



*National Institutes of Health
1st Gene Therapy Policy Conference*

Conference Agenda

Introduction (8:00 - 8:30 am)

- 8:00 - 8:10 Opening Remarks
Speaker Lana Skirboll, Ph. D.
 Associate Director for Science Policy, NIH, Bethesda, MD
- 8:10 - 8:30 Meeting Overview and Historical Background: Human Gene Transfer Research in the U.S.
Speaker Claudia Mickelson, Ph.D.
 Massachusetts Institute of Technology, Cambridge, MA

Session I: Scientific Prospects for Enhancement Through Gene Transfer (8:30 - 10:30 am)

- 8:30 - 8:50 Enhancement of Human Traits
Speaker Theodore Friedmann, M.D.
 University of California San Diego, La Jolla, CA
- 8:50 - 9:10 Current State and Theoretical Feasibility
Speaker Hunt Willard, Ph.D.
 Case Western Reserve University, Cleveland, OH
- 9:10 - 9:30 Assessing Long-term Safety and Efficacy
Speaker W. French Anderson, M.D.
 University of Southern California, Los Angeles, CA
- 9:30 - 10:30 Session I Panel Discussion: Scientific Prospects for Enhancement Through Gene Transfer
Moderator Hunt Willard, Ph.D.
 Case Western Reserve University, Cleveland, OH
- Panelists W. French Anderson, M.D.
 University of Southern California, Los Angeles, CA
- R. Michael Blaese, M.D.
 Clinical Gene Therapy Branch, NHGRI, NIH, Bethesda, MD
- Christopher Evans, Ph.D.
 University of Pittsburgh School of Medicine, Pittsburgh, PA
- Theodore Friedmann, M.D.
 University of California San Diego, La Jolla, CA
- Alan Goldhammer, Ph.D.
 Biotechnology Industry Organization, Washington, D.C.
- Chester Whitley, Ph.D., M.D.
 University of Minnesota Hospital and Clinic, Minneapolis, MN
- 10:30-10:40 Coffee Break***

Session II: The Treatment/Enhancement Distinction: Conceptual, Ethical, and Social Issues (10:40-1:45)

10:40-11:00 Conceptual Issues
Speaker Eric Juengst, Ph.D.
 Case Western Reserve University, Cleveland, OH

11:00-11:20 Ethical Issues
Speaker Thomas H. Murray, Ph.D.
 Case Western Reserve University, Cleveland, OH

11:20-11:40 Social Issues
Speaker Sheila M. Rothman, Ph.D.
 Columbia University, New York, NY

11:40-12:45 Lunch (several excellent restaurants in the area—list included in registration packet)

12:45 - 1:45 Session II Panel Discussion: The Treatment/Enhancement Distinction: Conceptual, Ethical, and Social Issues

Moderator Eric Juengst, Ph.D.
 Case Western Reserve University, Cleveland, OH

Panelists Ronald Cole-Turner, Ph.D.
 Pittsburgh Theological Seminary, Pittsburgh, PA

 William Dommel, Jr., J.D.
 Office of Protection from Research Risk, DHHS, Bethesda, MD

 Glenn McGee, Ph.D.
 University of Pennsylvania, Philadelphia, PA

 Gerald McKenny, Ph.D.
 Rice University, Houston, TX

 Thomas H. Murray, Ph.D.
 Case Western Reserve University, Cleveland, OH

 Erik Parens, Ph.D.
 The Hastings Center, Briarcliff Manor, New York

 Sheila M. Rothman, Ph.D.
 Columbia University, New York, NY

 Paul Wolpe, Ph.D.
 University of Pennsylvania, Philadelphia, PA

 Doris Zallen, Ph.D.
 Virginia Polytechnic Institute and State University, Blacksburg, VA

**Session III: Development of a "Treatment/Enhancement" Distinction as Part of a Guidance Document
(1:45 - 3:45)**

1:45 - 2:05 Operational Criteria for Treatment/Enhancement Distinction
Speaker Anita Silvers, Ph.D.
San Francisco State University, San Francisco, CA

2:05 - 2:25 Current Regulatory Significance
Speaker Maxwell Mehlman, Ph.D.
Case Western Reserve University, Cleveland, OH

2:25 - 2:45 Development of a Guidance Framework Document
Speaker Claudia Mickelson, Ph.D.
Massachusetts Institute of Technology, Cambridge, MA

2:45-3:45 Session III Panel Discussion: The Development of a "Treatment/Enhancement" Distinction as
Part of a Guidance Document

Moderator Claudia Mickelson, Ph.D.
Massachusetts Institute of Technology, Cambridge, MA

Panelists Dan Brock, Ph.D.
Brown University, Providence, RI

Norman Daniels, Ph.D.
Tufts University, Boston, MA

Nancy King, J.D.
University of North Carolina, Chapel Hill, NC

Charles McCarthy, Ph.D.
Kennedy Institute of Ethics, Washington, D.C.

Maxwell Mehlman, Ph.D.
Case Western Reserve University, Cleveland, OH

Philip Noguchi, M.D.
Division of Cellular and Gene Therapies, CBER, FDA, Rockville, MD

Karen Rothenberg, J.D., MPA
University of Maryland School of Law, Baltimore, MD

Anita Silvers, Ph.D.
San Francisco State University, San Francisco, CA

3:45 - 4:00 *Coffee Break*

4:00 - 5:30 *Break-out sessions per panel--includes opportunity for public comment*