PROGRAM CHAIRS

Annual Meeting Program Co-Chairs
Monique Anawis, MD, JD, FCLM
David Donnersberger, Jr., MD, JD, MA, FCLM

Dental Session Chair
Bruce Seidberg, DDS, MScD, JD, FCLM

PROGRAM BOOK
On behalf of the American College of Legal Medicine's President-Elect, Tom McLean, MD, MS, JD, FCLM, Acting President, and the Board of Governors, we invite you to enjoy our 55th Annual Conference. The excellent faculty of speakers will be addressing many contemporary and controversial issues in health law and health policy. The program also includes a number of sessions designed to provide physicians, dentists and attorneys with tools and information that will immediately impact their everyday practice. These sessions include: the traditional update of judicial and legislative actions, technology and legal medicine, medical malpractice, international health law session, and a special Moot Court styled debate on the virtues of Physician Peer Review.

Again this year, there is a special medical ethics session. This session is designed for physicians who are required to receive two hours of medical ethics CME credits to renew their license.

The Stewart Reuter lecture will be given by Henry Butler, JD, PhD, George Mason University Foundation Professor of Law and Executive Director, Law & Economics Center, and is entitled “Intent and Consequences: What to Make of So-Called ‘Unintended Consequences’ in Health Care Law and Policy”. The S. Sandy Sanbar Lecture will be presented by David Ozar, Professor, Department of Philosophy, Loyola University Chicago; Clinical Ethics Consultant, NorthShore University HealthSystem, and is entitled “The Unbefriended: A New Protected Class of Patients?”

In addition to these fine presentations, the 55th Annual Meeting will contain several traditional sessions including: the Cyril Wecht Luncheon with guest speaker Katherine Ramsland, PhD, Program Director, Master of Arts in Criminal Justice, and Professor of Forensic Psychology, DeSales University; the - Leadership Breakfast, the Awards Banquet and the poster presentation session.

Perhaps most importantly, the College will again host two receptions on Friday and Saturday evening which will provide valuable networking opportunities. Finally, Bruce H. Seidberg, DDS, MScD, JD, FCLM, will chair an expanded two-day dental program, which will run concurrently with the main program.

Whether you are a first time attendee, physician, dentist, attorney, nurse or healthcare worker in need of medical ethics CME, or a long-time Fellow or member of the College, we invite you to the 55th Annual Meeting of the American College of Legal Medicine.

Monique Anawis, MD, JD, FCLM
David Donnersberger, Jr., MD, JD, MA, FCLM
2015 Annual Meeting Program Co-Chairs
# 2015 ACLM 55th Annual Meeting
## Schedule-at-a-Glance

### Thursday, February 26

<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>12:00pm - 6:00pm</td>
<td>Registration Desk, <em>Brera Commons</em></td>
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<tr>
<td>12:00pm - 6:00pm</td>
<td>Board of Governors Meeting, <em>Brera 1</em></td>
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<td>1:00pm - 6:00 pm</td>
<td>ABLM Program/Review, <em>Brera 2</em></td>
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<td>6:00pm - 10:00pm</td>
<td>ABLM Board Meeting, <em>Brera 2</em></td>
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<tr>
<td>7:00pm - 10:00pm</td>
<td>Committee Meetings</td>
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### Friday, February 27

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<td>POSTER PRESENTATION, <em>Brera 6</em></td>
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<td>7:00am - 8:00am</td>
<td>Continental Breakfast, <em>Brera 6</em></td>
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<td>7:00am - 8:30pm</td>
<td>POSTER VIEWING, <em>Brera 6</em></td>
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<tr>
<td>8:00am - 9:50am</td>
<td>General Session I, <em>Brera 4-5</em> RECENT DEVELOPMENTS IN LEGAL MEDICINE</td>
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<tr>
<td>9:50am - 10:00am</td>
<td>Networking Break, <em>Brera 6</em></td>
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<tr>
<td>10:00am - 11:00am</td>
<td>General Session II, <em>Brera 4-5</em> TECHNOLOGY AND LEGAL MEDICINE</td>
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<tr>
<td>11:00am - 12:00pm</td>
<td><em>Stewart Reuter Lecture Brera 1</em></td>
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<td>11:00am - 1:30pm</td>
<td>JLM Editorial Board Meeting Lunch, <em>Brera 2</em></td>
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### Saturday, February 28

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<td>6:30am - 6:30pm</td>
<td>Registration Desk, <em>Brera Commons</em></td>
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<tr>
<td>7:00am - 8:00am</td>
<td>Dr. Dorothy Rasinski-Gregory Women's Leadership Breakfast, <em>Brera 1</em></td>
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<tr>
<td>7:00am - 8:30pm</td>
<td>Continental Breakfast, <em>Brera 6</em></td>
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<td>7:00am - 8:30pm</td>
<td>POSTER VIEWING, <em>Brera 6</em></td>
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<tr>
<td>8:00am - 9:15am</td>
<td>General Session V, <em>Brera 4-5</em> THE PEER REVIEW “DEBATE”</td>
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<td>8:00am - 9:45am</td>
<td>DENTAL SESSION III, <em>Brera 3</em></td>
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<td>9:15am - 9:25am</td>
<td>Networking Break, <em>Brera 6</em></td>
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<td>9:25am - 10:35am</td>
<td>General Session VI, <em>Brera 4-5</em> MEDICAL MALPRACTICE UPDATE</td>
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<tr>
<td>10:15am - 12:15pm</td>
<td>DENTAL SESSION IV, <em>Brera 3</em></td>
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<tr>
<td>10:35am - 10:45am</td>
<td>Networking Break, <em>Brera 6</em></td>
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*All General Sessions include a Q&A*
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| 10:45 - 12:00pm | General Session VII, *Brera 4-5*  
**INNOVATORS AND ENTREPRENEURS IN LEGAL MEDICINE*** |
| 12:00pm - 1:00pm | Cyril Wecht Luncheon, *Brera 2*  
This lecture made possible through a grant from the ACLM Foundation  
**THE SEVEN HABITS OF HIGHLY EFFECTIVE DIs: KEY COGNITIVE FACTORS IN PSYCHOLOGICAL AUTOPSIES**  
*Katherine Ramsland, PhD, Program Director, Master of Arts in Criminal Justice, and Professor of Forensic Psychology, DeSales University*** |
| 1:15pm - 3:00pm | General Session VIII, *Brera 4-5*  
**HEALTHCARE REFORM — THE ACA TODAY*** |
| 1:30pm - 3:00pm | DENTAL SESSION V, *Brera 3*** |
| 3:00pm - 3:15pm | Networking Break, *Brera 6*** |
| 3:15pm - 4:30pm | Sandy Sanbar Lecture, *Brera 4-5*  
This lecture made possible through a grant from the ACLM Foundation  
**THE UNBRIENDED: A NEW PROTECTED CLASS OF PATIENTS?**  
*David Ozar, Professor, Department of Philosophy, Loyola University Chicago; Clinical Ethics Consultant, NorthShore University HealthSystem*** |
| 4:30pm - 4:40pm | Networking Break, *Brera 6*** |
| 4:30pm - 6:30pm | Annual Meeting of the Fellows, *Brera 4-5*** |
| 5:30pm - 6:30pm | Young Leadership Committee Meeting, *Brera 1*** |
| 7:00pm - 9:00pm | Annual Awards Banquet, *Gracia 1-2*  
**GAMBLING DISORDER AND HEALTH LAW**  
*Stacey A. Tovino, JD, PhD, Lincy Professor of Law, Lehman Professor of Law, William S. Boyd School of Law, University of Nevada, Las Vegas*** |
2015 ACLM 55th Annual Meeting
EVENTS

EVENING FUNCTIONS
As a benefit of membership, tickets to the President's Welcome Reception and the Annual Awards and Networking Banquet are included with your full conference registration. Additional tickets may be purchased for guests and single day registrants.

President's Welcome Reception
Date: Friday, February 27, 2015
Time: 6:30 pm – 8:30 pm
Location: Gracia 3
Attire: Business Casual
Cost: One ticket is included in your full conference registration fee. Additional tickets are $25.00 each.

Take some time to catch up with colleagues and meet new friends in the medical-legal community over cocktails and light hors d'oeuvres at the annual ACLM President's Welcome Reception.

Annual Awards and Networking Banquet
Date: Saturday, February 28, 2015
Time: 7:00 pm – 9:00 pm
Location: Gracia 1-2
Attire: Business
Cost: One ticket is included in your full conference registration fee. Additional guest tickets are $50.00 each.

ADDITIONAL FUNCTIONS
Dr. Dorothy Rasinski-Gregory Women’s Leadership Breakfast
Date: Saturday, February 28, 2015
Time: 7:00 am – 8:00 am
Location: Brera 1
Attire: Business Casual
Cost: Included in registration fee

Join us for the 9th Annual Dr. Rasinski-Gregory Women’s Leadership Breakfast. Share your career transition experiences and become more involved in the ACLM committees and educational programs.

Cyril Wecht Luncheon
Date: Saturday, February 28, 2015
Time: 12:00 pm – 1:00 pm
Location: Brera 2
Attire: Business Casual
Cost: $35.00 (Tickets are not included in the registration fee)
2015 ACLM 55TH ANNUAL MEETING
ABLM/ABMM NEEDS & OBJECTIVES

Needs
The overall program, developed for the American Board of Legal Medicine and the American Board of Medical Malpractice, is designed to educate the American College of Legal Medicine and medical, dental and other course attendees about current issues that involve the ethical and legal aspects of Medical Malpractice. Such knowledge of Malpractice is a very important component of the medical professional and practice. Physicians are not sufficiently knowledgeable about the sunny issues in malpractice. When providing care to patients, medical professionals need to know about the ethical and legal aspects of practice in order to provide quality health care, diminish defensive medicine, avoid medical errors and contain medical cost.

Objectives
At the conclusion of this workshop, practitioners should be able to:
1. Understand the medical malpractice lawsuit process
2. Know the causes of action of medical malpractice
3. Understand all discovery techniques and trial procedure.
4. Appreciate the ethical and liability issues involving hospital and their employees and independent contractors.
5. Appreciate the methods and techniques utilized by judges in resolving medical malpractice cases.
6. Know about medical malpractice stress syndrome
7. Know the liability issues involving pathologists and clinical laboratories.
8. Understand how to Search for, Select and Prepare an Expert Medical Witness for Trial.
9. Know the recent developments in sports liability cases.

ABLM/ABMM ACCREDITATION INFORMATION

Accreditation Statement
This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the American College of Legal Medicine and the American Board of Legal Medicine & the American Board of Medical Malpractice. The American College of Legal Medicine is accredited by the ACCME to provide continuing medical education for physicians.

The American College of Legal Medicine designates this live activity for a maximum of 5.00 AMA PRA Category 1 Credits™, which includes 2.00 hours of Medical Ethics credits. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Conflict Resolution Statement
The American College of Legal Medicine CME Office has reviewed this activity’s speaker and planner disclosures and resolved all identified conflicts of interest, if applicable.

General Disclaimer
The statements and opinions contained in this program are solely those of the individual authors and contributors and not of the American College of Legal Medicine. The appearance of advertisements is not a warranty, endorsement or approval of the products or services advertised or of their effectiveness, quality or safety.

The content of this publication may contain discussion of off-label uses of some of the agents mentioned. Please consult the prescribing information for full disclosure of approved uses. The American College of Legal Medicine disclaims responsibility for any injury to persons or property resulting from any ideas or products referred to in the abstracts or advertisements.

Special Assistance/Accommodation Statement
We encourage participation by all individuals. If you have a disability, advance notification of any special needs will help us better serve you. Call (847) 447-1713 or email kellyf@ewald.com if you require special assistance to fully participate in the meeting.

Policy on Faculty and Sponsor Disclosure
It is the policy of the American College of Legal Medicine that the faculty and sponsors disclose real or apparent conflicts of interest relating to the topics of this educational activity, and also disclose discussions of unlabeled/unapproved uses of drugs or devices during their presentation(s). Detailed disclosures will be made in the course handout materials.

Disclosure Report
The disclosure report for this meeting may be found in your registration packet.
Educational Needs

Physicians, dentists, attorneys and educators who practice in the healthcare industry and its related fields recognize that the practice of medicine is complicated by abundant legislative requirements, administrative rules and regulations and Federal/State court decisions interpreting those laws. It is difficult to maintain a working knowledge of these developments. This meeting will provide details of new legislation, rules and court decisions, societal changes and shifts in the market place that will impact the practice of medicine. Key changes impacting the practice of medicine during the past one to two years include: the impact of technology including Electronic Medical Records (EMRs); accountable care organizations and their evolution; state imposed ethics requirements as part of the continuing education process; physicians seeking non-traditional employment; medical malpractice; the outsourcing of healthcare services; and social networking’s impact on the practice of medicine.

Objectives

The 55th Annual Conference of the American College of Legal Medicine will focus on a diverse range of current legal medicine topics.

By the conclusion of this meeting, participants should be able to:

1. Describe recent legislative and court opinions affecting medical and dental practice.
2. Integrate medical and legal ethics into their daily practice.
3. Translate the impact of globalization on public health policy.
4. Integrate new regulatory changes into current practice.
5. Describe dental and legal issues involved in today’s health care.
6. Explain the practice of legal medicine and healthcare initiatives on a global or international perspective.
7. Outline the action steps required to comply with the HIPAA “final rule” compliance changes, which became effective September 23, 2013.
8. Understand the impact of technological approaches in the synthesis of designer drugs, and creative prosecution of the non-scheduled, illicit, analog drugs.
9. Explain the legal and regulatory aspects of vaccine development and deployment.
10. Assess realistic future possibilities regarding the fate of the ACA.
CME Accreditation Statement
The American College of Legal Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medicine education for physicians.

The American College of Legal Medicine designates this live activity for a maximum of 20 AMA PRA Category I Credits™, which includes a maximum of 1.25 hours of Medical Ethics credits. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Conflict Resolution Statement
The American College of Legal Medicine has reviewed this activity’s speaker and planner disclosures and resolved all identified conflicts of interest applicable.

CLE Accreditation Statement
The American College of Legal Medicine designates this program for up to 20 hours of Continuing Legal Education (CLE) credit, which includes a maximum of 1.25 Legal Ethics credits. The precise amount of the CLE will vary by state.

Dental Credits
Certificates of attendance will be available to submit to your State for CERP credit consideration.

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DISCLAIMER STATEMENT
Statements, opinions and results of studies contained in the program and abstracts are those of the presenters/authors and do not reflect the policy or position of the ACLM, nor does the ACLM provide any warranty as to their accuracy or reliability.

