100	NA	NA
Library Assistants	NA	NA	NA	NA
Documentation Coordinators	2,300	3,300	500	700
Greenhouse Assistants	1,600	2,200	700	1,000
Laboratory Support Workers	NA	NA	100	100
Quality Control Inspectors	1,600	2,300	1,900	2,200
HS TOTALS ONLY	5,600	7,900	3,200	4,000
AA or Certificate				
Animal Technicians	200	300	NA	NA
Assay Analysts	5,800	8,900	2,200	3,200
Instrumentation/Calibration Technicians	2,700	3,800	1,900	2,200
Laboratory Assistants	5,200	7,800	1,900	2,700
Manufacturing Technicians	1,600	2,000	7,400	9,900
Validation Technicians	1,600	2,300	1,900	2,200
AA TOTALS ONLY	17,100	25,100	15,300	20,200
Bachelor's				
Biochemical Development Engineers	300	400	300	500
Clinical Research Associates	5,200	7,200	1,100	1,700
Customer Service Representatives	1,000	1,400	400	600
Documentation Specialists	600	900	200	300
Graphic Designers	300	400	100	100
Manufacturing Engineers	400	500	200	200
Manufacturing Research Associates	9,500	13,900	2,900	4,400
Medical (Technical) Writers	400	500	NA	NA
Microbiologists	800	1,300	800	1,100
Plant Breeders	600	800	NA	NA
Process Development Associates	5,300	7,300	1,800	2,800
Process Development Engineers	700	900	500	700
Production Planners/Schedulers	400	500	600	800
Quality Assurance Auditors	300	300	200	200
Quality Control Analysts	300	300	200	200
Quality Control Engineers	400	500	200	200
Research Associates (R&D)	12,100	17,500	2,900	4,400
Safety Specialists	NA	NA	NA	NA
Sales Representatives	400	400	500	600
Scientific Programmer Analysts	900	1,500	300	500
Technical Service Representatives	1,100	1,400	700	1,000
BACHELORS TOTALS ONLY	41,000	57,900	13,900	20,300

Job Title	Research & Testing		Drug Manufacturing	
	2000	2010	2000	2010
Masters				
Bioinformatic Specialists*	2400	4300	100	200
Biostatisticians	NA	NA	NA	NA
MASTERS TOTALS ONLY	2400	4300	100	200
Doctorates				
Research Scientists	12,100	17500	2900	4400
OVERALL TOTALS	**78,200**	**112,700**	**35,400**	**49,100**
PERCENTAGE PHD	**15.47**	**15.53**	**8.19**	**8.96**
PERCENTAGE NON-PHD	**84.53**	**84.47**	**91.81**	**91.04**
PERCENTAGE PHD - minus plant breeder title	**15.59**	**15.64**	**NA**	**NA**
TOTAL BIOTECHNOLOGY JOBS in CALIFORNIA, 2000				**113,600**
TOTAL BIOTECHNOLOGY JOBS in CALIFORNIA, PREDICTED 2010				**161,800**
PREDICTED NEW BIOTECHNOLOGY JOBS CREATED BY 2010				**48200**
PREDICTED PERCENTAGE INCREASE JOBS (2000-2010)				**42.43**

[1]Figures and numbers from "Under the Microscope: Biotechnology Jobs in California," Peters & Slotterbeck, updated June 2005, California Economic Development Department

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Manufacturing Engineers	400	500	200	200
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