

**Stem Cell Therapies: Opportunities for Assuring the Quality and  
Safety of Unregulated Clinical Offerings – A Workshop**

**November 18, 2013**

National Academy of Sciences Building, Room 125  
2101 Constitution Avenue, NW, Washington, D.C.

**MEETING OBJECTIVES**

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- Discuss the current environment in which patients are receiving unregulated stem cell offerings
- Examine the stem cell treatments that are being offered
- Assess the potential benefits and risks to individual health
- Consider the evidence base needed to substantiate the clinical application of stem cell technologies
- Evaluate legal hurdles for establishing standards and criteria to govern stem cell trials and treatments
- Discuss potential solutions for assuring the quality of stem cell offerings

**AGENDA**

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- 8:00 – 8:30 a.m. **Sign-in**  
**Breakfast and coffee, NAS 125**
- 8:30 – 8:45 **Welcome, Introduction of Moderators, Meeting Goals, and Charge to Participants**  
*Alta Charo, University of Wisconsin and Planning Committee Chair*

**SESSION I: STEM CELL THERAPIES – KNOWN AND UNKNOWN**

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**Moderator:** *Ralph J. Cicerone, National Academy of Sciences*

- 8:45 – 9:10 **Stem Cells as Regulated Therapeutics**  
*John Wagner, University of Minnesota*
- 9:10 – 9:25 **Clinical Offerings that Use Stem Cells**  
*Timothy Caulfield, University of Alberta*

9:25 – 9:40 **Patients Seeking Unproven or Unregulated Treatments: Why and How**  
*Alan Petersen, Monash University*

9:40 – 10:20 **Moderated Panel Discussion**  
Panelists: *John Wagner, Timothy Caulfield, Alan Petersen*

10:20 – 10:35 **BREAK**

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**SESSION II: QUALITY ASSURANCE – PART I**

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**Moderator:** *Ellen Feigal, California Institute for Regenerative Medicine*

10:35 – 10:50 **Regulatory and legal frameworks for offering stem cell therapies in the United States**  
*Margaret Foster Riley, University of Virginia School of Law*

10:50 – 11:05 **Regulatory and legal frameworks for offering stem cell therapies in Italy**  
*Paolo Bianco, Sapienza Università di Roma*

11:05 – 11:20 **Regulatory and legal frameworks for offering stem cell therapies in Japan**  
*Toshio Miyata, Health and Global Policy Institute*

11:20 – 11:35 **Regulatory and legal frameworks for offering stem cell therapies in Mexico**  
*María de Jesús Medina Arellano, Universidad Autónoma de Nayarit*

11:35 – 11:50 **Regulatory and legal frameworks for offering stem cell therapies in China**  
*Qi Zhou, Institute of Zoology Chinese Academy of Sciences*

11:50 – 12:30 **Moderated Panel Discussion**  
Panelists: *Margaret Foster Riley, Paolo Bianco, Toshio Miyata, María de Jesús Medina Arellano, Qi Zhou*

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**LUNCH SEMINAR**

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12:30 – 12:50 **BREAK**

12:50 – 1:00 **Introductory Comments**  
*Irving Weissman, Stanford University School of Medicine*

1:00 – 1:15 **A Patient's Story**  
*Michael Phelan*

1:15 – 1:45 **Medical Tourism: Patients Seeking Stem Cell Treatments**  
*I. Glenn Cohen, Harvard University Law School*

1:45 – 2:00 Discussion

2:00 – 2:15 **BREAK**

**SESSION III: QUALITY ASSURANCE – PART II**

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**Moderator:** *Amy Comstock Rick*, Parkinson's Action Network

2:15 – 2:30 **Quality of Information: Advertising**  
*David Vladeck*, Georgetown University

2:30 – 2:45 **Quality of Information: ISSCR Statements and Guidelines**  
*George Daley*, Harvard University

2:45 – 3:15 **Quality of Professional Services: Medical and Society-Based Accreditation**

**Professional society efforts calling for evidence-based medicine and appropriate independent oversight**

*Douglas Sipp*, International Society for Cellular Therapy

**Professional society efforts in parallel with government regulation**

*Glenn L. Schattman*, Society for Assisted Reproductive Technology

3:15 – 3:55 **Moderated Panel Discussion**  
Panelists: *David Vladeck, George Daley, Douglas Sipp, and Glenn L. Schattman*

3:55 – 4:10 **BREAK**

**SESSION IV: MOVING FORWARD**

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**Moderator:** *Harvey V. Fineberg*, Institute of Medicine

4:10 – 5:10 **Moderated Panel Discussion**  
Panelists: *Glenn L. Schattman, David Vladeck, María de Jesús Medina Arellano, Timothy Caulfield, Michael Phelan, Gil Van Bokkelen*

**WORKSHOP WRAP-UP**

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- 5:10 – 5:25      **Summary of Salient Points and Final Words**  
*Alta Charo*, University of Wisconsin and Planning Committee Chair  
*Harvey V. Fineberg*, Institute of Medicine  
*Ralph J. Cicerone*, National Academy of Sciences
- 5:25              **Adjourn**