Every effort has been made to faithfully reproduce the abstracts as submitted. However, no responsibility is assumed by the ACLM for any injury and/or damage to persons or property from any cause, including negligence or otherwise, or from any use or operation of any methods, products, instruments or ideas contained in the material herein.
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<td>ABLM Program/Review Course, Brera 2</td>
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<td>RECENT DEVELOPMENTS IN MEDICAL MALPRACTICE: ETHICAL AND LEGAL ASPECTS (Pre-registration Required)</td>
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<td>S. Sandy Sanbar, MD, PhD, JD, FCLM, Program Chairman</td>
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<td>7:45am - 8:00am</td>
<td>Welcome/Announcements, Brera 4-5</td>
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<td>Thomas R. McLean, MD, MS, JD, FCLM, ACLM President-Elect, Acting President</td>
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<td>Monique Anawis, MD, JD, FCLM, ACLM Annual Meeting Co-Chairs</td>
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### Poster Titles

- **Pregnancy and Catastrophic Brain Injury: A Legal Update**  
  Christopher M. Bukle, M.D., J.D

- **A Brief History of Quarantine and Quarantine Laws in the United States**  
  John Daniels, JD, DO, MBA, MPH, MT (ASCP)

- **Pediatric vs. Adult Malpractice: An Aged-Based Comparison of Paid Claims Stratified by Error Type and Clinical Outcomes**  
  Andrew Fleck, MS4; Richard J. Kelly, MD, JD, MPH, FCLM

- **Comparing Characteristics of Anesthesia-Related Malpractice Claims to Surgical and Diagnostic Claims**  
  Andrew Fleck, MS4; Daniel S. Orlovich, PharmD, MS3; Richard J. Kelly, MD, JD, MPH, FCLM

- **Comparison and Trends of Inpatient and Outpatient Anesthesia Claims Reported to the National Practitioner Data Bank**  
  Andrew Fleck, MS4; Daniel S. Orlovich, PharmD, MS3; Richard J. Kelly, MD, JD, MPH, FCLM

- **Anesthesia Delivery and Cancer Risk – What Should Anesthesiologists Tell Their Patients?**  
  Lauren McLaughlin, DO; Keleigh McLaughlin, MS-III; John Adam McLaughlin, MD, JD, FCLM; Laura Gordon MS-III

- **Attending Physician Fatigue: Is There a Need for Regulation?**  
  Chen Nisynboim, LLB; Richard J. Kelly, MD, JD, MPH, FCLM

- **A Balanced Perspective on Drug Shortages**  
  Daniel S. Orlovich, PharmD, MS3; Richard J. Kelly, MD, JD, MPH, FCLM

- **Negligent Credentialing and Hospital Corporate Negligence: Targeting the System**  
  Debra Petracca, MBA; Thomas Bojko, MD, MS, JD, FCLM

- **Cerebral Palsy Litigation: Change Course or Abandon Ship**  
  Thomas P. Sartwelle, BBA, LLB; James C. Johnston, MD, JD

*All General Sessions include a Q&A*
8:00am - 9:50am
**General Session I, Brera 4-5**
RECENT DEVELOPMENTS IN LEGAL MEDICINE
- Federal and State Legislative Updates ................................ 38
- Federal Court Rulings
- Federal Agency Update
- State Court Rulings
**Moderator: Jack Snyder, MD, JD, FCLM, Cato Research Washington**
**Panelists:**
- Veling W. Tsai, MD, JD, FCLM, Caring ENT
- Jayme Matchinski, JD, Partner, Clark-Hill PLC
- R. Gregory Cochran, MD, JD, FCLM, Partner, Nossaman, LLP

9:50am - 10:00am
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10:00am - 11:00am
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- Mobile Healthcare Delivery Platforms ........................................ 47
- Law and Transhumanism at the Threshold of Medical Human Enhancement .......................... 52
**Moderator: Thomas R. McLean, MD, MS, JD, FCLM, ACLM President-Elect, Acting President**
**Panelists:**
- David Benjamin, PhD, Clinical Pharmacologist and Forensic Toxicologist; F-AAFS, FCP, FCLM, FASHRM Adjunct Associate Professor, Dept. of Pharmaceutical Sciences - Northeastern University
- Karin M. Zaner, JD, Attorney at Law, Kane, Russell, Coleman and Logan, PC
- Sander Rabin, MD, JD, CEO - The Center for Transhuman Jurisprudence, Inc.

11:00am - 12:00pm
**Stewart Reuter Lecture, Brera 1**
This lecture made possible through a grant from the ACLM Foundation
INTENT AND CONSEQUENCES: WHAT TO MAKE OF SO-CALLED “UNINTENDED CONSEQUENCES” IN HEALTH CARE LAW AND POLICY
**Henry Butler, JD, PhD, George Mason University Foundation Professor of Law and Executive Director, Law & Economics Center, George Mason University School of Law**

11:00am - 1:30pm
JLM Editorial Board Meeting Lunch, Brera 2

12:00pm - 1:00pm
Lunch Break
(Attendee lunch on your own)

1:00pm - 2:35pm
**General Session III, Brera 4-5**
FEDERAL REGULATION OF HEALTHCARE
- Changes in Medical Practice Incorporation and Tax Status in 2015
- Update on GME Funding Reforms
- Doctors, Medicare Audits and Alleged Overpayments
**Moderator: Paul Blaylock, MD, JD, FCLM**
**Panelists:**
- Jayme Matchinski, JD, Partner, Clark-Hill PLC
- Alejandro Moreno, MBBS, MPH, JD, FCLM, University of Texas Southwestern Residency Programs, Austin, TX
- C. William Hinnant Jr., MD, JD, DABU, FCLM, Hinnant Medical and Law Offices, LLC

1:30 pm - 3:00 pm
**DENTAL SESSION I, Brera 3**
**Moderator: Chester Gary, DDS, JD, FCLM**

1:30 - 2:00pm
Evidence-Based Dentistry . . . 172
Russ Christensen, DDS
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<td>2:00 - 2:30pm</td>
<td>Evidenced Based Dentistry — What it Shows and What it Doesn’t</td>
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<td><em>Dean Mert N. Aksu, DDS, JD, MHSA, FCLM</em></td>
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<td>2:30 - 3:00pm</td>
<td>Ethical Questions About the Content of Peer Reviewed Journal Articles</td>
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<td><em>Pamela Zarkowski, JD, MPH, FACD</em></td>
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<td>2:35pm - 2:45pm</td>
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<td><strong>STATE REGULATION OF HEALTHCARE</strong></td>
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<td>» Public Health Updates in Light of Ebola and Public Health Police</td>
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<td>» Legal and Regulatory Aspects of Vaccine Development and Deployment..63</td>
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<td>» Physician Non-Compete and Non-Solicitation Agreements: Illinois</td>
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<td>Updates and National Trends.</td>
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<td>Moderator:</td>
<td>*Mary Jean Wall, MD, JD, FCLM, President, North Central Radiology</td>
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<td>and Imaging, Bellevue, Ohio; Lead Nuclear Physician, Healthspan,</td>
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<td>Cleveland, Ohio; President, Ohio State Medical Association</td>
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<td>Panelists:</td>
<td>*Eli Avila, MD, JD, MPH, FCLM, Commissioner of Health, Orange County</td>
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<td>Department of Health</td>
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<td><em>Jack Snyder, MD, JD, PhD, Asst. Managing Director, CATO Research Ltd.</em></td>
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<td><em>W. Kent Carter, JD, Partner, Clark-Hill PLC</em></td>
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<tr>
<td>3:30 pm - 5:30 pm</td>
<td><strong>DENTAL SESSION II, Brera 3</strong></td>
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<tr>
<td>Moderator:</td>
<td><em>Frank Riccio, DDS, JD, FCLM</em></td>
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<tr>
<td>3:30 - 4:00pm</td>
<td>Dentistry at the Crossroads — Statistics from the ADA</td>
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<tr>
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<td>*David Preble, DDS, JD, CAE, Vice President, Practice Institute,</td>
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<td>American Dental Association</td>
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<tr>
<td>4:00 - 4:30pm</td>
<td>Dental Specialization: The New and Old — Non ADA Paradigms</td>
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<td><em>Daniel L. Orr, II, DDS, MS, PhD, MD, JD, FCLM, DABLM</em></td>
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<tr>
<td>4:30 - 5:00pm</td>
<td>Impact of New DEA Controlled Substance Regulations on Clinical Practice</td>
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<td><em>Clark Whitmire, DMD, JD, FCLM, FACD, CW</em></td>
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<tr>
<td>5:00 - 5:30pm</td>
<td>Options for Pain Medicine in Dentistry</td>
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<td><em>Richard Harold, DMD, JD, FCLM</em></td>
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<tr>
<td>6:30 pm - 8:30 pm</td>
<td><strong>President’s Welcome Reception, Gracia 3</strong></td>
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**Saturday, February 28**

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<td>6:30am - 6:30pm</td>
<td><strong>Registration Desk, Brera Commons</strong></td>
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<tr>
<td>7:00am - 8:00am</td>
<td>Dr. Dorothy Rasinski-Gregory Women’s Leadership Breakfast,</td>
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<td><em>Brera 1</em></td>
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<tr>
<td>Moderator:</td>
<td><em>Monique Anawis, MD, JD, FCLM, ACLM Annual Meeting Co-Chair</em></td>
</tr>
<tr>
<td>7:00am - 8:30am</td>
<td>Continental Breakfast, <em>Brera 6</em></td>
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<tr>
<td>7:00am - 8:30pm</td>
<td><strong>POSTER VIEWING, Brera 6</strong>                                         (see page 11)</td>
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<tr>
<td>8:00am - 9:15am</td>
<td><strong>General Session V, Brera 4-5</strong></td>
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<tr>
<td></td>
<td>THE PEER REVIEW “DEBATE”</td>
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<tr>
<td></td>
<td>» Hospital Peer Review: Engine of quality or costly paper-tiger?...76</td>
</tr>
<tr>
<td>Moderator:</td>
<td><em>Dale Cowan, MD, JD, FCLM, UH Parma Medical Center</em></td>
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<tr>
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<td>Panelists:</td>
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<td><em>C. William Hinnant Jr., MD, JD, DABU, FCLM, Hinnant Medical and Law</em></td>
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<td></td>
<td><em>R. Gregory Cochran, MD, JD, FCLM, Partner, Nossaman, LLP</em></td>
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### 2015 ACLM 55th Annual Meeting

#### 2015 Scientific Program Schedule

<table>
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<th>Time</th>
<th>Session/Panel</th>
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| 8:00 am - 9:45 am | **Dental Session III, Brera 3**  
**Moderator:** Joseph Graskemper, DDS, JD, FCLM, DABMM |
| 8:00 - 8:25 am  | A Diagnostic Tool to Reduce Your Risk When Reading CBCT Scans  
*178 Dale Miles, BA, DDS, MS, Cone Beam Radiographic Services* |
| 8:25 - 8:55 am  | The Wisdom Triangle: Panoramic CBCT or Coronectomy  
*181 Navot Givol, DMD, OMFS, Soroka University Medical Center* |
| 8:55 - 9:20 am  | Informed Consent as an Integral Part of Treatment Planning: Educator Perspectives  
*186 Toan "Bill" Tham, DDS, JD, FCLM* |
| 9:20 - 9:45 am  | Minimizing Malpractice Lawsuits and Patient Complaints Related to Dental Implant Treatment  
*190 Rollin Matsui, BSc, DDS, LLB, FCLM* |
| 9:15 am - 9:25 am | Networking Break, Brera 6 |
| 9:25 am - 10:35 am | **General Session VI, Brera 4-5**  
**Medical Malpractice Update**  
» Recent Updates in Certificates of Merit Requirements  
» Update on Mammography Medical Malpractice: Breast Density Law from Connecticut to Pennsylvania  
» Fear of Malpractice and Defensive Medicine in the Emergency Department  
**Moderator:** Martin J. Stillman, MD JD, FCLM, Hennepin County Medical Center  
**Panelists:**  
Rosemary McGeady, MD, JD, FCLM  
Saurabh Jha, MBBS, MRCS, MS  
Darren P. Mareiniss, MD, JD, MBe, FCLM, Department of Emergency Medicine, University of Maryland School of Medicine |
| 10:15 am - 12:15 pm | **Dental Session IV**  
**Moderator:** Daniel L. Orr, II, DDS, MS, PhD, MD, JD, FCLM, DABLM |
| 10:15 - 10:45 am  | Criminal Liability of Health Care Professionals — What You Need to Know  
*Frank Riccio, DDS, JD, FCLM* |
| 10:45 - 11:15 am  | Dentists and the Law: Headlines We’d Rather Not See  
*200 Irene Bober-Moken, DMD, MPH, FACD* |
| 11:15 - 11:45 am  | Dental Office Regulatory Compliance  
*Chester Gary, DDS, JD, FCLM* |
| 11:45 - 12:15 pm  | Teaching Dental Students Legal Reasoning: A Case Study in Fee Splitting  
*205 Bernard Friedland, BChD, MSc, JD, FCLM, Harvard School of Dental Medicine* |
| 10:35 am - 10:45 am | Networking Break, Brera 6 |
| 10:45 - 12:00 pm | **General Session VII, Brera 4-5**  
**Innovators and Entrepreneurs in Legal Medicine**  
» Medical Liability and Innovation: A Review of Canadian Health Care  
**Moderator:** Monique Anawis, MD, JD, FCLM, Annual Meeting Co-Chair  
**Panelists:**  
Raymund King, MD, JD, FCLM, Law Offices of Raymund C. King, MD, JD, PLLC  
B. Chandler May, MD, JD, MS, FCLM  
Ken J. Berger, MD, JD, FCLM |
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### 2015 Scientific Program Schedule

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<tbody>
<tr>
<td>12:00pm - 1:00pm</td>
<td><strong>Cyril Wecht Luncheon, Brera 2, Pg. 94</strong>&lt;br&gt;This lecture made possible through a grant from the ACLM Foundation&lt;br&gt;THE SEVEN HABITS OF HIGHLY EFFECTIVE DIS: KEY COGNITIVE FACTORS IN PSYCHOLOGICAL AUTOPSIES&lt;br&gt;Katherine Ramsland, PhD, Program Director, Master of Arts in Criminal Justice, and Professor of Forensic Psychology, DeSales University</td>
</tr>
<tr>
<td>1:15pm - 3:00pm</td>
<td><strong>General Session VIII, Brera 4-5</strong>&lt;br&gt;HEALTHCARE REFORM — THE ACA TODAY&lt;br&gt;- ACA Overview 106&lt;br&gt;- The Affordable Care Act 2015: Where Have All the Failures Gone? 115&lt;br&gt;- HIPAA “Final Rule”&lt;br&gt;Moderator: David Donnersberger, Jr., MD, JD, MA, FCLM, ACLM Annual Meeting Co-Chair&lt;br&gt;Panelists:&lt;br&gt;Richard Kelly, MD, JD, MPH, FCLM, University of California Irvine Medical Center&lt;br&gt;John P. Conomy, MD, JD, President, Health Systems Design and CompEval Corporations, Cleveland, Ohio&lt;br&gt;Clifford Warren Lober, MD, JD, PA</td>
</tr>
<tr>
<td>1:30 pm - 3:00 pm</td>
<td><strong>DENTAL SESSION V, Brera 3</strong>&lt;br&gt;Moderator: Rollin Matsui, BSc, DDS, LLB, FCLM&lt;br&gt;The “Sunshine” Act: Relevance to Dental Practice and Research 209&lt;br&gt;Kalu Ogebuke, BDS, MSc, DMSc, JD, FCLM, DABMM, Professor, The University of Texas School of Dentistry at Houston</td>
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<tr>
<td>2:00 - 2:30pm</td>
<td><strong>Patient Abandonment and Termination</strong> 213&lt;br&gt;Joseph Graskemper, DDS, JD, FCLM, DABMM, Associate Clinical Professor, Stony Brook University School of Dental Medicine</td>
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<tr>
<td>2:30 - 3:00pm</td>
<td><strong>An Overview of Dental Licensure in the USA</strong>&lt;br&gt;Nicholas Panomitros, DDS, MA, JD, LLM, FCLM</td>
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<tr>
<td>3:00pm - 3:15pm</td>
<td>Networking Break, Brera 6</td>
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<td>3:15pm - 4:30pm</td>
<td><strong>Sandy Sanbar Lecture, Brera 4-5</strong>&lt;br&gt;This lecture made possible through a grant from the ACLM Foundation&lt;br&gt;THE UNBEFRIENDED: A NEW PROTECTED CLASS OF PATIENTS?&lt;br&gt;David Ozar, Professor, Department of Philosophy, Loyola University Chicago; Clinical Ethics Consultant, NorthShore University HealthSystem</td>
</tr>
<tr>
<td>4:30pm - 4:40pm</td>
<td>Networking Break, Brera 6</td>
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<tr>
<td>4:30pm - 6:30pm</td>
<td>Annual Meeting of the Fellows, Brera 4-5</td>
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<tr>
<td>5:30pm - 6:30pm</td>
<td>Young Leadership Committee Meeting, Brera 1</td>
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<tr>
<td>7:00pm - 9:00pm</td>
<td><strong>Annual Awards Banquet, Gracia 1-2</strong>&lt;br&gt;GAMBLING DISORDER AND HEALTH LAW&lt;br&gt;Stacey A. Tovino, JD, PhD, Lincy Professor of Law, Lehman Professor of Law, William S. Boyd School of Law, University of Nevada, Las Vegas</td>
</tr>
<tr>
<td>7:00am - 1:00pm</td>
<td>Registration Desk, Brera Commons</td>
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<tr>
<td>7:00am - 1:00pm</td>
<td><strong>POSTER VIEWING, Brera 6</strong>&lt;br&gt;(see page 11)</td>
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<tr>
<td>7:00am - 8:00am</td>
<td>Continental Breakfast, Brera 6</td>
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**Sunday, March 1**

