

Cell Therapy Medical Tourism: Patient Care, Advocacy and Protection

Cell Therapy Medical Tourism: Time for Action

- ❖ Medical tourism for terminal diseases has a long and inglorious tradition
- ❖ Significant risks to
 - » Patients
 - » The field of cellular therapy
- ❖ Mainstream medicine has not responded to protect patients
- ❖ What can the cell therapy community do?
- ❖ Balance needs to
 - » Mitigate patient risks
 - » Promote scientific development
 - » Compassionate and early access to promising therapy

Spectrum of Cell Therapy Medical Tourism

**Clinical
Trials**

- Pilot Studies
- Phase I, II, III

**Innovative
medical
care**

- Non-approved, possibly unproven therapy provided by legitimate (regulated; with oversight) caregivers with appropriate informed consent

Unethical

- Unproven, unregulated medical procedures marketed as beneficial therapy without informed consent

International Society for Cellular Therapy

ISCT



Patients' Rights

Right to information

- » Accurate representation regarding safety and efficacy record of treatment
- » Likely side effects
- » Need for centralized repository of therapies

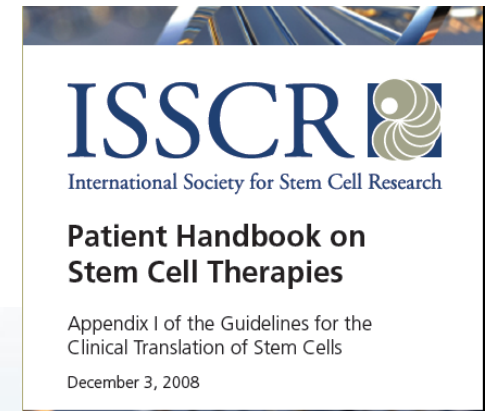
Informed consent

- » Clinical trials
- » Unproven therapies

Right to seek treatments

What Can Cell Therapy Stakeholders Do? Options for Discussion

- ❖ Raise awareness
 - » Public service announcements/messages
 - » Web site banners/announcements
 - » Patient education initiatives
- ❖ Incentives for publication
- ❖ Consumer tools
 - » Cell therapy guide for patients and caregivers
 - » ISSCR: www.closerlookatstemcells.org
- ❖ Partnership with patient advocacy groups
 - » Trusted source of non-biased information
- ❖ Aggressive regulatory compliance inspections and enforcement



What Can Cell Therapy Stakeholders Do?

Options for Discussion

- ❖ New regulations
 - » Advertising and promotion
 - » Patient treatment reporting/registration
 - » Adverse event reporting
 - » Import/export of patient treatment materials
- ❖ Global regulatory harmonization
 - » Adverse event reporting requirements
 - » Standardized informed consent
 - » Investigator conflict of interest/financial disclosure requirements
- ❖ Ensuring sufficient resources
 - » What can stakeholders do together?

Vision

A broad based coalition of all stakeholders focused on patient advocacy and protection in the area of cell therapy medical tourism

- **Speaking with a unified voice and leveraging our**
 - **Scientific expertise**
 - **Reputations**
 - **Diverse audiences**



www.loyaltyhammer.com

For Additional Information

Cytotherapy, 2010; 12: 965–968

informa
healthcare

ISCT WHITE PAPER

Cell therapy medical tourism: Time for action

KURT C. GUNTER¹, ARTHUR L. CAPLAN², CHRIS MASON³, RACHEL SALZMAN⁴,
WILLIAM E. JANSSEN⁵, KAREN NICHOLS⁶, LUIS F. BOUZAS⁷, FRANCESCO LANZA⁸,
BRUCE L. LEVINE⁹, JOHN E. J. RASKO¹⁰, AKIHIRO SHIMOSAKA¹¹
& EDWIN HORWITZ¹²