

# Curriculum Vitae Dennis Melamed

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## **PRINCIPAL, MELAMEDIA LLC (1989 to present)**

Founded regulatory affairs research, training and publishing company that produces content for its own publications and for other organizations in a wide variety of business areas, including healthcare, biomedical research and clinical trials, data stewardship, data security, labor relations, environmental protection and intellectual property.

### **PRODUCER, HEALTHCARE WEBINAR SERIES, MELAMEDIA LLC (2001 to present)**

Conceive, develop, produce and market webinars and other e-learning materials for education and training in the healthcare industry. Topics focus on cutting edge challenges in medical privacy and data security, clinical trials research, biomedical intellectual property protection, litigation, insurance and labor relations.

### **EDITOR/PUBLISHER, *Health Information Privacy/Security Alert* (1997 to present)**

Established the first independent U.S. periodical publication exclusively focused on maintaining the data security, confidentiality and privacy of health data; write about and analyze federal and state regulations and court decisions defining the use of health data.

### **EDITOR/PUBLISHER, *HIPAA & Breach Enforcement Statistics* (2010 to present)**

Established one of the first independent periodicals to analyze the statistics on the enforcement of the privacy and security rules under the Health Insurance Portability and Accountability Act (HIPAA) and the causes of data breaches under the Health Information Technology for Economic and Clinical Health Act (HITECH).

## **ADJUNCT PROFESSOR, DREXEL COLLEGE OF MEDICINE (2007 to present)**

Conceived and developed four courses for an online master's program in a nationally recognized medical school; teach and update the courses, which focus on the regulatory challenges affecting biomedical research and manufacturing, including:

- Health information technology and data stewardship;
- Current federal regulatory issues in pharmaceutical research;
- Trends in medical device regulation; and
- Biotechnology and research.

## **CONSULTING WORK**

### **REVIEWER, *The HITECH Business Associate Contract Bible: Provisions for Covered Entities, Business Associates and Subcontractors* (2013)**

Published by American Bar Association Health Law Section.

### **AUTHOR/CONSULTANT, NATIONAL GOVERNORS ASSOCIATION 'S STATE ALLIANCE FOR E-HEALTH (2010)**

Provided regulatory and organizational analyses of strategies for managing patient consent for electronic health information using health information exchanges for major national association of state political leaders.

### **AUTHOR/CONSULTANT, NATIONAL GOVERNORS ASSOCIATION 'S STATE ALLIANCE FOR E-HEALTH (2009)**

Provided regulatory and organizational analyses of strategies on harmonizing regulations for sharing patient health data across multiple jurisdictions for major national association of state political leaders.

**OTHER CONSULTING WORK:** Developed materials and provided consulting on education and communications for major public policy associations involved in intellectual property protection, including the **BUSINESS SOFTWARE ALLIANCE** and the **INTERNATIONAL ANTI-COUNTERFEITING COALITION**; directed and recruited congressional and industry reviewers for a study on U.S. research and development spending funded by the **CALVERT SOCIAL INVESTMENT GROUP**; provided advice and analysis on education, training and evaluation materials to meet accrediting requirements for data collection, security and confidentiality to **URAC**, a leading nonprofit accrediting organization for managed care organizations; and consulted on content and wrote a chapter for the Ford Foundation-funded project, *Through the Corridors of Power — a Guide to Federal Rulemaking*, a reference volume on the Office of Management and Budget's role in regulatory policy under the Reagan Administration.

## WRITING & PUBLISHING

(partial list)

**AUTHOR**, *HIPAA/HITECH Enforcement: 2003-2013 – The Role of Patient Complaints in Medical Privacy and Data Security* (2013)

Conceived, developed and wrote white paper analyzing the first decade of federal enforcement of medical privacy and data breach laws; recruited industry experts to serve as reviewers; produced webinar for sharing results with policymakers and compliance professionals.

**EDITOR/PUBLISHER**, *Drug & Biologic Guidance Watch* (2003 to 2009)

Conceived and established weekly international news service tracking biomedical product regulations and guidance documents from approximately 50 nations and international regulatory organizations for biomedical product industry executives, contractors and policymakers.

**EXECUTIVE EDITOR**, *Drug GMP Report* (1992-2003)

Developed and produced editorial content for monthly publication on U.S. and international good manufacturing practices (GMP) regulations governing biomedical product industries for independent publisher.

**AUTHOR AND LEAD EDITOR**, *HIPAA Handbook Reference Set* (2001-2003)

Recruited and supervised authors, and wrote and edited a three-volume educational reference set on the privacy, data security and electronic transaction regulations under HIPAA.

**DEVELOPMENT/START-UP EDITOR**, *CRO Industry Watch* (1999-2002)

Developed and produced editorial content for monthly publication focused on contract research organizations (CROs) and outsourcing in the pharmaceutical research, development and marketing sectors for independent publisher.

**OTHER WRITING EXPERIENCE:** Served as a Washington correspondent for a variety of publications and publishers, including **Business Week**, McGraw-Hill World News, *Platt's Oilgram News* and Business Publishers, Inc.;

Started and managed a variety of specialty publications in highly regulated industries, including *BioWatch*, *Environment Daily*; *Robotics World* and *The Indoor Air Review*;

Published public policy, research and general interest articles for a variety of national publications including, *New Scientist*, *Governing*, *American History*, *iHealthBeat* and *Newsday*.