- **7:00am - 1:00pm**<br>Registration Desk, Brera Commons
- **7:00am - 1:00pm**<br>**POSTER VIEWING, Brera 6** (see page 11)
- **7:00am - 8:00am**<br>Continental Breakfast, Brera 6
8:00am - 9:30am  General Session IX, Brera 4-5
INTERNATIONAL TOPICS IN LEGAL MEDICINE
» Judicial Response to Healthcare Regulation of Medical Negligence — Current Trends in India ............... 121, 128
Moderator: Alejandro Moreno, MBBS, MPH, JD, FCLM, University of Texas Southwestern Residency Programs, Austin, TX
Panelists:
Kate Diesfeld, JD, Department of Public Health, School of Public Health and Psychosocial Studies, Faculty of Health and Environmental Sciences
Barrister Ola-olu Ajibola Osanyin, LLM, Head of Chambers, 1st Counsel Solicitors, Medical Law Consultants
Dr. Santosh Kakade, MS, D.Ortho, FICS, LLM, PhD in law, MBA Hospital Management, Executive MBA Finance

9:00am - 9:10am Networking Break, Brera 6

9:10am - 10:05am General Session X, Brera 4-5
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» Orr Award ............... 149
» Gene Basanta Poster Award
Moderator: Robert W. Buckman, PhD, FCLM, President ACLM Foundation

10:05am - 10:45am Networking Break, Brera 6

10:45 - 12:00pm General Session XI, Brera 4-5
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» Tools for Analyzing Ethical Problems/Scenarios
» Medical Ethical Issues and Dilemmas: Doing What's Right When No One Is Looking... 166
Moderator: Karin Waugh Zucker, MA, JD, LLM, FCLM, Prof., US Army - Baylor University Graduate Program in Health and Business Administration, Ft. Sam Houston, Texas
Panelists:
Karin Waugh Zucker, MA, JD, LLM, FCLM, Prof., US Army - Baylor University Graduate Program in Health and Business Administration, Ft. Sam Houston, Texas
Martin J. Boyle, JD. Adjunct, US Army - Baylor University Graduate Program in Health and Business Administration, Ft. Sam Houston, Texas
Weldon (Don) Havins, MD, JD, Professor and Director, Medical Jurisprudence, Touro University Nevada
Mitchell D Forman, DO, MACP, Dean, Touro University Nevada College of Osteopathic Medicine

12:00pm Closing Remarks, Brera 4-5
David Donnersberger, Jr., MD, JD, MA, FCLM
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1967 Carl E. Wasmuth, MD, LLB, FCLM
1966 Charles U. Letourneau, MD, LLB, FCLM
1965 Charles U. Letourneau, MD, LLB, FCLM
1964 Charles U. Letourneau, MD, LLB, FCLM
1963 Louis J. Gelber, MD, LLB, FCLM
1962 Maurice B. Shure, MD, FCLM
1961 Rueben M. Dicker, MD, LLM, FCLM

* Deceased
GOLD MEDAL AWARD RECIPIENTS

2014 Dale H. Cowan, MD, JD, FCLM
2013 Bruce H. Seidberg, DDS, MScD, JD, FCLM
2012 Stewart Reuter, MD, JD, FCLM
2011 No Medal Awarded
2010 Richard S. Wilbur, MD, JD, FCLM
2009 Marshall B. Kapp, JD, MPH, FCLM
2008 Philip S. Cifarelli, MD, JD, FCLM, FACP, FACP
2008 Marvin H. Firestone, MD, JD, FCLM
2007 Theodore LeBlang, JD, FCLM
2006 W. Eugene Basanta, JD, LLM
2005 Fillmore Buckner, MD, JD, FCLM
2004 Arnold “Skip” Rosoff, JD, FCLM
2004 Sal Fiscina, MD, JD, FCLM
2003 Peter Rheinstein, MD, JD, MS, FCLM, FAAFP
2002 Richard Gibbs, MD, LLB, JD, FCLM (posthumous)
2001 Ed Hollowell, JD, FCLM
2001 Richard Tyler, MD, JD, FCLM
2000 Sandy Sanbar, MD, JD, PhD, FCLM
2000 Lee S. Goldsmith, MD, LLB, FCLM
1999 No Medal Awarded
1998 Donald Harper Mills, MD, JD, FCLM
1998 Monroe Trout, MD, JD, LLB, FCLM
1997 James Zimmerly, MD, JD, MPH, LLD, FCLM
1997 Harold L. Hirsh, MD, JD, FCLM
1996 Cyril H. Wecht, MD, JD, FCLM
1996 Dorothy Rasinski-Gregory, MD, JD, FCLM

HONORARY FELLOWS SINCE 2000

2013 Nicolas P. Terry, BA, FCLM
2012 Bill McCollum, JD
2011 Connie Mariano, MD
2010 No Honorary Fellow Chosen
2009 No Honorary Fellow Chosen
2008 Arthur Caplan, PhD
2007 Carl E. Schneider, JD
2006 William M. Sage, MD, JD, FCLM
2005 Lori B. Andrews, JD, FCLM
2004 Michael M. Baden, MD
2004 Barry C. Scheck
2003 Henry C. Lee, PhD
2003 Amnon Carmi, MA
2002 Karen H. Rothenberg, JD, MPA
2001 Carol Henderson, JD
2000 George J. Annas, JD, MPH
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REGISTRATION DESK HOURS/EXHIBIT HOURS
Registration/Information Desk hours are as follows:
- Thursday, February 26, 2015: 12:00 pm - 6:00 pm
- Friday, February 27, 2015: 6:00 am – 5:30 pm
- Saturday, February 28, 2015: 6:30 am – 6:30 pm
- Sunday, March 1, 2015: 7:00 am – 1:00 pm

Exhibit Hall Hours are as follows:
- Friday, February 28, 2015: 6:30 am – 1:00 pm

Poster Session 1
- Location: Brera 6
- Friday, February 27, 7:00 am - 8:30 pm

Poster Session 2
- Location: Brera 6
- Sunday, March 1, 7:00 am - 1:00 pm

Poster Committee Chair: Karin Waugh Zucker, MA, JD, LLM, FCLM
Mert N. Aksu, DDS, JD, MHSA, FCLM, Professor, Department of Patient Management. Mert N. Aksu was named Dean of the University of Detroit Mercy School of Dentistry on July 1, 2008. At the UDM School of Dentistry, he served as a faculty member and administrator since 1993.

Aksu earned a BS in Biological Sciences and Psychology from the University of Michigan Dearborn, DDS from the University of Michigan School of Dentistry, and a JD from Wayne State University, and a Master’s in Health Services Administration from the University of Michigan. Aksu is a former attending staff of Henry Ford Health Systems, a member of the State Bar of Michigan, and is a Fellow with the American College of Legal Medicine and a member of Omicron Kappa Upsilon, the Dental Honor Society. Fellow with the American and International College of Dentists, Fellow with the Pierre Fauchard Society, and Fellow with the Academy of General Dentistry. Dr. Aksu also has served on advisory committee for Deltal Dental of Michigan and Blue Cross Blue Shield of Michigan. Dr. Aksu is currently completing his requirements for Board Eligibility in Dental Public Health.

Throughout his career, Aksu began a number of activities to further the mission of UDM and the school. He was the founding chairperson of the Department of Patient Management, enhanced community outreach opportunities, and fostered an environment of patient care, based on a comprehensive care model.

Through strong collaboration with faculty and staff, the School strengthened the delivery of oral health care and implemented a state-of-the-art electronic patient record system. Dr. Aksu was responsible for creating the vision for what is today the new location of the School at the Corktown Campus on Martin Luther King Drive.

Dean Aksu has helped position the dental school for strong growth in educating additional dental professionals and providing care for more patients who are underserved. The School of Dentistry recently received a successful CODA review of its plan to increase class size from 98 to 144 and UDM is currently in the third year of its class expansion.

Up until June of 2012, Dr. Aksu maintained a private practice in general dentistry with an emphasis on adult comprehensive care. Dr. Aksu serves on the Board of Managers and is a Member of the Doctors’ Advisory Panel of Great Expression Dental Centers, a privately held dental group owned by the Ontario Municipal Employees Retirement System.

Monique A. Anawis, MD, JD, FCLM, is the Medical Director for the Office of the Illinois Attorney General [OAG] Lisa Madigan. As the Medical Director and an Assistant Attorney General, she works with attorneys and mediators in the OAG’s Health Care Bureau on consumer investigations and appeals, the Consumer Fraud Bureau on pharmaceutical and device cases, and the Special Prosecutions Bureau on criminal investigations and prosecutions. Additionally, Dr. Anawis works on OAG matters of policy and legislation, general law, healthcare fraud, and veterans’ benefits. She is a practicing board-certified ophthalmic surgeon, fellow of the American Academy of Ophthalmology, fellow of the Institute of Medicine, and a fellow and member of the Board of Governors of the American College of Legal Medicine. She is an Assistant Professor of Clinical Ophthalmology at Northwestern University Feinberg School of Medicine, and a clinician and lecturer for the medical residency program at Weiss Memorial Hospital. She was the vice-president of her hospital medical staff and a member of the peer review and credentials committees and co-chair of the medical executive board. As a magna cum laude graduate of Brown University, she also earned her medical degree with honors from Brown University Alpert School of Medicine and serves as a member and secretary of the Brown University Alumni Medical Board. As past chair and member of the Blindness Prevention Task Force of the NGO and Vision 2020 partner, Health For Humanity, Dr. Anawis has lectured and continues to instruct and collaborate with physicians in the U.S., Mongolia and Europe.

Dr. Anawis has served as the Chair of the Health Care Section Council of the Illinois State Bar Association and its health care legislation subcommittee. She is a member of the American Health Lawyers Association Alternative Dispute Resolution panel and the American Bar Association Health Care Section. She has served on the Ethics, Education and National Health Law Moot Court Committees of the American College of Legal Medicine. Dr. Anawis has served as an Adjunct Professor of Health Law at John Marshall Law School in Chicago. She graduated from DePaul Law School with honors and a Certificate of Health Law. A key goal of Dr. Anawis’s dual careers in law and medicine is to communicate and clarify the complexities of healthcare to her fellow physicians, attorneys and the public. She is a lecturer, trained mediator, consultant and attorney to physicians, health care providers, institutions and fellow attorneys both nationally and internationally focusing on medical malpractice, medical staff/hospital matters, regulatory matters, ethics, health policy and U.S. health care reform.

Eli N. Avila, MD, JD, MPH, FCLM. The Honorable Eli Narciso Avila currently serves as the 9th Commissioner of Health for Orange County, NY. In this current public health executive role, he presides over the health and welfare of Orange County’s approximately 400,000 diverse citizens and manages a $67 million dollar budget. Since his arrival in Orange County, the New York State Bar has appointed him to the Committee for Mass Disaster Response and he is an active member of the Public Health Law Section, where he has collaborated on three webinars to assist the New York State Legislature as it adapts legislation to conform to the merger of primary care and traditional public health under the Affordable Care
Act. Currently, he is addressing health outcomes by confronting chronic health issues such as diabetes and hypertension, by tackling childhood obesity, by increasing childhood immunization rates, by removing health disparities, by increasing efficient linkages to care, and by increasing screening for Hepatitis C among baby boomers.

Prior to this position, he served as the 26th Secretary of Health of the Commonwealth of Pennsylvania managing a $1 billion budget and a staff of 1,700. He received unanimous bipartisan Senate confirmation. Dr. Avila was the first Latino in the state’s history to hold this cabinet position. As Secretary, Dr. Avila was the top health regulator in Pennsylvania, the senior health policy advisor to the executive branch and served as a liaison to the Governor and the US Dept. of Health and Human Services for the Pennsylvania Department of Health. During his tenure he was instrumental in the authoring and passage of sixteen health related laws, was the first state health official in the country to provide testimony and a detailed national health education and epidemiological surveillance plan for communities near Marcellus Shale Hydraulic Fracturing activities, removed regulatory obstacles to mobile lab testing and rapid HIV/Hepatitis C screening, provided updated/uniform Hospital Accreditation and EMS Regulations, and addressed disparity issues by holding Pennsylvania’s first statewide Health Equity Conference and by facilitating telemedicine into isolated rural areas.

Prior to this role, Dr. Avila served as the Chief Deputy Commissioner of Health Services and Director of Public Health for Suffolk County, NY, the seventh largest county in the US, where he managed a $400 million budget and a staff of 1,400. As a physician-attorney, Dr. Avila has held a variety of roles of diverse scope and responsibility including: Senior Examining Occupational Medicine Physician for federal agents in Albany, NY, Associate General Counsel for an environmental biotechnology company, Law Associate for an intellectual property law firm, Clinical Instructor in Ophthalmology and Surgical Attending at Columbia University, and Medical Director of an ophthalmology practice where he performed emergency eye trauma surgery and corneal transplant surgery.

In 2012, Dr. Avila graduated from the prestigious National Preparedness Leadership Initiative, a joint program between the Harvard Kennedy School of Government and the Harvard School of Public Health. In 2011, he completed the highly exclusive Executive Education program for State Health Officials at the Harvard School for Public Health. His academic pedigree includes graduating from Phillips Academy as a full scholarship student under the “A Better Chance” program, an ScB in Biology from Brown University, an MD from the Brown Medical School, a JD with cum laude honors from the St. John’s University School of Law, and an MPH with highest honors from the Mount Sinai School of Medicine.

David M. Benjamin, PhD, is a trained Clinical Pharmacologist & Forensic Toxicologist, a trained arbitrator and mediator, and a nationally-recognized scholar in Legal Medicine, Reducing Medication Errors, the Drug Development process and Forensic Toxicology.

Dr. Benjamin spent 12 years in the pharmaceutical industry conducting clinical trials in patients and contributed to many INDs and NDAs which were accepted by the Food and Drug Administration.

Dr. Benjamin teaches Regulatory and FDA Law, and Forensic Toxicology at Northeastern University in Boston where he holds the rank of Adjunct Associate Professor, and also has taught Legal Medicine and Reducing Medication Errors in the Harvard Medical School Risk Management Program and at Tufts Medical School. He is a prolific author with more than 275 presentations and publications.

Although he is not an attorney, Dr. Benjamin has been teaching Scientific Evidence in Professor James Stare’s Forensic Science course at George Washington University Law School in Washington, DC over the past 10 years. Dr. Benjamin also has taught Liquor Liability & DUI Defense at MCLE, and has taught ten seminars for judges on ethanol pharmacology and Breathalyzer testing from 1999-2006. In 2003 Dr. Benjamin was featured on Forensic Files on Court-TV describing his experience as an expert in the famous Massachusetts case, Com. v Christina Martin, the “LSD in the Jello” case, which he did pro bono.

Irene G. Bober-Moken, DMD, MPH, FACD. Previously a radiation health physicist, Dr. Irene Bober-Moken switched to dentistry and graduated in 1981 from the New Jersey Dental School. She served 23 years in the United States Air Force beginning her career in a post-graduate program in General Dentistry. After 16 years of clinical practice, Dr. Bober-Moken went on for specialty training: completing her Master’s Degree in Public Health at the University of Texas Health Science Center (UTHSC) School of Public Health in 1998 and receiving a certificate in Dental Public Health from UTHSC at San Antonio-School of Dentistry 1999. She would return to UTHSCSA after retiring from the USAF in 2004, becoming an Assistant Associate Clinical Professor at the School of Dentistry. Dr. Bober-Moken is a Diplomate of the American Board of Public Health Dentistry, a Fellow of both the Academy of General Dentistry, American College of Dentists and the Academy of Dentistry International (ADI). She is a member of several professional organizations including the American Dental Association (Secretary Treasurer of Panama Canal Dental Society, Alternate to the ADA House of Delegates 1983-85), American Association of Public Health Dentistry, American Academy of the History of Dentistry, and Omicron Kappa Upsilon.
Robert W. Buckman, PhD, FCLM, is a practicing Clinical Pharmacologist who served the State of Illinois as the Chair of the Drug Formulary for the Department of Public Aid for 25 years. During that period of time, he served as a Senior Consultant for the Illinois State Medical Society Drug and Therapeutics Committee. He also served, in his career, as Senior Vice President, Director of Medical Affairs Worldwide, for the global Interpublic Advertising Group of Companies.

