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June 6, 2017

The Honorable Krishnaswamy VijayRaghavan
Secretary of the Department of Biotechnology
6th-8th Floor, Block 2
CGO Complex, Lodhi Road
New Delhi - 110 003
India

Dear Dr. VijayRaghavan:

As President of the International Society for Stem Cell Research (ISSCR), I am writing to share our concerns about the premature marketing of unproven stem cell treatments to patients around the world, and to bring your attention to the extremely troubling claims and potentially dangerous practices of some clinics in India.

The International Society for Stem Cell Research (ISSCR) represents nearly 4,000 researchers, scientists, physicians, medical and legal ethicists and academics in the United States and over 60 other countries. The ISSCR has released professional guidelines and articulated rigorous standards for the clinical translation of stem cells used around the world.

We commend you for the outstanding work you did in 2013 on the “National Guidelines for Stem Cell Research,” and believe that the updates made by the Indian Council of Medical Research Department of Health Research and Department of Biotechnology in the “National [Guidelines](#) for Stem Cell Research” provide an excellent framework to ensure that clinical translation with human stem cells is conducted in a responsible and ethical manner. Specifically, the guidelines affirm:

“[A]ny stem cell use in patients must only be done within the purview of an approved and monitored clinical trial with the intent to advance science and medicine, and not offering it as therapy. In accordance with this stringent definition, every use of stem cells in patients outside an approved clinical trial shall be considered as malpractice”.



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However, the ISSCR is concerned that, unfortunately, because the Guidelines are not mandatory, nefarious clinics continue to sell unproven and scientifically dubious interventions as “therapies” to patients unaware of the potential risks and the lack of evidence to support efficacy.

For example, one such clinic based in Maharashtra in India suggests to patients they can use stem cells derived from the bone marrow to treat autism, cerebral palsy, dementia, muscular dystrophy, mental retardation, motor neuron disease, spinal cord injury, stroke, and traumatic brain injury. Claims that the same “stem cell treatment” will work for a wide variety of conditions or diseases should be viewed with significant skepticism as we point out in our website, a [Closer Look at Stem Cells](#) (see Nine Things to Know About Stem Cell Treatments). ***Furthermore, there is currently no compelling clinical evidence that bone marrow-derived stem cell therapies are effective in the treatment of any of these diseases.***

The marketing of unproven treatments raises major ethical and integrity concerns and may jeopardize the safety of patients. Patient welfare and transparency in all communications are core principles of the [ISSCR 2016 Guidelines for Stem Cell Research and Clinical Translation](#) which help assure the public of the integrity of stem cell science and its translation to medicine. Among other things, the ISSCR guidelines call for processing and manufacture of any cell product as well as the conduct of clinical trials to be performed under expert, independent review and oversight.

It is critical that any unproven stem cell-based intervention provided outside of a formal clinical trial has appropriate review and oversight. This review should include scrutiny of the potential risks and benefits of the intervention for the particular disease or injury, and of the informed consent process. Data should be collected on the safety and efficacy of the experimental therapeutics in all patients according to appropriate regulatory guidance, and these data should be made broadly available. A medical standard of care cannot be developed without such information, leaving patients vulnerable.



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The ISSCR asks that you use your authority as the Secretary of the Department of Biotechnology to initiate the investigation of fraudulent, deceptive, and/or illegal practices by clinics marketing unapproved stem cell therapies in India, and to advocate for the establishment and strict enforcement of regulations governing the introduction of stem cell-based medical interventions into commercial use.

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

Thank you for your prompt attention to this issue.

Sincerely,

Sally Temple, Ph.D.
President, ISSCR
Scientific Director, Principal Investigator and Co-Founder, Neural Stem Cell Institute,
Rensselaer, NY 12144