

# 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.ccmj.org/content/75/suppl.6](http://www.ccmj.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.*

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

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](mailto:ccjm@ccf.org) (e-mail); [www.ccmj.org](http://www.ccmj.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.

---