He is a graduate of the Graduate School of Loyola University of Chicago and the medical program of Loyola’s Stritch School of Medicine Clinical Pharmacology program. He was privileged to be one of the Navy’s first Medical Scholars named under the Health Professions Scholarship Program whereby he was able to complete his Clinical Pharmacology training. During active duty, Dr. Buckman was on the adjunct faculty of the Naval Academy with an adjunct clinical appointment at the National Naval Medical Center as he served as the Clinical Pharmacologist for the 3rd and 7th Naval Fleets.

Dr. Buckman is an adjunct faculty member of the University of Wisconsin and lectures in the area of pharmacological therapeutics. He holds memberships in numerous medical/scientific societies. Currently he is celebrating his company’s 27th anniversary supplying the academic support for continuing medical education programs for the healthcare industry and scientific support for the legal profession.

His career in legal medicine spans a time period of 27+ years specializing in therapeutics and drug safety. He recently has been appointed as an arbitrator judge in a three member panel by the American Arbitration Association to hear complex commercial cases dealing with issues where medicine and law intersect. Dr. Buckman is a Fellow of the College, President of the ACLM Foundation, and an ex officio member of the College’s Board of Governors. He also is the second recipient of the President’s Distinguished Service Award in the 50-year history of the College.

Henry N. Butler, BA, PhD, JD, a leading public policy analyst and specialist in law and economics, is a Foundation Professor of Law and Executive Director of the Law & Economics Center at George Mason. He has devoted much of his career to improving the country’s civil justice system through judicial education programs. Professor Butler most recently served as the first executive director of the Searle Center on Law, Regulation, and Economic Growth at Northwestern University School of Law. He has held prior appointments at The Brookings Institution, Chapman University, the University of Kansas, the University of Chicago, and Texas A & M University. From 1986 to 1993, he was a law professor at George Mason and during that period also served as an Associate Dean and Director of the Law & Economics Center.

He received a MA and PhD in economics from Virginia Polytechnic Institute and State University and a JD from the University of Miami School of Law. He received a Bachelor’s degree in economics from the University of Richmond.

R. Gregory Cochran, MD, JD, FCLM, is a physician/healthcare attorney with broad experience in transactions, regulatory counseling and peer review, licensing administrative law and in legal issues unique to foundations and integrated healthcare delivery systems. Dr. Cochran’s clients include medical staffs, medical groups, individual physicians, hospitals and health systems.

His work is informed by more than a decade of experience as an emergency medicine physician, allowing Dr. Cochran the opportunity to offer a deep understanding of the legal issues impacting his clients through first-hand industry experience.

John Paul Conomy is a native of Cleveland, Ohio and educated in that city (Cleveland Public and Parochial Schools, St. Joseph High School) and graduated with honors from John Carroll University. He studied Medicine at St. Louis University where he received his MD degree in 1964. After serving as Medical House Officer at the University, Veteran’s Administration and City Hospitals in St. Louis, he returned to Cleveland and was trained in Neurology (Professor Joseph M. Foley) and Neuropathology (Professor Betty Q. Banker) at University Hospitals of Cleveland, Cleveland Metropolitan General Hospital (MetroHealth Medical Center) and Case Western Reserve University. After decorated service in the United States Air Force, Dr. Conomy served as a Career Research and Teaching Fellow at the Institute of Neurosciences at the University of Pennsylvania (Professor James Sprague, Philadelphia) prior to returning to Cleveland as an Assistant then Associate Professor of Medicine (Neurology) at Case Western Reserve University. In 1975 Dr. Conomy was appointed Chairman, Department of Neurology, at the Cleveland Clinic Foundation, Chairman of Clinical Research and Director of its Neurology Residency Program, positions he held until 1992. Dr. Conomy is a certified specialist in Neurology and Forensic Medicine and serves as an examiner for several medical and surgical specialty boards.

Dr. Conomy attended the Schools of Law at Case Western Reserve University and Cambridge University (England) and received his JD in 1992. Dr. Conomy has served as Professor of Clinical Neurology and Adjunct Professor of Law at Case Western Reserve University Schools of Medicine and Law and has held faculty positions at the Universities of Texas (Southwestern, San Antonio) and Pennsylvania State University. He has held consultancies in the Tower Hamlets District of London (England) and has served as a lecturer and Visiting Professor in Law and Medicine in ninety countries throughout the world. He is the Founder of the Mellen Center for Multiple Sclerosis Treatment and Research and Founder of the International Consortium of Multiple Sclerosis Centers. Dr. Conomy
holds deep interests in the history of medicine, medical ethics, health law and human rights.

Dr. Conomy has held numerous research and clinical investigative grants and awards in the fields of cardiovascular diseases, diabetes, epilepsy and multiple sclerosis. He is a Fellow of the American Neurological Association, the American Academy of Neurology, the American College of Legal Medicine and The Royal Society of Medicine (England) as well as an active principal in many organizations related to adult and childhood disorders of the nervous system and to medical law and ethics. He is a member of Alpha Omega Alpha Medical Honor Society, the World Association of Medical Law, Who’s Who in America and an Honorary Fellow of Medical Societies in Canada, Mexico and England. He is the author of more than 150 peer-reviewed publications and more than a dozen books. He is cited among America’s Top Physicians and lectures on matters of health and law. He is engaged in the planning and operational design of comprehensive treatment, educational and research facilities dealing with diseases of the nervous system and systems of health delivery in the US and internationally. Dr. Conomy directed the Brain Injury Program at University Hospitals of Cleveland’s Extended Care Campus from 2003 to 2008. Dr. Conomy practices Neurology in Cleveland. He is the President of Health Systems Design and CompEval Corporations. He is the father of three adult professionals and of Francesca Maria, now age 15 years. Dr. Conomy is married to Dr. Jill Mushkat Conomy and is an avid bibliophile, traveler, cyclist, skier, music lover and photographer.

**Kate Diesfeld, JD**, was a resident of Alaska, attorney at Protection and Advocacy in Los Angeles, and Legal Supervisor of the Kent Law Clinic (Mental Health and Learning Disability) in Canterbury, England. She represented patients before England’s Mental Health Review Tribunal for 8 years. She led a team that established New Zealand’s first free community law centre for people with disabilities. At the University of Waikato School of Law, she was the Associate Dean of Research. She is the co-editor of *Involuntary Commitment and Therapeutic Jurisprudence* (Ashgate, 2003) and *Elder Law in New Zealand* (2014).

**David Donnersberger, MD, JD, MA, FACP**, is a clinical assistant professor of medicine at the University of Chicago-Pritzker School of Medicine. He is a senior attending at Northshore University Health System in Evanston, IL, where he chairs the Institutional Ethics Committee and sits on the Executive Committee of the Professional Staff. He is site-director of the University of Chicago-Pritzker School of Medicine Junior Medicine Clerkship at Northshore University Health System. He completed the combined MD/JD Program at Southern Illinois University Schools of Law and Medicine. He completed his internship in internal medicine at Yale-New Haven Hospital and his residency in internal medicine at Northwestern-McGaw Center for Graduate Medical Education. He served as the Chief Resident in Internal Medicine at Evanston Hospital in Evanston, IL. He is in private practice in internal medicine in Winnetka, IL.

**Mitchell D. Forman, DO, MACP**, is a practicing rheumatologist and Dean of the Touro University Nevada College of Osteopathic Medicine in Henderson, Nevada. He is Certified by the American Board of Osteopathic Internists and the American Board of Rheumatology. He has been selected a Master of the American College of Physicians. Currently, he serves as the president of the Nevada State Medical Association. Dr. Forman was instrumental in developing a curriculum in medical jurisprudence, ethics, and professionalism. In collaboration with the UNLV School of Theater Arts, he has produced filmed ethics issues vignettes which are being used around the globe.

**Bernard Friedland, BChD, MSc, JD, FCLM**, graduated from the Univ. of Stellenbosch Dental School near Cape Town in South Africa in 1980. From 1982 to 1985 he undertook his specialty training in oral and maxillofacial radiology at the University of Toronto. He was on faculty at Harvard School of Dental Medicine from 1985 to 1988. After a stint in law school and private law practice, he returned to Harvard in 1993. Dr. Friedland is an assistant professor in the Dept. of Oral Medicine Infection & Immunity at Harvard School of Dental Medicine. His area of expertise is oral & maxillofacial radiology. He has published in both the medicolegal and scientific literature. Dr. Friedland maintains an active oral & maxillofacial radiology practice in the Harvard School of Dental Medicine Faculty Group Practice.

**Chester J. Gary, DDS, JD** is an attorney at law, admitted in New York and Florida, with a practice concentrated on issues related to health care providers. He represents dentists and physicians in practice acquisitions and mergers, partnership formation, employment agreements, and dentists, personally, in malpractice litigation. He serves as a member of the New York State Dental Association (NYSADA) Attorney Referral Panel and District Chair of the NYSADA Professional Liability Claims Committee, which reviews dental malpractice claims in the eight counties of Western New York. He is Clinical Assistant Professor and Course Director of Practice and Risk Management, University at Buffalo School of Dental Medicine, author and certified presenter of the New York State mandated Dental Ethics and Jurisprudence Course, and is in the part-time private practice of general dentistry. Dr. Gary is also Editor of the *Eighth District Dental Society Bulletin*, Reviewing Editor of the *Journal of the American Dental Association* and *New York State Dental Journal*, fellow of the American College of Legal Medicine and American College of Dentists, and member of the Erie County, New York and Florida Bar Associations.

Joseph P. Graskemper, DDS, JD, FCLM, DABMM, currently practices full-time in Bellport, NY. He graduated from Xavier University, attended Case Western Reserve Graduate School, obtained his dental degree from Ohio State University in 1977 and his law degree from Thomas Jefferson School of Law in San Diego, CA in 1987. After dental school, where he was awarded a Navy Dental Scholarship, he was stationed at Camp Pendleton with the 1st Fleet Marine Division as a Lieutenant, US Navy Dental Officer. He has been awarded Fellowships from the Academy of General Dentistry, American Endodontic Society, International Congress of Oral Implantologists, American Society of Osseointegration, The American College of Legal Medicine, and American College of Dentists. Recently, Dr. Graskemper became a Diplomat in the American Board of Medical Malpractice.

Besides practicing dentistry full-time, he also is an Associate Clinical Professor in the 4th year General Practice Program at Stonybrook School of Dental Medicine, and teaches the Professionalism and Ethics in Dentistry course for residents and Dental Law at the 2nd, 3rd, and 4th year dental students. He is the past Director of Professional Responsibility courses and past Editor-in-Chief of the Stonybrook School of Dental Medicine GPR Literature Review Journal. Currently, he is the faculty advisor to the Student Professionalism and Ethics Association Club at Stonybrook. He belongs to many professional organizations and has served as a consultant to several state dental boards. He is a Board member of the International Dental Ethics and Law Society and the American Board of Medical Malpractice. Dr. Graskemper has authored many peer-reviewed articles, has lectured and published nationally and internationally. He recently published a book, Professional Responsibility in Dentistry: A Guide to Law and Ethics.

Prior to moving to Long Island to be closer to family, Dr. Graskemper was the sole owner of a fee-for-service multi-specialty group practice in La Jolla, CA, having an Endodontist, Periodontist, Oral Surgeon, Prosthodontist, Orthodontist, Implantologist, and a General Dentist. He also was the President of Dentcom Advertising. While in California, he was also the owner of Sorrento Valley Ceramic Arts, a full service dental lab, and Chief of the Scripps Memorial Hospital Dental Staff.

He is very active in his community by being a Past President of the Patchogue Kiwanis Club, Past Chairman of the Board of Trustees of Maryhaven Center of Hope, a large Long Island wide agency serving severely mentally and physically handicapped individuals of all ages. He currently is active in the Patchogue and the Bellport Chambers of Commerce; and a past Chamber Member of the Year in Bellport. Currently, he is on the Board of Directors of the Suffolk County Dental Society, Board of Directors of International Dental Ethics and Law Society, and the Board of Governors of the American College of Legal Medicine.

Richard S. Harold, DMD, JD, FCLM, is an Associate Clinical Professor and Practice Coordinator in the Department of Diagnosis and Health Promotion. Dr. Harold, a Massachusetts native, owned and operated a general dentistry practice in Malden for over 25 years before joining the Tufts faculty. He received his BS degree from Massachusetts College of Pharmacy in 1975, and his DMD degree from Tufts University School of Dental Medicine in 1980. Dr. Harold is also an attorney and received his JD from New England School of Law in 1995. He is a member of the Massachusetts Bar. Dr. Harold has developed and participated in several dental public health programs. He helped establish a dental clinic in Flores, Honduras, where he has visited over the years providing dental services to residents. Within the Malden Public Schools, Dr. Harold provided a dental screening and educational program to grade school students. Dr. Harold holds membership in the American Dental Association, American Dental Education Association and the Massachusetts Dental Society. He is a Fellow of the American College of Legal Medicine. Dr. Harold has a specific interest in dental-legal issues and is a consultant in the areas of dental record keeping, documentation, prescription writing, regulatory issues, dental negligence and standards of care. He has lectured locally and nationally and has published several dental-legal articles.

Weldon (Don) Havins, MD, JD, is In-House Counsel for Touro University Nevada where he is also Professor of Medical Jurisprudence, Professor of Ophthalmology and Associate Dean for Clinical Initiatives. Don is a Fellow of ACLM, is certified by the ABLM, and is a member of the Board of ACLM.

C. William Hinnant, Jr., MD, JD, FCLM, DABU is the Principal in the firm Medicolegal Consultants, LLC and is a practicing Urologist.

His legal practice focuses on Health Litigation, White Collar Crime, Medical Malpractice, Personal Injury, Peer Review and Credentialing Issues, Workers Compensation, ERISA litigation and Insurance Law. He has authored Amicus Briefs for the College and other various health-related organizations as well as regulatory comments and is a member of the Bar of the United States Supreme Court. He has handled various appellate matters in both federal and state courts and serves on the adjunct faculty at Clemson University. He continues to practice urology as well, his interests including microsurgery and uroscopy.

Bill is the ACLM’s Secretary and Corporate Counsel, serving on several committees of the College, and also a member of the World Association for Medical Law. He and his wife Virginia have
four grown children, are self-described “political junkies” and enjoy traveling, the arts, sports, gardening, cooking and their three dachshunds, Elliot, Misty and June Bug (although June Bug can sometimes be hard to enjoy). They are annual participants in the Renaissance Weekend program organized by Former President Bill Clinton and former Ambassador to the Court of St. James, Phil Lader, and encourage all ACLM members with an interest to consider joining them there.

Santosh Kakade, MS, DOrtho, FICS, LLM, PhD in Law, MBA Hospital Management, Executive MBA Finance

Raymund King, MD, JD, FCLM, is the principal and founder of the Law Offices of Raymund C. King, MD, JD, PLLC, in Plano, TX. Previously featured in Forbes Magazine “Texas Legal Profiles,” named one of Fortune Magazine’s “America’s Premier Lawyers” as well as a Texas SuperLawyer “Rising Star” in Healthcare Law, Dr. King represents a broad spectrum of clients ranging from healthcare to corporate to entertainment law.

Dr. King obtained his undergraduate degree from the University of Dallas, and then earned his medical degree from the University of Texas Medical School in Houston, TX. At the end of his residency training at the department of Otolaryngology/Head & Neck Surgery at the University of Oklahoma Health Sciences Center, he earned the distinction of being one of the physicians who treated victims of the Oklahoma City Bombing. After ten years of medical practice as an otolaryngologist/head & neck surgeon, Dr. King obtained his law degree from the Oklahoma City University School of Law, and in 2004 he was awarded the Distinguished Young Alumnus Award from the OCU law school.

