

Statement on Unproven Stem Cell Interventions for Lung Diseases (July 2016)

A central component of the mission of medical societies is to translate new scientific information into patient education. The undersigned lung, respiratory, and thoracic societies, and patient advocacy groups strongly believe that patients and their families along with the general public should have at their disposal unbiased and scientifically sound information on new potential therapeutic options including stem cell-based treatments.

Continuing advances in stem cell biology have created justified excitement at the prospect of personalized stem cell-based therapies through the use of clinically relevant cell populations. We recognize the enormous potential of stem cells for disease management including acute and chronic ailments of the respiratory system. As we learn more about the therapeutic potential of stem cells and other cell therapies in clinical trials of non-lung diseases and in initial trials in lung diseases, we hope to move towards further consideration and potential implementation of these approaches.

However, as with all medical interventions, patient safety must be the top priority of any prospective stem cell-based therapy or treatment. As yet, there is very little known about the short- and long-term effects in terms of safety and efficacy of administering any type of stem cell-based therapy to patients with lung diseases. Until we know more, we must be strongly concerned that the treatment could cause adverse effects and could worsen the patient's condition rather than improve it.

At present, there are only a small number of peer reviewed and appropriately regulated approved clinical trials in the United States, Canada, the European Union, Brazil, Asia and Australia investigating cell therapy approaches for lung diseases. These can be found on the website of the National Institutes of Health at www.clinicaltrials.gov, of the European Medicines Agency at <https://www.clinicaltrialsregister.eu/ctr-search/search>, and of UMIN-ICDR in Japan at <http://www.umin.ac.jp/icdr/index.html>. We are watching these carefully to determine whether they will demonstrate that stem cell-based treatments could be effective and safe for treating lung diseases.

Thus, we are particularly wary of the ever-increasing examples of direct-to-consumer advertising of untested, unapproved, and potentially dangerous “stem-cell” treatments that take place in several countries. One may come across information on the internet or other sources about stem cells being administered to patients with lung diseases such as emphysema, pulmonary hypertension, cystic fibrosis, or pulmonary fibrosis in several locations worldwide including the United States. We fully acknowledge that patients with severe irreversible lung diseases are under extreme physical and emotional distress that provide the motivation to resort to expensive unproven treatments.

Nevertheless, we strongly caution all patients that the claims of benefit being made by many of these programs have not been substantiated nor have they been reviewed by experts in the field or any regulatory agency. These programs are usually characterized by:

- Exorbitant fees
- Misrepresentation of risks and benefits
- Overreliance on, and advertisement of, patient testimony
- Poor patient follow-up
- Absence of regulatory oversight and objective clinical evidence for claimed benefits

Therefore, they differ substantially from therapies approved by legitimate regulatory agencies, from well-designed, controlled, and appropriately regulated clinical trials, and from regulated compassionate use of innovative cell therapies. **Because of the potential for harm and the lack of any proven benefit, we strongly caution patients not to participate in these or any other comparable unauthorized or unapproved stem cell interventions, unless independent credible, reliable, and objective sources of information are available to substantiate the information and claims being made.**

To better educate the lung scientific community about the complex issues of stem cell medical tourism, we propose the inclusion of relevant sessions, whenever possible, in future national and international conferences related to lung biology and disease. Representatives of regulatory agencies, patient advocacy groups, and bioethics and health policy scholars should be included as speakers and discussants. We also urge patient advocacy groups and foundations to work together with their national lung, respiratory, and thoracic societies, their local chapters, and with regulatory agencies on the issues of stem cell medical tourism and unproven stem cell interventions. Open channels of communication between these organizations and dissemination of reliable, evidence-based information through patient networks including social media, will ensure that lung disease patients make informed and safe decisions regarding cell-based treatments.

One such reliable source of information is the International Society for Stem Cell Research (ISSCR), which has developed an excellent web-based resource that includes the ISSCR patient handbook (<http://www.isscr.org/home/publications/ClinTransGuide>, <http://www.closerlookatstemcells.org/stem-cells-and-medicine>). The handbook provides information on mechanisms for monitoring or substantiating the claims being made by various organizations that purport to offer “stem cell therapies.”

Additional resources are provided by the International Society for Cellular Therapy (<http://www.celltherapysociety.org/?page=PTF2015>, <http://bit.ly/1IAjOIV>), the California Institute for Regenerative Medicine (www.cirm.ca.gov), the Canadian Stem Cell Network (<http://www.stemcellnetwork.ca/>) and the Canadian Stem Cell Foundation (stemcellfoundation.ca).

This Assembly on Respiratory Cell & Molecular Biology Stem Cell Working Group statement is supported by the following lung, respiratory, and thoracic societies and patient advocacy groups:

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