

PROCEEDINGS OF  
**A NATIONAL DIALOGUE  
ON BIOMEDICAL CONFLICTS OF INTEREST  
AND INNOVATION MANAGEMENT**

SEPTEMBER 20, 2006

Supplement 2 to Volume 74, March 2007

**Supplement Editor**

GUY M. CHISOLM III, PHD  
Vice Chairman, Lerner Research Institute  
Professor, Department of Cell Biology  
Cleveland Clinic

**From the editor: The rapidly changing landscape of biomedical conflicts of interest** .....S3  
*Guy M. Chisolm III, PhD, Vice Chairman, Lerner Research Institute, and Professor, Department of Cell Biology, Cleveland Clinic*

**Opening comments: The mandate of innovation management** .....S6  
*Delos M. Cosgrove, MD, CEO and President, Cleveland Clinic*

**Research, Innovation, and Safety: Doing the Right Thing**

**Prologue: A case study in biomedical conflicts** .....S8  
*Nina Totenberg, Legal Affairs Correspondent, National Public Radio*

**Fostering innovation without compromising integrity** .....S10  
*Philip A. Pizzo, MD, Dean and Professor of Pediatrics and of Microbiology and Immunology, Stanford University School of Medicine*

**Innovation and industry-academia interactions: Where conflicts arise and measures to avoid them** .....S12  
*P. Roy Vagelos, MD, Chairman, Regeneron Pharmaceuticals, Inc.; Chairman, Theravance, Inc.; Former CEO, Merck & Co., Inc.*

**Overregulation of conflicts hinders medical progress** .....S14  
*Thomas P. Stossel, MD, Professor of Medicine, Harvard Medical School*

**Panel discussion: Research, innovation, and safety: Doing the right thing** .....S16  
Moderated by *Nina Totenberg, Legal Affairs Correspondent, National Public Radio*  
Panelists: *Philip A. Pizzo, MD; Thomas P. Stossel, MD; and P. Roy Vagelos, MD*

**Guiding Principles: Where Are We Headed?**

**Conflict-of-interest management: Efforts and insights from the Association of American Medical Colleges** .....S23  
*Darrell G. Kirch, MD, President and CEO, Association of American Medical Colleges*

**Medical devices and conflict of interest: Unique issues and an industry code to address them** .....S26  
*Paul A. LaViolette, MBA, Chief Operating Officer, Boston Scientific Corporation;  
Member, Board of Directors, and Chairman, Special Committee on Codes of Ethics, AdvaMed*

(continued on next page)

Copyright © 2007 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) 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.



<b>The challenge for NIH ethics policies: Preserving public trust <i>and</i> biomedical progress</b> .....	<b>S29</b>
<i>Norka Ruiz Bravo, PhD, Deputy Director for Extramural Research, National Institutes of Health</i>	
<b>Panel discussion: Guiding principles: Where are we headed?</b> .....	<b>S32</b>
<i>Moderated by Nina Totenberg, Legal Affairs Correspondent, National Public Radio</i>	
<i>Panelists: Darrell G. Kirch, MD; Paul A. LaViolette, MBA; and Norka Ruiz Bravo, PhD</i>	
<b>Keynote Address</b>	
<b>Building and retaining trust in the biomedical community</b> .....	<b>S38</b>
<i>Dick Thornburgh, Counsel, K &amp; L Gates; Former Governor of Pennsylvania; Former Attorney General of the United States</i>	
<b>Applications in the Real World: Defining Boundaries and Managing Innovation</b>	
<b>Interactions of the public and private sectors in drug development:</b> .....	<b>S45</b>
<b>Boundaries to protect scientific values while preserving innovation</b>	
<i>Gail H. Cassell, PhD, DSc (hon), Vice President, Scientific Affairs, and Distinguished Lilly Research Scholar for Infectious Diseases, Eli Lilly and Company</i>	
<b>Beyond disclosure: The necessity of trust in biomedical research</b> .....	<b>S49</b>
<i>Jeffrey P. Kahn, PhD, MPH, Maas Family Chair in Bioethics and Director, Center for Bioethics, University of Minnesota</i>	
<b>Panel discussion: Applications in the real world: Case studies in defining boundaries and managing innovation</b> ...	<b>S51</b>
<i>Moderated by Claudia R. Adkison, JD, PhD, Executive Associate Dean, Administration and Faculty Affairs, Emory University School of Medicine</i>	
<i>Case studies submitted by Michael J. Meehan, Esq., Senior Counsel and Corporate Assistant Secretary, Cleveland Clinic, and Claudia R. Adkison, JD, PhD</i>	
<i>Panelists: Gail H. Cassell, PhD, DSc (hon); Jeffrey P. Kahn, PhD, MPH; Philip A. Pizzo, MD; and Thomas P. Stossel, MD</i>	
<b>Conflicts, Compliance, and Enforcement: Government Priorities and Initiatives</b>	
<b>Protecting subjects without hampering research progress:</b> .....	<b>S60</b>
<b>Guidance from the Office for Human Research Protections</b>	
<i>Bernard A. Schwetz, DVM, PhD, Director, Office for Human Research Protections, US Department of Health and Human Services</i>	
<b>Fraud, conflict of interest, and other enforcement issues in clinical research</b> .....	<b>S63</b>
<i>James G. Sheehan, Associate US Attorney, US Attorney's Office, US Department of Justice</i>	
<b>Panel discussion: Conflicts, compliance, and enforcement: Government priorities and initiatives</b> .....	<b>S68</b>
<i>Moderated by Jeffrey P. Kahn, PhD, MPH, Maas Family Chair in Bioethics and Director, Center for Bioethics, University of Minnesota</i>	
<i>Panelists: Bernard A. Schwetz, DVM, PhD, and James G. Sheehan</i>	
<b>Guidelines and Performance: Creating a Culture of Ethics</b>	
<b>Creating an institutional conflict-of-interest policy at Johns Hopkins: Progress and lessons learned</b> .....	<b>S70</b>
<i>Edward D. Miller, MD, Dean of the Medical Faculty, Johns Hopkins School of Medicine; CEO, Johns Hopkins Medicine</i>	
<b>Managing ethical performance in organizations: Insights from the corporate world</b> .....	<b>S73</b>
<i>Edward Soule, CPA, PhD, Associate Professor, McDonough School of Business, Georgetown University</i>	
<b>Panel discussion: Guidelines and performance: Creating a culture of ethics</b> .....	<b>S77</b>
<i>Moderated by Susan H. Ehringhaus, JD, Associate General Counsel for Regulatory Affairs, Association of American Medical Colleges</i>	
<i>Panelists: Edward D. Miller, MD, and Edward Soule, CPA, PhD</i>	

Articles in these proceedings were developed by the *Cleveland Clinic Journal of Medicine* staff from transcripts of audiotaped presentations at the “National Dialogue on Biomedical Conflicts of Interest and Innovation Management” and then reviewed and revised by the respective speakers.