

## **Statement on Qualifications as ICOC Vice Chair from Duane Roth**

In determining the right candidate for the vice chair role, I believe it is important to examine the responsibilities and qualifications outlined in Proposition 71, what has worked well for the ICOC to date and the qualifications that each candidate brings to the table in relation to the position.

According to Prop 71, "*The vice-chairperson's primary responsibilities are to support the chairperson in all duties and to carry out those duties in the chairperson's absence.*" The qualifications for the vice chairman are outlined in Prop 71 and include three criteria, 1) documented history of stem cell advocacy, 2) must have been active in one of several disease advocacy patient groups, and 3) cannot be employed by or on leave from any prospective grant or loan recipient institution. Finally, it notes that the vice chairman preferably would have attributes and experience complementary to those of the chairperson. In the following paragraphs, I describe my qualifications and experiences to serve as vice chair.

Obviously the vice chairman must meet the Prop 71 qualification criteria and therefore the "attributes and experiences complementary to those of the chairperson" appears to be the key consideration for the vice chairperson service. In my opinion, the authors of the initiative were correct in suggesting this preference, as the complementary attributes and experiences of Chairman Klein and Vice Chairman Penhoet have served the ICOC very well. Dr. Penhoet brought to the vice chair position considerable experience in the Biotech industry having served as CEO of Chiron. He also had first-hand advocacy experience having served as Chairman of the California Healthcare Institute (CHI), and through his leadership at CHI and the Gordon Moore Foundation, had considerable non-profit governance experience. Together these experiences and attributes made Vice Chairman Penhoet an ideal "fit" with those of Chairman Klein. Bob delegated to Ed the responsibility for managing and assisting with numerous policies and procedures, including among others the establishment of the IP Policy. Bob also relied on Ed to provide policy recommendations where his knowledge and experience of working with State and Federal legislators on product development, reimbursement, financing, tax incentives and FDA regulation proved invaluable. I think the entire board is very disappointed that the conflict rules prevent Ed from continuing to serve.

As a member of the ICOC for the past two and a half years, I have had the opportunity to work with fellow Board members to oversee the implementation of the CIRM mission. I was involved in the development of the Strategic Plan and the refinements we have made over the years and therefore am supportive of the mission and priorities currently being implemented. In addition to attending all of the ICOC board meetings, I have served on the Governance and Finance standing committees, as a member of the IP Task Force as Chair of the Loan Program Task Force and as Co-Chair with Dr. Love of the task force to define a "California Supplier".

I believe the overarching goal behind Prop 71 is to support the research and development that will lead to products that will treat and/or cure a broad range of diseases and to assist

in getting these products licensed by the FDA and widely available to patients. My set of experiences includes over 30 years of Pharma and Biotech operating responsibility, having begun my career at Johnson & Johnson and then at Wyeth before starting a Biotech company, Alliance Pharmaceutical Corp. In these operating roles, I oversaw more than 20 FDA product approvals including diagnostic products, medical devices and drugs. I was fortunate to have been the product manager at Johnson and Johnson for the first ever FDA license of a monoclonal antibody product in 1979. As CEO of Alliance, I have experienced first-hand the difficulties involved in developing innovative new therapeutic products, having spent 15 years and millions of dollars on our lead product only to have an unexpected side effect derail the product in its final phase 3 clinical trial. Finally, I recently joined the SAIC Fredrick Board which manages the National Cancer Institute in Fredrick, Maryland.

For the past 20 years, I have been highly active in healthcare-related policy including FDA regulation, CMS reimbursement, and capital formation. My experience includes leadership roles with industry advocacy organizations including two terms as Chairman of BIOCUM (San Diego Biotechnology trade association) , as member of the Board and Executive Committee of CHI, and as a member of the Executive Committee and Treasurer of the national Biotechnology Industry Organization (BIO). I served on the BIO task force that successfully advocated for the passage of the Prescription Drug User Fee Act (PDUFA) leading to an increase of hundreds of FDA medical reviewers, and the Food and Drug Modernization Act (FDMA) of 1997 that standardized product review timelines. I also have considerable non-profit board-level experience including as the past Chair of the UC San Diego Sulpizio Cardiovascular Center, the UC San Diego Foundation, as Chairman of the San Diego Economic Development Corp. and as CEO of CONNECT.

With regard to meeting the Prop 71 defined qualifications for the vice chair of ICOC, I have been active for more than 15 years in disease and patient advocacy organizations in leadership roles including the American Heart Association, having served as the Chairman of the annual Heart Walk for three years and receiving its Outstanding Leadership Award, the MS Society (Humanitarian Award) and the American Lung Association.

With regard to stem cell advocacy, I was active in the Prop 71 campaign leading the effort to win the endorsements of BIOCUM, CHI, and BIO as well as the San Diego Economic Development Corp., the San Diego Chamber of Commerce and the Lincoln Club of San Diego (Republican Business organization). My service on the ICOC board has provided me an opportunity to advocate for stem cell science in many groups including State and Federal legislators, disease associations and venture capital investment conferences.

In summary, I think my experiences and attributes including product development, innovation financing, regulatory and reimbursement policy, industry leadership and governance in both for-profit and non-profit organizations complement Chairman Klein's experiences and attributes. I would like to serve in the role of vice chairman and if

elected I would use all my various experiences and energy to contribute as requested by the Chairman and the ICOC for advancing the purpose of this important cause.