

**Tackling the issues in the commercialization
of unvalidated cell interventions**
*The ISCT Presidential Task Force on the Use of
Unproven Cellular Therapies*

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A global issue

❖ Hundreds of clinics in dozens of countries

- » Primarily advertise 'stem cells', but also progenitor cells, immune cells, xenogeneic ('fresh') fetal cells, etc.

❖ Unsupported marketing claims

- » Targeting > 100 diseases (including ALS, autism, diabetes, CHF, spinal cord injury, MS) plus aesthetic, anti-aging

❖ Increasingly sophisticated, organized, activist industry challenging regulatory frameworks

Presidential Task Force

- ❖ 20 members, representing 10 countries
 - » Led by ISCT President (Kurt Gunter) and President-Elect (Massimo Dominici)
- ❖ Academia, medicine, industry, policy, law, ethics
- ❖ Cell therapeutics in general
 - » Not only 'stem cells'

Goals

- ❖ Review major scientific, ethical issues
- ❖ Work with ISCT Scientific Committees to review state-of-the-science with respect to various cell types, indications
- ❖ Develop effective communications strategies
 - » Publish follow-up position statement in *Cytotherapy*
 - » Develop tools to aid patient decision-making
 - » Serve as public advocates for the field
 - » Contribute to ISCT communications (*Telegraft*, social media, etc.)
- ❖ Establish/reinforce collaborations to address the issues more effectively

Working Groups

- ❖ Definitions
- ❖ Scientific Evidence and Biological Rationale
- ❖ Issues in Laboratory cell Processing
- ❖ Issues in Clinical Practice
- ❖ Regulatory Aspects
- ❖ Commercial Implications
- ❖ Communications
- ❖ ISCT Policy

Liaisons

- ❖ To be engaged once a working draft is developed
- ❖ Facilitate broader collaboration, representation

- ❖ Regulatory

- ❖ Ethics

- ❖ Patient/disease advocacy associations

Key issues

- ❖ Develop an appropriate terminology
- ❖ Define levels of scientific evidence needed to justify routine use
- ❖ Address questions of ‘experimental,’ ‘innovative’ use
- ❖ Understand global regulatory landscape, identify gaps, contradictions

Key issues

- ❖ Ethics of unregulated direct-to-consumer (patient) marketing
- ❖ Implications for industry
- ❖ Develop effective communications strategies for patient outreach, refuting common myths
- ❖ Reach out other organizations concerned with or affected by cell therapy DTC marketing

A call for collaboration

- ❖ Scientific societies
- ❖ Medical associations
- ❖ Industry groups
- ❖ Patient/disease advocacy groups
- ❖ Ethics
- ❖ Healthcare economics

ISCT WHITE PAPER

Cell therapy medical tourism: Time for action

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