Dr. King’s law firm represents numerous entrepreneurs in both corporate healthcare and non-healthcare entities in start-up as well as merger/acquisition mode. He also represents individuals and corporations in the entertainment industry.

Clifford Warren Lober, MD, JD

Darren P. Mareiniss, MD, JD, MBe, is a cum laude graduate of Dartmouth College, where he received an AB in Genetics and Developmental Biology. He received his MD from New York University School of Medicine, where he was a member of the Alpha Omega Alpha Honor Medical Society. Dr. Mareiniss received his JD from the University of Pennsylvania Law School and a Master’s of Bioethics from the University of Pennsylvania School of Medicine. He completed graduate medical training in Emergency Medicine at The Johns Hopkins Hospital.

Currently, Dr. Mareiniss is an Instructor in the Department of Emergency Medicine at the University of Maryland School of Medicine in Baltimore, MD. He has published and lectured extensively on bioethics and varied medico-legal topics including crowding, malpractice, disaster preparedness, end-of-life decision making and ICU triage.

Jayme Matchinski, BS, JD, concentrates her practice on health care and corporate law. She handles regulatory compliance, reimbursement, licensure and certification issues affecting health care providers, health care transactions, and the purchase, sale and formation of health care entities. She has also successfully represented health care providers in reimbursement claims against insurance carriers and the Centers for Medicare and Medicaid Services.

Jayme works with physicians, as well as not-for-profit and for-profit health care systems in the licensure, certification, legal structure and reimbursement structuring of post-acute venues of care, including sleep disorder centers, rehabilitation hospitals, ambulatory surgery centers, long term acute care hospitals, skilled nursing facilities, inpatient and outpatient rehabilitation facilities, nursing homes and assisted living facilities.

For a number of years Jayme has been in private practice. She is the former vice president of a national healthcare consulting firm.

While still in law school Jayme served externships with the Air & Water Division of the U.S. Environmental Protection Agency, as well as with the Honorable George W. Lindberg, U.S. District Court, Northern District of Illinois. In addition, Jayme participated in a summer study program of law and economic policy at Ningbo University in the People’s Republic of China.

Jayme is a member of the editorial advisory board of Sleep Diagnosis and Therapy Journal, and an advisory member of the board for the Sleep Center Management Institute in Atlanta, GA.

Jayme is an active law school alumnus, participating in Valparaiso University School of Law’s alumni/law student networking and student development programs. She serves on the Chicago and National Councils for Valparaiso University School of Law.

In January 2011, Jayme was re-elected for a second two-year term to the Board of Directors of Volunteer Optometric Services to Humanity (VOSH) Illinois Chapter. She has worked with the Heartland Alliance for Human Needs & Human Rights to provide pro bono representation to individuals seeking political asylum.

Rollin M. Matsui, BSc, DDS, LLB, FCLM, received his BSc from the University of Toronto in 1975, DDS from the Faculty of Dentistry, University of Toronto in 1979 and his LLB from Osgoode Hall Law School, York University in 1991. He is a Fellow of the American College of Legal Medicine, American College of Dentists, International College of Dentists, Academy of Dentistry International and Pierre
Fauchard Academy. He is also a past-president of Tau Tau Chapter (University of Toronto) of the Omicron Kappa Upsilon Honour Dental Society and a former Councillor of the Royal College of Dental Surgeons of Ontario (RCDSO), having served on the Complaints, Discipline and Registration Committees of the provincial dental regulatory body. He is a member of the Oral Health Journal Editorial Board for Ethics and Jurisprudence.

He provides dental-legal lectures to dental students at the Faculty of Dentistry, University of Toronto as well as to dentists in the numerous continuing education courses which he has conducted over the past 22 years. He maintains a full-time law practice in Richmond Hill and a part-time dental practice in Toronto, Ontario. He provides legal advice to dentists regarding dental practice issues, patient disputes, dental insurance claim inquiries / audits, RCDSO regulatory complaints, investigations and professional misconduct related matters, reviews held by the Health Professions Appeal and Review Board and various business agreements involving dentists, dental hygienists and non-dentists.

Bruce Chandler May, MD, JD, MS, FCLM. Dr. May attended college at Southern Methodist University, in Dallas, TX, where he earned his BSEE (1970), MSEEE/ME (1972). He received his MD from the University of Texas at Houston (1976), and spent his internship at Childrens Hospital Los Angeles (pediatrics). Dr. May spent his surgical residency at Kaiser Permanente - San Francisco and at the University of Pittsburgh, Eye & Ear Hospital (head and neck surgery). Dr. May went to Law School at the Santa Barbara College of Law (1999).

Dr. May has California State Licenses in Medicine, Qualified Medical Evaluator and Law - California State Bar. He is Board Certified in Otolaryngology/Head and Neck Surgery and Subspecialty - Otolaryngic Allergy – 2006 Examiner.

Dr. May belongs to the following professional societies:
- Fellow, American College of Legal Medicine, 2006-present
- Member, California Medical Association
- Member, Santa Barbara Medical Society
- Fellow, American Academy of Otolaryngology / Head & Neck Surgery 1981-present
- Fellow, American Academy of Otolaryngic Allergy 1991-present
- Centurions Deafness Research Foundation – Former Member
- California Society of Otolaryngology / Head & Neck Surgery – Former Member

Dr. May has held the following positions:
- Active Member of the Santa Barbara Cottage Hospital Level II Trauma Team 2000-2015
- Expert Witness, Otolaryngology / Head and Neck Surgery

1994-present
- Former Council Member, American Academy of Otolaryngic Allergy 1994-1996
- Former President, Santa Barbara County ENT Society
- Former Member, Board of Governors, American Academy of Otolaryngology / Head and Neck Surgery
- Former Member, California Medical Association Scientific
- Advisory Board on Head & Neck Surgery (6 years)
- Former Chairman, Otolaryngology, Santa Barbara Cottage Hospital
- Former Member, Board of Directors, Santa Barbara Medical Foundation Clinic

Thomas R. McLean, MD, MS, JD, FCLM, ACLM President-Elect, Acting President of ACLM, MD- University of Chicago; JD- UMKC CEO Third Millennium Consultants

Rosemary McGeady, MD, JD, FCLM, received her Bachelor of Sciences degree in Biology from St. Peter's College in 1978 and her MD from St. Louis University School of Medicine in 1982. After medical school, she served in the National Health Services Corps in St. Louis. She then practiced Internal Medicine in California and Virginia before seeking subspecialty training in Cardiology, completing her Fellowship at The Robert Wood University of Medicine and Dentistry in 1992. Rosemary was a partner in the New Brunswick Cardiology Group for over a decade, specializing in Invasive Cardiology, Nuclear Cardiology and Echocardiography. Rosemary is Board Certified in Internal Medicine since 1985.

As a youngster, she was inspired by her father, Paul J. McGeady, Legal Counsel for Morality in Media and a First Amendment attorney and a noted anti-pornography lawyer. Keenly interested in both professions, she initially chose medicine over law. After a very successful 20 years in medicine, she returned to school in 2001 to pursue her oft dreamed-of law degree. She achieved this goal in 2005, when she graduated cum laude from Seton Hall University School of Law. She was admitted to the New Jersey Bar in December of that year.

She had an active medical-legal consulting firm prior to joining Levinson-Axelrod in 2007, Med Law Consulting. She concentrated on technology assessments, peer-review and insurance appeals. She recently gave Grand Rounds at the University of Pennsylvania on the topic of Medical Malpractice prevention. She is an avid Rotorcraft pilot, Master Scuba Diver and downhill skier. Rosemary lives in Montgomery Township with her two daughters.

Rosemary is a Fellow of the College of Legal Medicine and a Fellow of the American College of Cardiology. She is focusing at Levinson Axelrod on Medical Malpractice, hoping to bring to her clients the same one-on-one compassion and skill she brought to her patients during her more than two decades in medicine.
Dale Miles, BA, DDS, MS is an adjunct Professor of Oral and Maxillofacial Radiology at the University of Texas Health Science Center in San Antonio, TX. He is a Diplomate of both the American Board of Oral and Maxillofacial Radiology and the American Board of Oral Medicine. He has been named as one of the “Top Clinicians in CE” for the past 12 years by Dentistry Today. He has authored over 135 scientific articles and 6 textbooks, including the 2nd edition of his Atlas of Cone Beam Imaging for Dental Applications published by Quintessence. He has a web site for teaching dentists and auxiliaries about digital imaging and cone beam imaging at learndigital.net and a company in Fountain Hills, AZ called Cone Beam Radiographic Services, LLC, providing radiographic interpretation to dental colleagues and radiology laboratory services who use CBCT. To date he has read over 18,000 CBCT scans.

Alejandro Moreno, MBBS, MPH, JD, FCLM, is a faculty member at the University of Texas Southwestern Residency Programs in Austin, TX. In addition to his faculty appointment, he is an Associate Residency Program Director. In 1992, Dr. Moreno received his medical degree from University CES in Medellin, Colombia. In 1997, he completed his residency training at the Boston University Medical Center Residency Program in Internal Medicine. Dr. Moreno went on to a Fellowship Program in General Internal Medicine with the Boston University Medical Center and received a Master of Public Health (Health Law) from the Boston University School of Public Health in May 2000. He is board certified in Internal Medicine by the American Board of Internal Medicine. Dr. Moreno also holds a law degree from the St. Mary’s University School of Law. He practices law in Texas in the areas of immigration and human rights. Dr. Moreno is a Fellow of the American College of Physicians and of the American College of Legal Medicine.

Kalu Ogobreke, FRCPath, FCLM, DDS, JD, DMSc, FDSRCS, is a full Professor of Oral and Maxillofacial/Head and Neck Pathology, and Chair of the Department of Diagnostic and Biomedical Sciences at The University of Texas School of Dentistry at Houston (UT-SOD Houston). He also is an Adjunct Professor at the Georgia Regents University (GRU) Colleges of Dental Medicine and Graduate Studies in Augusta GA, where he previously was a tenured Associate Professor and interim chair of the Department of Oral Biology. Professor Ogobreke holds several visiting professorships at institutions in the United States and abroad.

Professor Ogobreke earned his dental degree from the University of Ibadan in Nigeria, a Master's degree in medical science from the University of Glasgow in Scotland, a doctor of medical sciences (DMSc, Oral Biology) from Harvard University, and a juris doctorate (JD) from Suffolk University Law School in Boston. He earned the fellowship in dental surgery of the Royal College of Surgeons of England (FDSRCS), the Royal College of Physicians and Surgeons of Glasgow (FDSRCPS), and the Royal College of Surgeons of Edinburgh (FDSRCE). Professor Ogobreke also earned a graduate certificate in the Business of Medicine from Johns Hopkins University. He completed a 2 1/2-year clinical research fellowship at the National Institutes of Health (NIH), Bethesda, MD. Professor Ogubreke is a board certified diplomate of the American Board of Oral and Maxillofacial Pathology (ABOMP), a fellow of the Royal College of Pathologists of the United Kingdom (FRCPath), a board certified diplomate of the American Board of Medical Malpractice (ABMM), and a fellow of the American College of Legal Medicine (ACLM). He completed the Certificate of Training in Forensic Dentistry program of McGill University, Montreal, Canada. Professor Ogubreke has been inducted into the fellowship of the American College of Dentists (FACD).

Professor Ogubreke is the principal investigator studying the role of the SIBLING family of proteins in oral cancer and precancers, and has been funded in this effort through a major grant from NIDCR, and through foundation grants from the Wendy Will Case Cancer Foundation (WWCCF). His clinical practice is in the specialty of diagnostic Oral and Maxillofacial Histopathology, Head and Neck Pathology, and Clinical Oral Medicine.

In 2007, Professor Ogobreke was awarded the first Neal W. Chilton Fellowship in Clinical Research by the American Association for Dental Research (AADR) and the Emerging Scientist award by GRU Research Institute. In 2010, he was named a Fulbright Scholar and served in that capacity for 10 months at the University of Lagos, Lagos, Nigeria (2010-2011). Professor Ogubreke is an attorney and admitted to practice law in three United States Jurisdictions (Georgia, Massachusetts, DC) and the United States Supreme Court. His interest is in Health Law and Policy, and Forensic odontology, and he is a frequent invited speaker on aspects of the interface between law and medicine at the annual meetings of the American College of Legal Medicine. Between 2010 and 2011 Professor Ogubreke received three separate Commendation Letters from GRU Presidents. He also received a Commendation Letter from Senator Johnny Isakson, a United States Senator from Georgia, following his selection as a Fulbright Scholar by the U.S. Department of States. In 2012, Professor Ogubreke received the Outstanding Faculty Award of GRU. His other notable achievements include being the only dental team member of the Nebraska Institute of Forensic Sciences (NIFS) that investigated the high-profile “Angele-Togba” homicide case in Monrovia, Liberia in 2008. Professor Ogubreke also led a team of forensic investigators for the identification of victim of a plane crash in Kaduna, Nigeria in June 2011. He is a Consultant/Site Visitor to the American Dental Association (ADA) Commission on Dental Accreditation (CODA), and served on the Constitution Committee of both the AADR and IADR. Professor Ogubreke has authored and co-authored several peer reviewed scientific articles in high impact journals and book chapters, and is the Editor and co-author of recently published book, Oral Cancer.
Daniel L. Orr II, BS, DDS, MS (anesthesiology), PhD, JD, MD, is an Oral & Maxillofacial Surgeon (OMS) practicing in Las Vegas, NV, is married and the father of nine children.

He was named 1968 Eagle Scout of the Year by the Los Angeles Area Council and as an adult was awarded the Silver Beaver by the Boulder Dam Area Council.

After graduating cum laude from BYU and with honors from USC School of Dentistry, he completed residencies in Anesthesiology at the University of Utah MC, where he also earned an MS in Anesthesiology, and in OMS at LA County/USC/MC. Dr. Orr then obtained a PhD in Biophysics from Columbia Pacific University. Dr. Orr subsequently graduated from William Howard Taft University School of Law and the University of Health Sciences Antigua School of Medicine.

Dr. Orr is a Diplomate of the American Board of Anesthesiology, the American Board of OMS, and the American Board of Legal Medicine. He has treated over 2,000 facial fractures and administered over 50,000 anesthetics.

Dr. Orr has been on the founding boards of an off-shore professional liability insurance company, a 501(c)(3) approved public charity, and an FDIC approved bank.

Dr. Orr is Professor and Director of OMS and Anesthesiology at the UNLV School of Dental Medicine and was selected the National Outstanding OMS Educator by AAOMS in 2011. He is a Clinical Professor of Anesthesiology and Surgery at the University of Nevada School of Medicine, and teaches high school and college level religious courses for The Church of Jesus Christ of Latter Day Saints.

He is the Editor of the NV Dental Association Journal, Past President of the American Association of Dental Editors and Journalists, a member of several professional editorial boards and reviews articles for JOMS, JADA, OOOOE, JACD, and others.

Dr. Orr is the Post-Mortem Coordinator for Nevada’s USPHS National Disaster Medical System, Chairman of the NSSOMS Anesthesia Committee, Past President of the NSSOMS, and is a Surveyor for the AAAHC.

He is admitted to the CA Bar and the U.S. Ninth Circuit Court of Appeals.

Dr. Orr is a member of the Sports Medicine Teams for UNLV Athletics, the AAA Pacific Coast League Las Vegas 51’s, the PRCA National Finals Rodeo, Past President of the D.A.R.E. Community Board, and the Medical Advisor and a Senior Patroller for the Las Vegas Area National Ski Patrol.

Ola-olu A. Osanyin, LLM, is a Medical Law Consultant. He is the Director of Medicolegal at Medical Tutors Ltd which is accredited by the Medical and Dental Council of Nigeria to provide Continuous Professional Development Courses for Nigerian Doctors. He is a member of The World Association for Medical Law (WAML), and member of the Medical and Health Law Committee of the Nigerian Bar Association (NBA). He is also the Director of The Center for Medical Law Research and Development (CMLRD). He is the Principal Partner of 1st Counsel Solicitors which is a Firm of Medical Malpractice Law Consultants in Lagos Nigeria. Olaolu is the Organizer of The Medical Law Seminar Series, which is a medicolegal training platform for Nigerian Health Care Professionals.

