July 3, 2017

The Honorable Evan Low, Chair
Committee on Business and Profession
California State Assembly
State Capitol, Room 2053
Sacramento, CA 95814

Dear Assembly Member Low:

On behalf of the International Society for Stem Cell Research (ISSCR), I want to thank you for the opportunity to share our support for Senate Bill 512, which would require clinics to post information warning patients if the practitioner performs stem cell therapies that have not yet been approved by the FDA. The ISSCR represents nearly 4,200 scientists and physicians in the United States and over 65 countries. The ISSCR has released professional guidelines and articulated rigorous standards for the clinical translation of stem cells around the world.

While stem cell science shows great potential to transform healthcare, much of this research is in its infancy, and currently only a handful of treatments has been proven safe and effective for use in patients. Many other claims that are not supported by rigorous scientific or clinical evidence have been made regarding the potential of stem cells to cure a wide range of diseases. Unfortunately, unscrupulous clinics in California and other states are peddling unproven stem cell therapies via misleading advertising and the false promise of cures. Consumers are often unaware that these products and treatments have not been proven safe or effective in clinical trials. These clinics prey on the hopes of desperate patients, who are unable to independently assess the science (or lack thereof) underlying the claims. Unfortunately, these “therapies” are often not effective, and worse, can harm, patients and their families, medically and financially.

Patient welfare is at the center of the ISSCR 2016 Guidelines for Stem Cell Research and Clinical Translation, which helps assure the public of the integrity of stem cell science and its translation to medicine. Among other things, the Guidelines stress the importance of the dissemination of information on risks, limitations, possible benefit, and available alternatives to enable well-informed decision-making by patients. ISSCR believes that the safety and effectiveness of stem cell therapies must be established in systematic and regulated clinical trials before those therapies should be sold to consumers.

The ISSCR is deeply concerned about the lack of scientific transparency and professional accountability of those engaged in the administration of unproven stem cell-based interventions outside of the context of regulated clinical trials. Senate Bill 512 is an excellent first step in ensuring that patients receive the information they need.

If the ISSCR can be of any assistance as you move forward on this critical issue, please contact me directly, or contact Kaye Meier on my staff (KMeier@ISSCR.org).

Sincerely,

Hans Clevers, MD, PhD
President, ISSCR
Professor of Molecular Genetics at Hubrecht Institute/University Medical Centre Utrecht