

February 12<sup>th</sup>,  
2015

8:45 a.m. – 4:00 p.m.

Main Auditorium  
Shriner's Hospital

UC Davis Health System Campus  
Sacramento, CA 95816

Registration  
Required

RSVP Deadline:  
February 4<sup>th</sup>, 2015  
By 12pm

Send Response  
with  
contact information  
to

Julie Bechtel  
916-734-6181

[julie.becht@ucdmc.ucdavis.edu](mailto:julie.becht@ucdmc.ucdavis.edu)

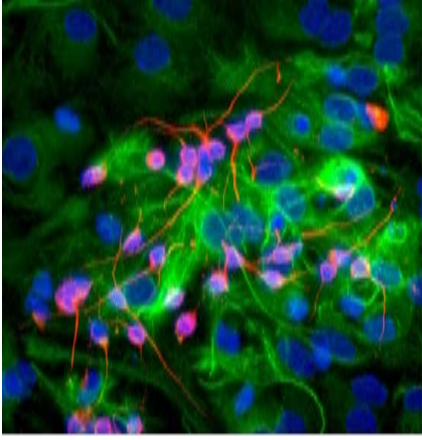
Presented by:  
UC Davis Bioethics Program

## "Right to Try" Laws, Medical Tourism, and Stem Cell Interventions"

### Agenda

- 8:45 AM Registration
- 9:00 AM Welcome and Introduction  
**Julie A. Freischlag**, MD, Vice Chancellor, Human Health Sciences and Dean, UC Davis School of Medicine
- 9:05 AM Patient Choices: Voices from the trenches: (TBA)
- 10:00 AM FDA Approval of Stem Cell Therapies: Does it Really Matter? **Paul Knoepfler**, PhD, UC Davis Med School
- 10:45 AM Break
- 11:00 AM Federal Regulation of Therapeutics in the US: Pro's and Con's.  
**Lisa Ikemoto**, JD, UC Davis Law School,  
**Nanette Joyce**, DO, UC Davis Med School and TBA
- 12:00 PM Lunch
- 12:45 PM Keynote Address: **Timothy J. Caulfield**, LL.B, LL.M., University of Alberta.  
"Science Hype & Pressure to Commercialize: Balancing Risks and Benefits"
- 1:30 PM **Alison Sorkin**, JD – University of Colorado Hospital, - "A frustrated state: Colorado's attempts to provide quicker access to experimental treatments"
- 2:00 PM **Mary Ann Chirba**, JD, ScD, MPH – Boston College Law School,  
"Impact of Recent FDA Guidance Efforts on Patient Access to Autologous Therapies"
- 2:30 PM **Leigh Turner**, PhD – University of Minnesota, - "U.S. Clinics Marketing Unapproved "Stem Cell" Inventions: Ethical Issues and Regulatory Concerns"
- 3:00 PM **Gerhard Bauer**, MD - University of California, Davis - "Cellular and gene therapy product manufacturing for novel clinical applications – Is tight regulatory oversight wanted or needed?"
- 3:30 PM Panel & Audience Discussion
- 4:00 PM Adjournment

Supported by  
UC Davis Clinical and Translational Science Center  
UC Davis MIND Institute



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**UC Davis  
2<sup>nd</sup> Annual Stem  
Cell Research  
Policy and Ethics  
Symposium**

Presented by:  
UC Davis Bioethics Program

**"Right to Try" Laws, Medical Tourism, and Stem  
Cell Interventions"**

**Confirmed Speakers Include:**

**Timothy Caulfield, LL.B, LL.M.**, University of Alberta, (*Keynote Speaker*). His keynote address will look at the challenges associated with science hype and pressures to commercialize stem cell research.

**Alison Sorkin, JD**, University of Colorado Hospital. She is legal counsel for the University of Colorado Hospital and will speak about the recent passage of Right to Try legislation in Colorado.

**Mary Ann Chirba, JD, ScD, MPH**, Boston College Law School. Her areas of expertise include the use of law and regulation to promote medical product safety, as well as emerging federal and international guidelines for stem cell research.

**Leigh Turner, PhD**, University of Minnesota. His presentation will include an analysis of the rapid proliferation of stem cell clinics within the United States, as well as how "right to try" laws may be solutions in search of a problem.

**Gerhard Bauer, MD**, University of California, Davis. He is Director of the Good Manufacturing Practices (GMP) stem cell production facility at UC Davis. He will address the importance of safety and oversight in cell manufacturing and manipulation.

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