David T. Ozar, PhD, is Professor, Department of Philosophy, Loyola University Chicago, where he was also Director/Co-Director of Graduate Studies in Health Care Ethics, 1985-2010. He is an Adjunct Professor in the Neiswanger Institute for Bioethics and Health Policy of Loyola’s Stritch School of Medicine and he has taught and lectured, especially on professional ethics, in Loyola’s schools of nursing, law, education, business, social work, and dentistry. From 1993 to 2006 he served as Director of Loyola’s Center for Ethics and Social Justice. Ozar has taught at Loyola since 1972. He completed his PhD in Philosophy at Yale University in 1974.

In 1975, Ozar initiated the Loyola Philosophy Department’s under-graduate course in health care ethics, which he has been teaching regularly ever since. In 1984, he designed the Philosophy Department’s Graduate Program in Health Care Ethics, which he directed or co-directed until 2010. This program offered a Master’s degree in Health Care Ethics, chiefly for health care professionals, and a subspecialty in Health Care Ethics for PhD students specializing in Moral Philosophy. More than ninety students received MA or PhD degrees from these programs. Ozar has also served on numerous departmental and university committees at Loyola including chairing an Institutional Review Board for the Protection of Human Subjects from 1980 to 1985.

In addition to his work at Loyola, Ozar is also in his thirtieth year as Associate Member of the Professional Staff, lecturer in medical ethics, member of the Institutional Ethics Committee, and consulting ethicist for NorthShore University Health System in Evanston, Illinois. He also served as a member of the Institutional Review Board for the Protection of Human Subjects of the Chicago Department of Health from 1986 to 1993 and as the consulting ethicist for the Midwest Hospice and Palliative Care Center from 1989 until 1998. He helped create the American Judicature Society’s Model Code of Ethics for Court Employees and has served as a consultant to the American Dental Association, the American Medical Association, many other professional organizations, and several dozen professional schools. He served for a number of years as a member of the Ethics Board of the Illinois Department of Children and Family
12 Notorious Serial Killers. She writes a regular blog about crime for Psychology Today, and has consulted for several television series. Holding graduate degrees in forensic psychology, clinical psychology, criminal justice, and philosophy, she teaches forensic psychology and criminal justice. Dr. Ramsland has worked with prominent criminalists, coroners, detectives, and FBI profilers. She trains law enforcement on psychological issues relevant to the field and speaks internationally about forensic psychology, suicidology, investigative psychology, forensic science, jury dynamics, and serial murder. She has appeared on over 100 documentaries, as well as The Today Show, 20/20, 48 Hours, Larry King Live and E! True Hollywood Story. Her latest project involves interviews with the “BTK Killer,” Dennis Rader.

Jha Saurabh, MBBS, completed his medical degree at the University of London, residency in radiology and a Master's degree in Health Policy Research from the University of Pennsylvania, where he serves as faculty. Scholarly interests include value of information and understanding why doctors order so many tests. Saurabh is a prolific writer with work appearing in the NEJM, BMJ, Forbes, Philadelphia Inquirer, American Thinker and popular medical blogs.

Frank J. Riccio, DMD, JD, FCLM, has maintained a private law practice in Braintree, MA since 1987. He has substantial jury trial experience in civil litigation. His areas of concentration include medical and dental negligence; trucking liability; liquor liability; general negligence; and crime victim representation. Mr. Riccio has been a clinical instructor in Oral Medicine at Harvard Dental School since 1995.

Mr. Riccio is a member of the Massachusetts Academy of Trial Attorneys, where he is a Regional Governor and Chairman of the Medical Negligence Committee. He is also a member of the Massachusetts Bar Association, where he is a former Co-Chair of the Health Law Council; the National Crime Victim Bar Association; the AAJ; and the Million Dollar Advocates Forum. He has been named a Boston Magazine Super Lawyer since 2005. He is on the Board of Directors of Massachusetts Citizens for Children.

Mr. Riccio became Board Certified as a Civil Trial Specialist by the National Board of Trial Advocacy in October 2000, and was re-certified in October 2005. He is a Fellow in the American College of Legal Medicine. He is also a certified mediator.

Mr. Riccio has lectured extensively in Massachusetts and throughout the country on many medical, legal and trial practice topics and was a co-host on the WCRN Worcester radio program, Talking About the Law.

Jack Snyder, MD, JD, PhD, FCLM, Asst. Managing Director, CATO Research Ltd., is a physician-attorney-executive with more than 25 years of clinical, research, and administrative experience in academic, governmental, and industrial sectors of biomedicine.
Jack currently directs corporate pharmacovigilance activities and manages the Washington (Rockville, MD) office of Cato Research Ltd., a full-service global CRO. Dr. Snyder has a keen interest in all aspects of product development, and derives a special satisfaction from collaborating with others to move new drugs, biologics, devices, and other products into the marketplace. Jack is a graduate of the Honors Medical Program at Northwestern University (BS, MD), the Georgetown University Law Center (JD), the Graduate Program in Forensic Science at George Washington University (MFS), the Johns Hopkins University Bloomberg School of Public Health (MPH), the Graduate Program in Pharmacology and Toxicology at the Medical College of Virginia (PhD), and the Johns Hopkins University Carey School of Business (MSIS, MBA, Graduate Certificates in Financial Management, Investments, and Competitive Intelligence). Jack served an internship in internal medicine at the Tulane University Medical Center; residencies in anatomic, clinical, and chemical pathology at the University of Miami Medical Center, the Johns Hopkins Hospital, and the Medical College of Virginia Hospitals; and an NIEHS-supported fellowship in clinical pharmacology and medical toxicology at the Medical College of Virginia.

Dr. Snyder is licensed to practice medicine and law, and is Board-Certified in Occupational Medicine, Medical Toxicology, Clinical Informatics, Anatomic Pathology, Clinical Pathology, Chemical Pathology, Toxicological Chemistry, Clinical Chemistry, General Toxicology, Quality Assurance & Utilization Review, Legal Medicine, Public Health, and Regulatory Affairs. Jack is a Certified Physician Investigator, and a Certified Physician Executive who also holds a Certificate of Qualification to direct clinical laboratories. Jack has directed clinical and research laboratories and projects; taught law, medicine, and forensic science at the Thomas Jefferson University and the George Washington University; authored more than 100 manuscripts in medical, legal, and scientific publications; and presented more than 100 papers at national and international meetings. Finally, Dr. Snyder is a past president of the American College of Legal Medicine, past Secretary of the American Board of Legal Medicine, and has attained fellow status in the American College of Medical Toxicology, the American Academy of Clinical Toxicology, the Association of Clinical Scientists, the American Society of Clinical Pathologists, the College of American Pathologists, the National Academy of Clinical Biochemistry, the American Board of Quality Assurance & Utilization Review, and the American College of Legal Medicine.

Dr. Tham is the Principal Investigator of double blind research oral rinse study to determine the effect on Periodontal Disease conducted at UNLV School of Dental Medicine. He is the course director of general clinic stream at the university, clinical sciences faculty, and a mentor for sixteen dental students. He is the founder and advisor of UNLV Asian American Dental Student Association. He is part of the Editorial Board of the Journal of Dentistry, Oral Disorders, and Therapy. He has published many articles in peer-reviewed journals and is the co-author of Rule of Law Index.

Dr. Tham is also a practicing attorney in Immigration and Nationality Law, Family Law, and Dental Malpractice, since getting his law degree from California Concord University School of Law in 2005. He is the past vice chair of American Bar Association Health Law Section, and currently the vice president and executive board member of Asian American Advocacy Clinic—a non-profit organization whose mission is to increase access to legal, advocacy, education, and support services for low income and linguistically and/or culturally marginalized communities.

He is the founding board and chairman of Global Oral Legal Dental Helping Hands Foundation, a non-profit organization to provide oral, dental services, and legal education worldwide.

Dr. Tham has over 23 years of experience in managing private practice, mentoring, research, and education. He has served as vice-president and secretary in several state-wide professional organizations, such as American Bar Association (ABA) Health Law Section, ABA Young Lawyer Section, and Tzu Chi Foundation Medical Section; currently, he is the chair of Disaster Relief and Medical Aid Section of Tzu Chi Las Vegas Foundation, chair elect of Professional, Ethical, and Legal Issues in Dentistry, and secretary of Practice Management Section of American Dental Education Association.

Professor Stacey A. Tovino, JD, PhD, is a leading expert in health law, bioethics, and the medical humanities. She has particular expertise in the regulatory and financial aspects of health law, and she frequently explores issues that lie at the intersection of health law and other fields, such as gaming law. Educated as both a lawyer and a humanist, Professor Tovino publishes her interdisciplinary work in textbooks, casebooks, edited readers, law reviews, medical and science journals, and ethics and humanities journals. Recent law review publications include articles in the Washington and Lee Law Review, Tulane Law Review, Florida State University Law Review, Houston Law Review, University of Richmond Law Review, Kentucky Law Journal, Penn State Law Review, Harvard Journal on Legislation, and Harvard Journal of Law and Gender, among many other general and specialty journals.

to Medicare and Medicaid financing of graduate medical education, the legal treatment of individuals with gambling disorder, the health information confidentiality implications of grateful patient fundraising, the ethical implications of significant physician involvement in health care philanthropy, and the implications of advances in neuroscience for health insurance law, disability benefit law, and disability discrimination law.

Professor Tovino is a frequent speaker on the local, national, and international level. She has been invited to guest lecture and present papers on a range of health law, bioethics and medical humanities topics at schools of law, medicine, public health, pharmacy, life sciences, health sciences and public policy, as well as undergraduate and graduate departments of neuroscience, biology, psychology, sociology, philosophy, and humanities across the country.

Prior to joining the faculty at Boyd, Professor Tovino served as Director of the Health Law and Policy Center and Associate Professor of Law at Drake University Law School (2008-10); Assistant Professor of Law at Hamline University School of Law (2006-08); Visiting Assistant Professor, Research Professor, and Adjunct Professor at the University of Houston Law Center (2003-06); and attorney in the Health Industries Group of the Houston office of the international law firm Vinson & Elkins (1997-2003). During her practice, Professor Tovino represented physicians, scientists, allied health professionals, general and special hospitals, academic medical centers, organ procurement organizations, blood banks, AIDS clinics, and nonprofit health care organizations in civil and regulatory matters.

Veling W. Tsai, MD, JD, is a clinical assistant professor in the Department of Head and Neck Surgery at the University of California at Los Angeles – David Geffen School of Medicine. Dr. Tsai is also an attending physician in the Department of Surgery, Division of Head and Neck Surgery at Olive View – UCLA Medical Center in Sylmar, CA. Additionally, Dr. Tsai is in private practice, and Chair of Department of Surgery at Alhambra Hospital in Alhambra, CA. He attended UCLA and received a Bachelor of Arts degree in Geography/Environmental Science, graduating with Latin honors. Dr. Tsai then received his dual law and medical degrees from Southern Illinois University - School of Medicine and School of Law. Dr. Tsai completed his Head and Neck Surgery residency training at UCLA. He is licensed to practice both law and medicine in the State of California. Dr. Tsai has served on the Ethics committee of the American Academy of Otolaryngology – Head and Neck surgery for the last 10 years. He is also currently a member of the Board of Governors for American College of Legal Medicine.

Dr. Tsai continues to be actively involved in scholarly research by serving on the editorial board for the *Journal of Legal Medicine*.

Karin M. Zaner, JD, practices in the Litigation Section at Kane Russell Coleman & Logan in Dallas, where she is a director. Her experience includes litigation of general business and commercial disputes before both state and federal trial courts, but she now focuses mainly on health care law. She was introduced to medical peer review law through her representation of Dr. Lawrence Poliner, which began in 1999. Dr. Poliner’s federal court lawsuit for malicious peer review was filed in May 2000, and the case was tried before a jury in August 2004, resulting in a verdict that totaled over $366 million. When the trial court’s judgment in the Poliner case was reversed by the Fifth Circuit in July 2008, Ms. Zaner wrote the petition for certiorari to the United States Supreme Court. Ms. Zaner now represents various clients (mainly physicians and physician groups) in a variety of health care matters, including those relating to HIPAA, peer review, credentialing, physician employment and non-competes, practice disputes, as well as Texas Medical Board issues.

Ms. Zaner attended the University of Texas at Austin and received a BA in 1991 with special honors in the Plan II Honors Program. She is a member of the Friar Society, the University’s oldest honorary society, established in 1911. She attended the University of Texas School of Law and received her JD in 1994. She is an active member of the Dallas Bar Association’s Health Law Section and the American College of Legal Medicine. She resides in Dallas with her husband and daughter.

Karin Waugh Zucker, MA, JD, LLM, FCLM, Prof., US Army - Baylor University Graduate Program in Health and Business Administration, Ft. Sam Houston, Texas
POSTER SESSIONS

POSTER PRESENTATION:
FRIDAY, FEBRUARY 27, 7:00 AM - 7:45 AM

POSTER VIEWING:
FRIDAY, FEBRUARY 27, 7:00 AM - 8:30 PM
SATURDAY, FEBRUARY 28, 7:00 AM - 8:30 PM
SUNDAY, MARCH 1, 7:00 AM - 1:00PM

Brera 6

See Separate Packet for Handouts
WELCOME &
ANNOUNCEMENTS
FRIDAY, FEBRUARY 27, 7:45 AM - 8:00 AM

Brera 4-5

Thomas R. McLean, MD, MS, JD, FCLM, ACLM President-Elect, Acting President
David Donnersberger, Jr., MD, JD, MA, FCLM, ACLM Annual Meeting Co-Chair
Monique Anawis, MD, JD, FCLM, ACLM Annual Meeting Co-Chair
GENERAL SESSION I
RECENT DEVELOPMENTS IN LEGAL MEDICINE

FRIDAY, FEBRUARY 27, 8:00 AM – 9:25 AM

Brera 4-5

MODERATOR:
Jack Snyder, MD, JD, FCLM, Cato Research Washington
Federal and State Legislative Update 2015

Velting Tsai, MD, JD, FCLM
Las Vegas, NV
Feb. 27, 2014

2014 Federal Legislation - Enacted

- S. 2141: Sunscreen Innovation Act
- S. 2917: Adding Ebola to the FDA Priority Review Voucher Program Act
- S. 2154: Emergency Medical Services for Children Reauthorization Act of 2014
- H.R. 3527: Poison Center Network Act
- H.R. 4067: To provide for the extension of the enforcement instruction on supervision requirements for outpatient therapeutic services in critical access and small rural hospitals through 2014.
- H.R. 5185: EARLY Act Reauthorization of 2014
- S. 2539: Traumatic Brain Injury Reauthorization Act of 2014
- S. 1557: Children's Hospital GME Support Reauthorization Act of 2013
- H.R. 3548: Improving Trauma Care Act of 2014
- H.R. 594: Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education Amendments of 2014
- H.R. 2019: Gabriella Miller Kids First Research Act
- H.R. 669: Sudden Unexpected Death Data Enhancement and Awareness Act

State Legislation Update

- Using National Conference of State Legislature database.
- Using the topics: Access to Primary Care, Authorize/Plan/Fund, Challenging and Alternatives, Essential Health Benefits, Health Centers, Health Information Technology, Health Insurance Exchanges, Health Insurance Reform, Medicaid and CHIP, Other, Prevention and Wellness, Workforce and Providers.
- 1194 healthcare related legislations introduced in 49 states in 2014
- 203 bills enacted in 43 states in 2014

Alabama

- S. 123, Enacted and signed as Act No. 2014-219, 4/2/2014. Authorizes the Alabama Health Insurance Plan (high-risk pool) to cease operations upon the availability of guaranteed issue health policy under federal law, giving time to current participants to transition out of the plan, provides for the transfer of unspent funds to the State General Fund.

