

# **IOM Report: Proposed CIRM Response (For discussion by the ICOC)**

**January 23, 2013**

# Recommendations Addressed



- 1. Conflicts
- 2. Increased Industry Involvement
- 3. Appeals/Grant Review Process
- 4. Programmatic Review/Role of Patient Advocates
- 5. Chair/President Division of Responsibilities
- 6. IP
- 7. Sustainability



# Recommendations Addressed (cont'd)



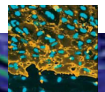
- 8. Other (Working Group make-up and reporting, SAB, RFA's, regulatory involvement, etc.)
- 9. What's required to make changes?



# Conflicts

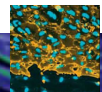


- IOM Report recommends maximizing “independent” Board votes on grants
- Currently 13 permanent Board slots with members appointed from institutions eligible for funding
- Proposal: Have 13 institutional members voluntarily abstain from voting on all grants brought before the Board for approval



# Conflicts (cont'd)

- This reduces Board to 16 eligible members to vote on grants, all economically independent, unless they are otherwise conflicted
- Eliminating economic conflicts frees Board to discuss individual grants, though in a Programmatic Review format (more on that below)
- Institutional members can still participate in discussions but cannot vote on the approval of grants



# Conflicts (cont'd)

- Proposed solution would be put in place for a one year trial period to see if it is effective
- If it is not effective, we would revisit and put in place a preferable alternative mechanism.



# Increasing Industry Involvement

- IOM Report recommended more industry involvement
- To get the greatest impact in this regard, the President and staff could increase industry participation on the GWG and the Clinical Development Advisory Panels as well as a material number of industry representatives on the recommended Scientific Advisory Board reporting to the President
- Encourage industry input on RFAs





# Appeals/Grant Review Process

- Background fact: Board has approved GWG recommendations more than 90% of the time
- IOM Report recommends eliminating extraordinary appeals
- Proposal: Redirect all scientific appeals to staff, who will evaluate to see if the GWG or a subset should consider them for further review
- Criteria: new information, material dispute, etc.
- Once appeals are finished, recommendations go to the Board





# Programmatic Review/Role of PA's



- IOM Report recommends against having voting PA ICOC members on the GWG
- PA's currently run Programmatic Review, which is the second part of GWG meetings; Chair ex officio
- Per staff and scientists on GWG, move Programmatic Review to Board (led by Board PA's, who have context having been at GWG)
- Proposal: Have current Board PA's attend GWG but not vote on any individual proposals; may



# Programmatic Review (cont'd)

- participate; Chair remains ex officio (no voting role)
- OK to have Programmatic Review at Board because economic conflicts removed
- Staff will recommend any projects they feel warrant Programmatic Review
- Programmatic Review may lead to additional funded projects and some removed from funding list
- Non-economically conflicted Board members will vote on entire slate following Programmatic Review



# Chair/President Division of Responsibilities



- IOM Report expresses concerns re overlapping responsibilities between Chair and President; recommends delegation of operational roles of Chair and Vice Chairs to President
- Proposal: Scientist/President should handle all operational responsibilities related to the science operation (the “inside” tasks). CFO under Pres
- Chair should handle all “external affairs” (quoting the LHC), including financial sustainability, government relations, bond financing (part



# Chair/President (cont'd)

finance, larger part political), communications with the outside world (i.e., beyond scientific media), etc. (the “outside” tasks)

- “Inside/Outside” combination gives CIRM full coverage of all areas needed to make Agency work – no overlapping responsibilities
- President’s staff reports to President; Chair’s staff reports to Chair



# IP

- IOM suggests greater conformity with Bayh-Dole
- Recommendation will be reviewed by the CIRM Industry and IP Subcommittee
- Topics include development of IP regs to date, with an eye on cost to CA citizens, accessibility and return on investment to the State
- Regs adjusted to make them more attractive to industry while ensuring a return to the State
- IOM Report recommends incorporating IP enforcement into sustainability platform; will do



# Sustainability

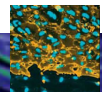
- Board pleased with all the validating comments in the report and that sustainability is set as a top priority
- Chair currently considering a variety of options, including a venture philanthropy fund
- Discussions will continue as plans fleshed out.



# Other



- Working Groups will report to the President
- Board members should continue to be voting members of the Standards Working Group (non-financial; involves ethics and policy issues) and the Facilities Working Group (can add value on lease negotiations, future construction terms, etc.)





## Other (cont'd)

- Matters in IOM report properly addressed and handled by staff will be so handled (Scientific Advisory Board, helping advance regenerative medicine regulatory pathway, RFA's, etc.)



# What's required to make changes?

- We believe this can all be accomplished through Board action and will not require either legislation or an additional ballot measure
- Corrective language (by-laws, regs, policies, etc.) will be presented to the Board at the March meeting
- Changes can be implemented immediately thereafter