## PUBLIC PRESENTATIONS

(partial list)

*Recent Trends on HIPAA/HITECH Enforcement*, Healthcare Business Network (2012)

*Practical Lessons on HIPAA Privacy Compliance*, Twentieth HIPAA Summit (2012)

*Security and Patient Privacy*. Symposium on Crossing the Infrastructure & HITECH Meaningful Divide: Crossing Traditional Boundaries (2012)

*HIE Barriers, Legal & Technical – Planning to Exchange Health Data Across a Network*. Workgroup for Electronic Data Interchange (2010)

**Testimony.** *State and Federal Consent Laws Affecting Interstate Health Information Exchange*: National Governors Association's State Alliance for E-Health Committee Meeting (2010)

*Enforcement Outlook: Why Prosecutors (& Everyone Else) Are Looking At Health Data Privacy and Security*, The World Health Care Congress 2nd Annual Leadership Summit on HITECH and HIPAA Compliance Management (2010)

**OTHER PRESENTATIONS:** Speeches and presentations focused on healthcare regulatory issues before national educational and public policy organizations including the Drug Information Association, the National Library of Medicine, National Association of Healthcare Quality, the World Healthcare Innovation Conference, *HealthLeaders* Roundtable Series and the Rx Expo.

## Educational and Compliance Seminar Presentations

(partial list)

Seminar presentations were conceived and conducted under the auspices of Melamedia, LLC. and qualified for continuing education credits from the International Association of Privacy Professionals; in several instances state bar associations provided continuing legal education credits.

- *Practical Realities of Ransomware: Protecting Your Organization from Attack & Regulatory Enforcement* (2016)
- *11th Annual Year-End Review of Medical Privacy & Security Enforcement* (2015)
- *Defending Your Organization's Name in the World of HIPAA* (2014)
- *The Risky World Beyond HIPAA: Health Data Breaches and Class Action Lawsuits* (2014)
- *Confronting HIPAA & HITECH Vulnerabilities in Health Data Registries* (2014)
- *The Effects of the Supreme Court Rulings on Same-Sex Marriage on Patient Rights, and HIPAA and HITECH Compliance* (2013)
- *Meeting the HITECH Requirements for Research* (2013)
- *The New World of Business Associates Under the HITECH* (2013)
- *Understanding & Deploying OCR's New Data De-Identification Guidance* (2013)
- *Managing Mobile Medical Apps for HIPAA & HITECH Compliance* (2012)
- *The Effects of HIPAA/HITECH Policies & Enforcement on the Workforce -3-Webinar Series* (2012)
- *Managing Occupational Health Data Under Healthcare Reform and Privacy Laws* (2011)
- *Patient Data Stewardship in the New World of Accountable Care Organizations* (2011)

- *Managing the Consolidated Responsibilities Under Meaningful Use & HIPAA* (2011)
- *The Nuts & Bolts of Insurance & Covering the Costs of Health Data Breaches* (2010)
- *Best Practices & New Issues in Data De-Identification for Healthcare & Electronic Health Records* (2009)
- *The New Patient Privacy Challenge: Where Breach Notification, HIPAA & Human Resources Meet* (2009)
- *Coordinating Electronic Health Record Incentives with HIPAA and Other Major Health Information Technology Initiatives* (2009)
- *Sharing Student Health Information Under the New Family Educational Rights and Privacy Act Final Rules* (2009)
- *Healthcare Compliance with the FTC Red Flag Rules* (2008)
- *Getting Ready for Patient Safety Reporting* (2008)
- *Sharing Health Information Under the New Family Medical Leave Act Rules* (2008)
- *Preparing for New Genetic Data Management Requirements* (2008)
- *Coping with the CMS Billing Rules for Clinical Research* (2007)
- *Confronting the Threats of Medical Identity Theft* (2007)
- *Personal Health Records and the New Risks over Privacy, Security and HIPAA: Addressing the Challenges of Patient-Controlled Health Information* (2007)
- *Navigating the New Safe Harbors for E-Health Records and E-Prescribing* (2006)
- *Protecting Patient Data at the Front Door: Vetting Prospective Employees for HIPAA and Other Data Protection Laws* (2006)
- *New Approaches for Clinical Trial Billing Under Medicare: Lessons Learned from the Rush University Medical Center Settlement* (2006)
- *Balancing Privacy with Public Health Surveillance in Disaster Response and Emergencies* (2005)
- *Responding to Government Investigations of Medical Privacy and Security Breaches* (2005)
- *Responding to Investigator-Initiated Research Problems* (2005)
- *Managing the Perils of Investigator-Initiated Research* (2004)
- *Coping with the HIPAA Privacy Rules on Research Databases and Repositories* (2004)
- *Strategies for Maximizing the Value of Biomedical Patents* (2003)
- *Resolving Key Issues in Clinical Trials Contracting* (2003)
- *Speeding Medical Products to Market: Strategies for Complying with the HIPAA Privacy Rules On R&D* (2002)

### OTHER RELEVANT EXPERIENCE

**COFOUNDER, PRIVACYSECURITYNETWORK.COM (2000-2003)**

Conceived, designed, developed and provided editorial content for an Internet website on health data confidentiality and security issues; developed an online dynamic database and assessment tool for determining applicability and effects of proposed HIPAA privacy rules on healthcare organizations.

**VICE CHAIRMAN OF THE BOARD, NATIONAL PRESS CLUB (1990-1991)**

Provided leadership for major national media association, including labor relations and general business affairs and public policy programming.

**MEMBER OF THE BOARD, NATIONAL PRESS CLUB (1988-1990)**

Oversaw operations of major national media association, including public policy programming and business affairs.

**ANALYST, U.S. CONGRESS, ENVIRONMENTAL & ENERGY STUDY CONFERENCE (1984-1985)**

Provided policy support and briefings for members of Congress; analyzed environmental, energy, budget and tax issues for nonpartisan congressional caucus.

### EDUCATION

A.B. in Government, The College of William & Mary

M.A. in Journalism, Pennsylvania State University