Arkansas

- H 1053, Enacted and signed as Act 2014-219, 4/2/2014. Appropriates Federal funds for the 2014-2015 fiscal year for personal services and operating expenses associated with the federal-state partnership health insurance exchange of the State. Permits funding to be used for salaries, leave and travel expenses, and for health data managed by the State Department of Health. Appropriated funds shall be deposited in the General Revenue Fund.
- H 1098, Enacted and signed as Act 180, 2/25/2014. Provides for the state Office of Health Information Technology appropriation for the 2014-2015 fiscal year, for personal services and operating expenses of the State Health Alliance for Records Exchange (SHARE) and the Office of Health Information Technology for the fiscal year ending June 30, 2015, a total of $8.2 million, which can apply to Medicaid and health insurance regulation. Effective through June 30, 2015.

California

- A 369, Enacted and signed as Act 4, 3/20/2014. Requires a health insurer and health plan to arrange for the completion of covered services by a nonparticipating (out-of-network) provider for a newly covered enrollee and a newly covered insured under an individual health care service plan contract or an individual health insurance policy whose prior coverage was terminated between whose prior coverage was withdrawn from the market between December 1, 2013, and March 31, 2014, for various chronic or acute conditions.
<table>
<thead>
<tr>
<th>State</th>
<th>Legislation</th>
<th>Details</th>
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<tbody>
<tr>
<td>Colorado</td>
<td>H 1053, Enacted and signed as Act 7, 2/20/2014. Provides that the Commissioner of Insurance may adopt rules to ensure consistent requirements for pediatric dental benefits in health benefit plans offered in the State regardless of the method by which a plan is purchased (both the Exchange and the commercial market.) Signed into law Feb. 19, 2014.</td>
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<tr>
<td>Maryland</td>
<td>S 134 and S 153, Enacted and signed 1/30/2014. Alters the purpose of the State Health Insurance Plan to include decreasing uncompensated care costs by providing access to affordable, comprehensive health benefits for specified bridge eligible individuals; repeals portion of the plan that closes the plan to a person not enrolled as of a certain date; provides enrollment shall be closed to bridge eligibles under certain conditions; authorizes the extension of closing certain enrollment; requires the adoption of related rules and regulations.</td>
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<tr>
<td>Maine</td>
<td>S 217, Enacted and signed as Act 449, Feb 26, 2014. Relates to the affordability and accessibility of chemotherapy treatment in the State; directs the Department of Professional and Financial Regulation, Bureau of Insurance and the Department of Health and Human Services, and the State Center for Disease Control and Prevention to jointly convene a work group to review and report on insurance coverage as it relates to the affordability and accessibility of chemotherapy treatment.</td>
<td></td>
</tr>
<tr>
<td>Mississippi</td>
<td>H. 1281, Enacted and signed, 3/26/2014. Provides that no health coverage plan shall restrict coverage for prescribed treatment based upon the insured's diagnosis with a terminal condition, provides that no health benefit paid with state funds specifically Medicaid and the state insurance plan shall restrict coverage for physician prescribed treatment based upon the individual's diagnosis with a terminal condition.</td>
<td></td>
</tr>
<tr>
<td>Nebraska</td>
<td>L 47 &amp; L 76, Enacted and signed 2/14/2014. Adopts the Health Care Transparency Act; creates an advisory committee; relates to the health care data base to provide objective analysis of health care costs and quality, promote transparency for health care consumers, and facilitates the reporting of health care and health quality data; provides for the facilitation of value-based, cost-effective purchasing of health care services by public and private purchasers and consumers; includes provisions regarding claims and eligibility standards.</td>
<td></td>
</tr>
<tr>
<td>New Mexico</td>
<td>S 3131, Enacted and signed as Act 63, 3/13/2014. Makes general appropriations and authorizing expenditures by state agencies: provides for an audit of insurance premium tax collections. The office of superintendent of insurance includes $50,000 to study the impact of a basic health plan in New Mexico.</td>
<td></td>
</tr>
</tbody>
</table>
New York

- S 6358, Enacted and signed as Act No. 58, 3/31/2014. The state commissioner “shall establish the managed care for persons with developmental disabilities advocacy program, hereinafter referred to as the advocacy program,” which shall provide support to eligible individuals with developmental disabilities enrolling in developmental disability individual support and care coordination organizations.

- S 6814, Enacted and signed as Act No. 60, 3/31/2014: Authorizes the state to implement and operate a basic health plan, to provide subsidized health coverage for residents with annual income between 138%-200% of federal poverty. It is to be established in accordance with section 369-gg of the social services law, and in compliance with provisions of the ACA, as part of the state health and mental hygiene budget for the 2014-2015 state fiscal year.

Oregon

- H 4109, Enacted and signed 4/1/2014. Requires Oregon Health Authority to commission an independent study of costs and impacts of expanding coverage by operating a basic health program in Oregon, consistent with the optional provision in the ACA, specifies goals of study, including number and characteristics of individuals who would be eligible to enroll in the basic health program, including legal resident aliens who are barred from Medicaid for five years, requiring report to Legislative Assembly by Nov. 30, 2014, appropriates $60,000 from General Fund to the authority for contract costs to conduct the study.

Tennessee

- S 1617, Enacted and signed as Act No. 583, 3/28/2014. Relates to health maintenance organization holding company systems, relates to enterprise risk, security holders, subsidiaries and investment authority, reinsurance agreements and consolidated tax allocation agreements.

Utah

- H 24 and signed. Regulates health and accident insurance, designates insurance fraud investigators as law enforcement officers, prohibits provider contracts, mental health and substance abuse treatment services for state employees, requires a written health plan policy to cover accidental death and dismemberment benefits, and establishes a Health Insurance Fraud Prevention Committee.

- S 31, Enacted and signed as Act No. 371, 4/1/2014. Requires, in cooperation with the Insurance Department, the Department of Health, and the Department of Workforce Services, the state to create a health insurance exchange that (i) provides information to consumers about private and public health programs for which the consumer may qualify, (i) provides a consumer companion of and enrollment in a health benefit plan, would provide a consumer website and a call center.

- H 76, Enacted and signed as Act No. 300, 4/1/2014. Modifies the Insurance Code to address inducements, addresses when a de minimis gift or meal may be given, prohibits an insurer from inducing a person to continue or terminate an insurance contract by offering a benefit not specified or related to the insurance contract, provides that an insurer may not make an agreement of insurance that is not clearly expressed in the insurance contract to be issued or renewed, provides that a licensee under this title may not absorb any gross premium insurance tax.

- H 141, Enacted and signed as Act No. 425, 4/2/2014. Amends provisions related to health insurance and state and federal health care reform, amends the time in which an employee of a state contractor must be enrolled in health insurance to conform to federal law, facilitates coordination of eligibility, quality reports, conversions, health insurance navigators, Indian health center exceptions, the Comprehensive Health Insurance Pool, renewal of insurance plans, the Individual and Small Employer Health Fair, the Individual and Small Employer Health Fair Adjustments Act and premium tax credits for small employers.

Vermont

- S 27, Enacted and signed, 03/21/2014. Replaces offensive terms for individuals with a disability with respectful language, relates to the right to an interpreter, interchange of state employees, employment, guardianship, mental health proceedings, adoption, mandatory continued health insurance and Medicaid.

Virginia

- H 33 & S 483, Enacted. Provides that a health carrier selling a health benefit plan in the small group or individual market that does not include the minimum essential pediatric oral health benefits required under the federal Affordable Care Act shall be deemed to have obtained reasonable assurance that the pediatric oral health benefits are provided to the plan’s purchaser.
Washington

- HB 2572, Enacted 4/4/2014. Seeks to improve "the effectiveness of health care purchasing and transforming the health care delivery system by facilitating whole-community health, promoting community health, and providing greater integration of chronic disease care and prevention into the health delivery system and community," and (2) supporting regional collaboration for community and population health. Requires Health to establish a regional collaborative with other health care delivery systems and communities. Would require regulation of managed care companies provided by the state to exchange and offer state-based health insurance exchanges.
- HB 6002, Enacted 4/4/2014. Would order an analysis of the impacts of using the Washington health benefit exchange as a mechanism for providing health insurance for part-time K-12 public school employees. The analysis shall include a review of how the exchange impacts:
  - Employer health care costs for the school district
  - Employer health care costs for the state
  - The overall impact of health care costs for individuals
  - The overall impact of health care costs for school districts
  - The overall impact of health care costs for the state
- SB 5931, Enacted and signed as Act 31, 3/17/2014. Requires health carriers offering health benefit plans to meet the definition of "bronze" to offer silver and gold level plans; requires nongrandfathered individual and small group health plans to conform with certain actuarial value tiers.
- SB 6016, Enacted as Act No. 84, 3/27/2014. Requires health carriers to offer transparency tools for members with certain price and quality information and to attest to the Office of the Insurance Commissioner that the tools meet certain requirements and that access is available on the health plans secured member website, directs a stakeholder committee to identify and recommend statewide measures of health performance, requires state agencies to use these measures to inform and set benchmarks for their purchasing.
- SB 6228, Enacted and signed as Act 224, 4/9/2014. Requires health carriers to offer transparency tools for members with certain price and quality information and to attest to the Office of the Insurance Commissioner that the tools meet certain requirements and that access is available on the health plans secured member website, directs a stakeholder committee to identify and recommend statewide measures of health performance, requires state agencies to use these measures to inform and set benchmarks for their purchasing.
- SB 6551, Enacted as Act No. 141, 3/28/2014. Requires the Insurance Commissioner to reauthorize the efforts to develop processes, guidelines, and procedures to ensure that health care administration meets the Office of the Insurance Commissioner to develop a work group to receive recommendations for state authorization requirements, provides health carriers with a waiver for prior authorization for non-emergency health care services for which a person may self-refer, requires a similar to disclose authorization methods and clinical protocols.

Health Insurance Exchanges

- 14 State-based;
- 3 Federally-supported State-based;
- 7 Partnership;
- 27 Federally-facilitated
GENERAL SESSION II
TECHNOLOGY AND LEGAL MEDICINE

FRIDAY, FEBRUARY 27, 10:00 AM - 10:45 AM

Brera 4-5

MODERATOR:
Thomas R. McLean, MD, MS, JD, FCLM, ACLM President-Elect, Acting President
“Technological Approaches in the Synthesis of Designer Drugs, and Creative Prosecution of the Non-Scheduled, Illicit, Analogue Drug”

David M. Benjamin, Ph.D.
Clinical Pharmacologist & Toxicologist
Adjunct Associate Professor, Dept. of Pharmaceutical Sciences,
Northeastern University, Boston, MA
Fellow, American Academy of Forensic Sciences (Toxicology)
Fellow, American Society for Healthcare Risk Management
Fellow, American College of Clinical Pharmacology
Fellow, American College of Legal Medicine
Member, Society of Forensic Toxicologists
medlaw@doctorbenjamin.com

What is a “Designer Drug”?

- Designer drug is an informal term for psychoactive drugs that are related, by structure and/or activity, to existing psychoactive drugs frequently used for “recreational” use.
- In many instances, designer drugs have been synthesized by small chemical modifications of known active drugs, and
- Resemble the “parent” drug as: structural analogues, stereoisomers and derivatives of those drugs.

Federal Analog Act

- Controlled Substance Analogue Enforcement Act of 1986
- Effective October 27, 1986
- Federal Analog Act, 21 U.S.C. § 813, is a section of the United States Controlled Substances Act which allowed any chemical “substantially similar” to a controlled substance listed in Schedule I or II to be treated as if it were also listed in those schedules, but only if intended for human consumption. These similar substances are often called designer drugs.*

Substantially Similar

- Substantially similar means that the chemical structures are very similar
- Substantially similar does not mean exactly the same; some level of difference is acceptable and all experts do not agree
- Substantially similar can be: (1) a readily cognizable (chemical) similarity between the alleged analog and the controlled substance prior to ingestion, (2) has a CNS effect equal to or greater than the substance scheduled in C-I or C-II, or (3) is metabolized to the alleged the controlled substance analog after ingestion, e.g., 1, 4 – butanediol -> GHB

Classification of Designer Drugs by Chemistry

- Legislation
- Control by classes
- Analogs (Chemical groups)
  - Compounds:
    - e.g., Spice, K-2
    - Designer stimulants, e.g.
    - Cathinones, bath salts
    - Synthetic cannabinoids,
    - Benzylpiperazines
    - Phenethylamines
    - Tryptamines
    - Pyrrolidinophenones

My thanks to Heather L. Harris, MFS, JD, D-ABC for permission to use her slides.

Synthetic Drug Abuse Prevention Act of 2012 – Chemical Classes

- Naphthoxyindoles
- Naphthylmethylindoles
- Naphthoylpyrroles
- Naphthylmethylindenes
- Phenylacetilindoles
- Cyclohexylphenols
- Benzoylindoles
- Adamantoylindoles
Chemical Structure of THC vs. Synthetic Cannabinoids – Substantially Similar?

THC; Tetrahydrocannabinol (−)-trans-Δ9-tetrahydrocannabinol, a dibenopyran.
CP-47,497 has been identified in Spice.
Modified from: Synthetic Cannabinoids
The Challenges of Testing for Designer Drugs
By Bridgit O. Crews, PhD
February 2013 Clinical Laboratory News: Volume 39, Number 2
Accessed online: Jan. 4, 2014

Mechanism of Action of the Cannabinoids

THC, Tetrahydrocannabinol
CP-47,497 has been identified in Spice.
Modified from: Synthetic Cannabinoids
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By Bridgit O. Crews, PhD
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Cannabinoceptor
Neurotransmitter (NT) from presynaptic neuron activates the postsynaptic neuron.

Endogenous and Exogenous Cannabinoids Reduce Neuronal Signaling

Postsynaptic Neuron
Neurotransmitter
Receptor
Endogenous Cannabinoid
Retrograde Signaling
CB1 Receptor
Presynaptic Neuron
Inhibition of Neurotransmitter Release

Synthetic Cannabinoids are thought to activate CB1 receptors directly, mimicking the effects of endocannabinoids.

CB1 Effects
- ↓ CGRP
- ↓ SENS
- ↓ Plasma extravasation
- ↓ Hyperalgesia
- ↓ Edema

CB2 Effects
- ↓ Histamine
- ↓ NGF sensitization
- ↓ Neutrophil migration
- ↓ NO production by macrophages

Cathinone ADRs

Cathinones

Mephedrone (Miaow Miaow)
(4-methylmethcathinone, 4-MMC)

Methyline
(β-k-MDMA, 3,4-methylenedioxy-N-methylcathinone)

MDPV (3,4-methylenedioxypyrovalerone)

Cathinones in “Bath Salts”

Mephedrone (Miaow Miaow)
(4-methylmethcathinone, 4-MMC)

Methylone
(β-k-MDMA, 3,4-methylenedioxy-N-methylcathinone)

MDPV (3,4-methylenedioxypyrovalerone)
Grazie, Drs. Papanti, Schifano & Botteon for this great paper!


Spice drugs and psychopathological ADRs -1
- Situational anxiety, agitation
- Long-lasting psychotic episodes triggered by cannabis
- “Spice” Anxiety, psychotic symptoms; hallucinations
- 16 year old “Spice” Altered mental status
- Visual hallucinations, agitation, restlessness and anxiety
- Long-lasting psychotic episodes

Spice drugs and psychopathological ADRs -2
- “Spice” Severe anxiety and paranoia, auditory and visual hallucinations, halted speech
- Anxiety, anger, euphoria/sadness, irritability, restlessness, memory changes, auditory/visual perceptual changes, paranoid thoughts.
- Subjects had no psychiatric history before using Synthetic Cannabinoids.

