

PROCEEDINGS OF THE ETHICAL CHALLENGES IN SURGICAL INNOVATION SUMMIT

MAY 8–9, 2008 • CLEVELAND CLINIC, CLEVELAND, OH

Supplement 6 to Volume 75, November 2008 • www.ccjm.org/content/75/suppl.6

Summit Directors and Supplement Editors

ALLEN BASHOUR, MD
Cleveland Clinic

ERIC KODISH, MD
Cleveland Clinic

Contents

Most of the articles in this supplement were developed from audio transcripts of the summit's presentations and panel discussions. The transcripts were edited by the Cleveland Clinic Journal of Medicine staff for clarity and conciseness, and were then review and revised/approved by the respective speaker or panelists. Exceptions are the articles followed by an asterisk () below, which were submitted as manuscripts by their authors.*

From the summit directors*	S1
Eric Kodish, MD, and Allen Bashour, MD	
Editors and contributors	S4
Welcome	
Ethics in surgical innovation: Vigorous discussion will foster future progress	S6
Delos M. Cosgrove, MD	
Panel 1: Surgical Innovation and Ethical Dilemmas	
Surgical innovation and ethical dilemmas: Precautions and proximity*	S7
Joseph J. Fins, MD	
Surgical innovation and ethical dilemmas: A panel discussion	S13
Isador Lieberman, MD; James Herndon, MD; Joseph Hahn, MD; Joseph J. Fins, MD; and Ali Rezai, MD	
Panel 2: Transplant Innovation and Ethical Challenges	
Pushing the envelope in transplantation: Three lives at stake*	S22
Pauline W. Chen, MD	
Transplant innovation and ethical challenges: What have we learned?	
A collection of perspectives and panel discussion	S24
Denton A. Cooley, MD; John J. Fung, MD, PhD; James B. Young, MD; Thomas E. Starzl, MD, PhD; Mark Siegler, MD; and Pauline W. Chen, MD	
We have come far, but selecting organ recipients remains an ethical minefield —Denton A. Cooley, MD	S24
Despite the odds, the transplant field has progressed rapidly —John J. Fung, MD, PhD	S25
A continued need for evidence-based guidance —James B. Young, MD	S26
What does—and does not—spur innovation? —Thomas E. Starzl, MD, PhD	S28
Panel discussion —Moderated by Mark Siegler, MD	S30

Copyright © 2008 The Cleveland Clinic Foundation. All rights reserved.

The statements and opinions expressed in this supplement to the *Cleveland Clinic Journal of Medicine* are those of the authors and not necessarily of the Cleveland Clinic Foundation or its Board of Trustees. They do not necessarily represent formal practice guidelines in effect at Cleveland Clinic.

The *Cleveland Clinic Journal of Medicine* [ISSN 0891-1150 (print), ISSN 1939-2869 (online)] is published 12 times yearly by the Cleveland Clinic Foundation.

Subscription rates: U.S. and possessions: personal \$108; institutional \$134; single copy/

back issue \$20. Foreign: \$134; single copy/back issue \$20. Institutional (multiple-reader) rate applies to libraries, schools, hospitals, and federal, commercial, and private organizations. Individual subscriptions must be in the names of and paid by individuals.

Postmaster address changes: *Cleveland Clinic Journal of Medicine*, NA32, 9500 Euclid Avenue, Cleveland, OH 44195. Subscription orders, editorial, reprint, and production offices (same address): 216-444-2661 (phone); 216-444-9385 (fax); ccjm@ccf.org (e-mail); www.ccjm.org (Web).

Printed in USA.

AMM Association of Medical Media

Keynote Address

Medical professionalism in a commercialized health care market*	S33
Arnold S. Relman, MD	

Panel 3: Inside the Operating Room

Inside the operating room—balancing the risks and benefits of new surgical procedures: A collection of perspectives and panel discussion	S37
Joel D. Cooper, MD; Ralph V. Clayman, MD; Thomas M. Krummel, MD; Philip R. Schauer, MD; Christopher Thompson, MD, MHES; and Jonathan D. Moreno, PhD	
How should we introduce and evaluate new procedures?—Joel D. Cooper, MD.....	S37
Idea to implementation: A personal perspective on the development of laparoscopic nephrectomy—Ralph V. Clayman, MD.....	S40
Special perspectives in infants and children—Thomas M. Krummel, MD.....	S43
Bariatric surgery: What role for ethics as established procedures approach new frontiers?—Philip R. Schauer, MD	S45
Natural orifice transluminal endoscopic surgery: Too much too soon?—Christopher Thompson, MD, MHES	S47
Panel discussion—Moderated by Jonathan D. Moreno, PhD	S49

Keynote Address

Will the United States maintain its position as a world leader in medical technology?.....	S55
Thomas J. Fogarty, MD	

Panel 4: Outside the Operating Room

Outside the operating room—economic, regulatory, and legal challenges: A collection of perspectives and panel discussion	S61
Lawrence K. Altman, MD; Michael A. Mussallem; Rebecca Dresser, JD; Paul A. Lombardo, PhD, JD; Peter A. Ubel, MD; and Christopher L. White, Esq	
Preface—Lawrence K. Altman, MD (Moderator)	S61
A device company perspective: Serving patients is the key to sustainable success—Michael A. Mussallem	S61
A regulatory and legal perspective: Issues in off-label device use—Rebecca Dresser, JD	S63
A historical perspective: The more things change, the more they remain the same—Paul A. Lombardo, PhD, JD.....	S65
An economic value perspective: Setting limits on health care can be ethical—Peter A. Ubel, MD.....	S67
An industry perspective: Proactive self-regulation through an industry code of ethics—Christopher L. White, Esq.....	S69
Panel discussion—Moderated by Lawrence K. Altman, MD	S70

Panel 5: New Surgical Devices and Ethical Challenges

New surgical devices and ethical challenges: A collection of perspectives and panel discussion	S74
Daniel Schultz, MD; Mary H. McGrath, MD, MPH; Thomas H. Murray, PhD; Roy K. Greenberg, MD; and Thomas J. Fogarty, MD	
An FDA perspective on device regulation—Daniel Schultz, MD.....	S74
Responsibilities of the media, FDA, and professional societies—Mary H. McGrath, MD, MPH	S77
Promoting swift, safe, and smart innovation—Thomas H. Murray, PhD	S80
Panel discussion—Moderated by Roy K. Greenberg, MD	S82

This proceedings supplement was funded by the Cleveland Clinic
Division of Medicine Humanities in Medicine Research and Education Fund.
