

# THE NATIONAL ACADEMIES

*Advisers to the Nation on Science, Engineering, and Medicine*

## **Ninth Meeting of the Science, Technology, and Law Panel**

**September 13-14, 2004**

**Keck 100**

**Washington, DC**

### **Monday, September 13, 2004**

#### **OPEN**

**8:30** *Continental Breakfast*

**8:45** *Welcome*

Panel Co-chairs:

Donald Kennedy

Richard A. Merrill

**9:00** *Balancing Privacy and Biomedical/Health Sciences Research*

The impact of the Health Insurance Portability and Accountability Act's privacy standards on medical research has been the source of heated debate since HIPAA was passed in 1996. Amendments to the Privacy Standards in 2003 provided more flexibility for research, but concerns remains that the rules still pose challenges for researchers covered by HIPAA.

Moderator: David Korn\*

Speakers: Peter Swire, Professor, Moritz College of Law, Ohio State University  
David Helms, President and CEO, AcademyHealth

**10:15** *Export Control Compliance Reports-Implications for Recent IG Reports for Academic Research*

In FY2000 Congress directed several agency Inspectors General to conduct an assessment of the adequacy of export controls measures to prevent the acquisition of sensitive U.S. technology and technical information by countries and individuals of concern. This spring, three agencies (Commerce, Defense, and Energy) released their reports to the public. Three other agency reports have not been made public. The Department of Commerce report raises particular concern for universities because, if implemented, its recommendations would severally limit the fundamental research exemption that universities have operated under for decades. In addition, an interagency report calls for the reexamination of the fundamental research and education exemptions for universities.

Moderator: Arthur L. Bienenstock\*

Speakers: Bernard Kritzer, Director Office of Strategic Trade and Foreign Policy

Controls, Bureau of Industry and Security, Department of  
Commerce  
Jared Cohon, President, Carnegie Mellon University  
Claude R. Canizares, Bruno Rossi Professor of Physics; Associate  
Provost; Associate Director for MIT of the Chandra X-ray  
Observatory Center, MIT  
Diane Auer Jones, Director, Government Affairs, Princeton University  
Richard Johnson, Partner, Arnold & Porter

**12:30 Lunch**

**CLOSED**

**OPEN**

**2:15 *Do Federal Standards Pre-Empt State Laws and Court Decisions? Reaction to FDA Involvement in Recent Product Liability Cases***

U.S. tort law has generally held that a defendant's compliance with regulatory requirements designed to prevent or minimize harm does not constitute a defense against liability for negligence or strict liability. Violation of such requirements, however, is generally conclusive evidence of culpable fault. In recent years this dual formulation has been questioned. A few courts have held, for example, that FDA approval of a drug negates tort liability for the product's side effects. And Congress, in some laws including the Medical Device Amendments to the Food and Drug Act, has preempted state laws -- including state tort verdicts -- that conflict with or go beyond FDA requirements. Both the cases and the statutory preemption are controversial. The general issue has attracted renewed attention recently because in a handful of cases FDA has filed briefs in private tort cases involving products it regulates, in which the agency supported the claim of the manufacturer that by doing everything required, it fulfilled its tort law duty. Our session will focus on the underlying general issue of whether, or when, regulatory compliance should ever bar tort recovery.

Moderator: Richard A. Merrill\*  
Speakers: Lars Noah, University of Florida Research Foundation Professor of Law  
William B. Schultz, Partner, Zuckerman Spaeder

**3:30 Break**

**CLOSED**

**\*STL Panel Member**

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**8:30**    *Breakfast*

**9:00**    *Welcome*

Co-chairs:     Donald Kennedy  
                   Richard A. Merrill

**9:15**    *Secrecy, Science, and National Security: Possible Joint Activity with ACHRE*

Ruth Faden, chair, of the Advisory Committee on Human Radiation Experiments, and other members of ACHRE, would like to organize with the STL Program, a symposium on the nature of secrecy and the proper role of secrecy in government and science. The 1995 report issued by the ACHRE addressed the issue of balancing national security and public trust and stated, “to the extent that the government conducts such activities with elements of secrecy, special protections of the rights and interests of individuals and the public are needed.”

Speaker:        Ruth Faden, Professor, Department of Health Policy and Management;  
                   Executive Director, Bioethics Institute; and Philip Franklin Wagley  
                   Professor of Biomedical Ethics, Johns Hopkins University

**10:15**   *Break*

**10:30**   *Technological Options for Voting*

As the November presidential election draws near, the integrity of the electoral process remains in doubt. Public debate has focused on the reliability and security of voting systems as well as on the broad range of issues that span the voting process, from the point of engaging the voter to the point of accurately capturing and tabulating the voter’s intent. What solutions can be provided to increase voter turnout and improve the transparency and reliability of voting?

Moderator:     Joel Cohen\*  
Speakers:       Anthony Stevens, Assistant Secretary of State, New Hampshire  
                   Avi Rubin, Professor, Computer Science, and Technical Director,  
                   Information Security Institute, Johns Hopkins University  
                   Barbara Simons, Past President, Association for Computing Machinery  
                   Ted Selker, Associate Professor of Media Arts and Sciences, MIT,  
                   *invited*

**12:30** *Lunch*

**2:00** *Adjourn*

**\*STL Panel Member**