Spice drugs and psychopathological ADRs -3
- Long-lasting psychotic episodes and substance-induced psychosis (auditory and visual hallucinations, paranoid delusions, flat affect, thought blocking, disorganized speech, alogia, psychomotor retardation, agitation, suicidal ideation, anxiety, dysthymia)

Spice drugs and psychopathological ADRs - 4
- Nonsensical speech, paranoia, delusions, disorganization
- Tremulousness, anxiety, confusion
- Anxiety, disorientation, tremulousness, “feeling psychotic”
- Motor retardation, auditory and visual hallucinations
- Delusions, aggressiveness, inappropriate affect

Spice drugs and psychopathological ADRs - 5
- Sedation, confusion, disorientation, agitation
- Unresponsiveness, agitation, paranoia, delusions
- Hx PTSD, brief substance-induced psychotic episode: 2 of 3 positive for THC
- “Spice” Persistent psychosis after SC intake, disorganized speech, poverty of thought, loosening of associations, paranoia, suicidality
Spice drugs and psychopathological ADRs - 6

- “Capgras delusions” a disorder in which a person holds a delusion that a friend, spouse, parent, or other close family member has been replaced by an identical-looking impostor. (Invasion of the Body Snatchers; Day of the Triffids)

Don’t Take Pharmacology from Strangers

Thanks to Richard S. Blum, MD for permission to use his slides

Ischemic stroke after use of the synthetic marijuana "spice"
Melissa J. Freeman, David Z. Rose, Martin A. Myers, et al. Neurology published online November 8, 2013, p. 3., Figure 2
GENERAL CONCERNS WITH MOBILE DEVICES

- Mobile devices (iPhones, iPads, Blackberrys, Androids) store and retain data including ePHI:
  - within the device's onboard memory;
  - within the memory chip or SIM ("smart") card.
- Small and portable (subject to loss and theft).
- May not restrict user access to data through encryption software or authentication features.
- Employer-issued mobile devices may be compliant.
- BUT use of personal devices raises concern.
- How to navigate mobile delivery platforms and devices?

GENERAL HIPAA DEFINITIONS AND CONCEPTS

- See Physician’s Guide to HIPAA for basics:
- WHAT IS PROTECTED HEALTH INFORMATION?
- WHAT EXACTLY CAN CONSTITUTE PHI?
- WHO IS A COVERED ENTITY?
- WHO IS A BUSINESS ASSOCIATE?
- WHAT IS A BUSINESS ASSOCIATE AGREEMENT?
- WHAT IS A PHI "BREACH"?

WHAT IS A PHI "BREACH"?

- Any impermissible disclosure of PHI is a breach unless "low probability that PHI was disclosed."
- Common pitfalls with MOBILE DELIVERY DEVICES—
  - Forwarding to unsecured e-mail addresses such as gmail, hotmail, yahoo (anything that is free is not HIPAA compliant);
  - Accessing and viewing PHI (electronic trail remains);
  - Disclosing PHI on social media (e.g., Facebook, but also possibly sites like Sermo, Medscape, Quantia MD.);
  - Stolen or lost mobile devices.
  - Non-HIPAA Compliant texting.

HIPAA CONDUIT EXCEPTION

- Is cell phone texting HIPAA Compliant?
- Logic for Conduit Exception—If PHI made it from Point A to Point B and the conduit did not look at substance, then not a PHI breach.
- No breach of PHI if the conduit entity
  - only transmits the encrypted PHI; and
  - never has access to the encryption key.
- Exceptions for entities such as:
  - US Postal Service, Federal Express, UPS;
  - Certain Internet Service Providers (but not gmail, hotmail, yahoo and otherwise "free" accounts);
  - Cell Phone providers generally (but which ones?).
- Does this omit important information from medical record?

MOBILE DEVICES POSE SPECIAL RISK

- Physicians and all covered entities should strictly observe certain protocols
  - www.healthit.gov/mobiledevices
  - For any mobile devices that contain PHI,
  - Maintain physical control at all times;
  - Use encryption and passwords;
  - Installing firewall and remote disabling software;
  - Use adequate security when using public Wi-Fi networks;
  - Deleting all PHI before discarding any device.
  - Sign a "Bring Your Own Device" agreement?
MOBILE DELIVERY DEVICE APPS

• Closed networks that are specifically HIPAA compliant (e.g., HIPAA chat)
  — allows physicians, nurses, employees to disclose general patient conditions;
  — solicit input from fellow employed physicians and colleagues;
  — implemented by a 3rd party and paid for by provider.

• Third party services that store medical records ("Universal Health Record" such as NextGen Patient Portal, My Charts by FollowMyHealth—)
  — obtains and stores online a patient’s medical records from a provider;
  — requires authorization from a patient just like a paper medical record;
  — keeps records encrypted, de-identified, and individually stored in separate “container” in the “intranet cloud”;
  — patient can access by password and authorize provider access.
  — but are these covered entities/BAs or just conduits?

MOBILE DELIVERY DEVICE APPS, contd.

• Other physician networks (such as Sermo and Quantia MD)
  — virtual doctor’s lounges, sharing of opinions and advice;
  — invites specific details, x-rays, photographs (even facial areas);
  — may violate HIPAA and patient privacy laws;
  — is disclosure of PHI legal or allowed?

• Beware of Facebook, Twitter, and Other Open Networks
  Example—N.J. physician vented details of tough day at ER that revealed details of patient care on Facebook. This allowed 3rd party to identify patient; physician got fired and in trouble with state licensing board.

COMPLIANCE: WHERE DOES A PHYSICIAN START?

• HIPAA Risk Assessment—outside vendors can provide;

• HIPAA Compliance (Initial and Ongoing)—
  — Appoint a HIPAA Compliance Officer;
  — Storage/destruction of paper and electronic PHI;
  — Data encryption;
  — Facility access and security measures;
  — Employee training within 60 days of hire and again at least once every two years (employees to sign verification of attendance);
  — Mobile device safeguards (passwords, remote wipes, timed lock-outs, wi-fi protection);
  — And the list goes on.
  — typically, duties set forth in a business associate agreement.

WHAT POLICIES SHOULD EXIST?

• Physical office security policies;

• Document retention policies;

• Work station log on and access;

• Network authorization parameters;

• E-mail and calendaring policies;

• Remote access safeguards;

• Protocols for use of mobile devices;

• “Bring Your Own Device” agreements;

• Cloud storage and/or document sharing agreements;

• Health record access agreements;

• Policies for storage, re-use, and disposal of devices.

PENALTIES FOR VIOLATION OF HIPAA

• Criminal penalties only be imposed when there is proof beyond a reasonable doubt that covered entity and/or business associate knowingly violated HIPAA or any of its regulations.

• Civil monetary penalties include fines ($100 to $50,000) and/or prison term (1 year to 15 years).

• Civil monetary penalties (a hearing may be requested)
  (1) $100/violation to $50,000 for an unknown violation in spite of due diligence,
  (2) $1,000/violation to $50,000 for a violation due to “reasonable cause,” or
  (3) $10,000/violation to $50,000 for a corrected violation due to “willful neglect.”

• Court challenge after final HHS Appeals Board decision available.

HIPAA V. STATE LAWS

• HIPAA preempts contrary state laws; HIPAA is a floor.

• States can do more—as shown by Texas HB 300 drastically changing the definition of a “covered entity.”

• HIPAA does not preempt state laws that relate to privacy and security of PHI.

• Thus, still need to comply with both the federal laws and any state law that offers more protection for health information.

• Government sources for compliance abound—access them!

• For example, Security Rule Guidance—www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html

• Questions? Comments? Thank you for this opportunity!
Physician’s Guide to HIPAA Compliance

UNDERSTANDING HIPAA: TOP 10 TIPS

1. **WHAT IS PROTECTED HEALTH INFORMATION?** – All "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. RULE OF THUMB: If it contains any type of health data (including payment information) and identifies the individual or there is a reasonable basis to believe it can be used to identify the individual, it is PHI.

2. **WHO IS A COVERED ENTITY?** – Health plans, health care clearinghouses, health care providers (includes physicians) conducting certain financial and administrative transactions electronically (e.g., claim submission, billing, and fund transfers). Actively-practicing physicians should assume "covered entity" status.

3. **WHO IS A BUSINESS ASSOCIATE?** – A person or entity to whom a covered entity discloses PHI so as to carry out, assist with, or perform a function on behalf of the covered entity (includes lawyers, vendors, subcontractors, experts, court reporters), except for employees of the covered entity.

4. **WHAT IS A BUSINESS ASSOCIATE AGREEMENT?** – A required contract that provides compliance with HIPAA security rule provisions mandating administrative, physical, and technical safeguards for PHI. A BAA must include restrictions on use and disclosure of PHI and set forth mandatory notification requirements to the Department of Health & Human Services (HHS) if a PHI security breach occurs.

5. **HOW IS PHI “SECURED”?** – PHI can be secured by destroying it (which renders it unusable) or complying with the encryption guidance standards set by HHS. Proper encryption ultimately avoids the breach notification obligations in event of unauthorized use or disclosure of PHI.

6. **WHAT CONSTITUTES “UNSECURED” PHI?** – PHI contained in hard copy form, as well as electronic storage or transmission of non-encrypted PHI.

7. **WHAT IS A PHI “BREACH”?** – Any impermissible disclosure of PHI is a breach unless "low probability that PHI was disclosed."

8. **ARE PEER REVIEW ACTIVITIES SUBJECT TO HIPAA?** – Peer review conducted through the proper channels falls into the exception for "health care operations." But common pitfalls (see reverse) exist that may expose physicians to HIPAA liability, so be cautious whenever transmitting PHI to any third party.

9. **WHAT PENALTIES EXIST FOR HIPAA VIOLATIONS?** – Criminal/civil penalties include fines ($100 to $50,000) and prison terms (1 year to 10 years). Intent is considered.

10. **USE GOVERNMENT RESOURCES FOR COMPLIANCE** – Find sample BAA contract language, notices of privacy practices, security compliance guidance, mobile device security compliance, and more by exploring the HHS’s web site.

For additional tips visit The Doctor’s Advocate blog, www.doctor-advocate.com.
AVOIDING COMMON HIPAA PITFALLS: TOP 10 TIPS

1. **BE AWARE THAT PHI IS EVERYWHERE** – PHI’s incredibly broad definition (see reverse, Tip No. 1) includes many common identifiers such as name, address, birth date, and social security number if they can be associated with health data content, which is usually the case in a health care environment.

2. **REVIEW OF ANOTHER PHYSICIAN’S PATIENT, REQUESTED OR NOT** – Collegiality is not an exception under HIPAA. Except in formally conducted peer review or quality assurance meetings, be very careful when another physician requests that you review PHI. Unless you are a treating or consulting physician for that patient (and the medical record reflects that status) do not access PHI.

3. **ACCESSING PHI WHEN NOT TREATING PATIENT** – As a physician, you may find yourself in health care environments (whether physically or virtually) in which you are not treating a patient. Medical records systems may contain PHI for patients that are not yours. You may be present in a health care facility where you do not have clinical privileges. Be aware that these situations pose risk and avoid them.

4. **DON’T DO IT BECAUSE OTHERS DID IT** – HIPAA implementation is far from perfect. As a physician, make sure you are safeguarding PHI of your patients and not accessing PHI of patients that are not yours, even if others do so, as that will not provide you a defense.

5. **AUDIO OR VIDEO RECORDING OF EVENTS** – While it may not be illegal in your state to record a conversation over the phone or in person if you are a party to it (check state law), surreptitious audio or video recording in health care environments should be absolutely avoided.

6. **USE APPROPRIATE LOCKS AND SAFEGUARDS** – Whether PHI is in electronic form or hard copy, it must be secured pursuant to HIPAA’s specific requirements. Hard copies should be locked in a file cabinet or desk drawer in a locked office while unencrypted electronic information should be password protected and properly safeguarded with firewalls. HIPAA compliant policies and procedures must be observed at all times.

7. **MOBILE DEVICES POSE SPECIAL RISK** – Physicians should strictly observe certain protocols (see www.healthit.gov/mobiledevices) with any mobile devices that contain PHI, including maintaining physical control at all times, using encryption and passwords, installing firewall and remote disabling software, using adequate security when using public Wi-Fi networks, and deleting all PHI before discarding any device.

8. **FORWARDING PHI FOR BUSINESS, LEGAL, OR ANY REASONS** – Attorneys, accountants, and business advisors are business associates (see reverse, Tip No. 3). If you forward PHI in any form, you must sign an appropriate BAA with them and comply with it. Also, unless an employee, any third-party/vendor who has access to PHI is a business associate, including copy services, experts, storage facilities, and other third parties. Janitorial services that “incidentally” have contact with PHI do not require a BAA.

9. **FORMAL HEALTH CARE OPERATIONS (INCLUDING PEER REVIEW) ARE EXEMPTED** – But a physician must operate within these formal channels and privileges by complying with all policies and procedures, and not outside of them. If you are the subject of the peer review, get the advice of a health care attorney to make sure you are able to defend yourself without violating HIPAA.

10. **DON’T BE A TARGET** – HIPAA violations have now become the focus of many health care entities, especially given visible public enforcement efforts and current technology that makes them easier to prove. Avoid even the appearance of HIPAA a violation and consult with a health care attorney if any issues arise.

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Copyright © 2014 Kane Russell Coleman & Logan PC. All rights reserved. This information is not, nor is it intended to be, legal advice. You should consult an attorney for individual advice regarding your own situation.
Whether you use a personally owned mobile device or one provided to you by an entity such as a health care organization, system, or medical or private practice, you should understand how to protect health information.

Follow these tips to help you secure the health information your patients entrust to you:

1. **Install and enable encryption to protect health information stored or sent by mobile devices.**
2. **Use a password or other user authentication.**
3. **Install and activate wiping and/or remote disabling to erase the data on your mobile device if it is lost or stolen.**
4. **Disable and do not install or use file-sharing applications.**
5. **Install and enable a firewall to block unauthorized access.**
6. **Install and enable security software to protect against malicious applications, viruses, spyware, and malware-based attacks.**
7. **Keep your security software up to date.**
8. **Research mobile applications (apps) before downloading.**
9. **Maintain physical control of your mobile device. Know where it is at all times to limit the risk of unauthorized use.**
10. **Use adequate security to send or receive health information over public Wi-Fi networks.**
11. **Delete all stored health information on your mobile device before discarding it.**

**Mobile Devices: Know the RISKS. Take the STEPS.**

**PROTECT & SECURE Health Information.**

Find out more at HealthIT.gov/mobiledevices
Transhumanism  
and  
the Future of  
Law and Medicine

Sander Rabin MD JD  
The Center for Transhuman Jurisprudence, Inc.  
The Future of our Minds, Bodies, and Genomes  
legal sheet  
Fifty-Fifth Annual Meeting  
American College of Legal Medicine  
27 February 2015

What is …?

Where are we headed?

What is human enhancement?

What are the politics of human enhancement?

What’s at the heart of the conflict?

The Two Cultures  
in the 21st Century
What exactly is playing God?

Is there an Archimedian point?

What is transhuman jurisprudence?

What is transhuman medicine?

What’s at stake?

Who gets to wear the prosopon?
Programmable Legal Capacity and Competence

What are the ends of medicine?

What are the legal options?

What are the medical options?

What are we up to?

A First World Summit on Human Enhancement
Enabling Technology
economic #heet

Coming in 2016
http://www.tranhumanjuris.com
@transhumanjuris
STEWART REUTER LECTURE

INTENT AND CONSEQUENCES: WHAT TO MAKE OF SO-CALLED “UNINTENDED CONSEQUENCES” IN HEALTH CARE LAW AND POLICY

FRIDAY, FEBRUARY 27, 11:00 AM - 11:45 AM

Brera 1

SPEAKER:

Henry Butler, JD, PhD, George Mason University Foundation Professor of Law and Executive Director, Law & Economics Center, George Mason University School of Law
GENERAL SESSION III
FEDERAL REGULATION OF HEALTHCARE

FRIDAY, FEBRUARY 27, 1:00PM - 2:20PM

Brera 4-5

MODERATOR:
Paul Blaylock, MD, JD, FCLM
GENERAL SESSION IV
STATE REGULATION OF HEALTHCARE

FRIDAY, FEBRUARY 27, 2:45PM - 4:45PM

Brera 4-5

MODERATOR:
Mary Jean Wall, MD, JD, FCLM, President, North Central Radiology and Imaging, Bellevue, Ohio; Lead Nuclear Physician, Healthspan, Cleveland, Ohio; President, Ohio State Medical Association
Public Health Updates in Light of Ebola and Public Health Police Powers Circumscribed by Due Process

2013 ACLM 55th Annual Meeting
February 27, 2015
General Session IV 2:45pm – 4:45pm

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Chief Deputy Commissioner of Health Services, Suffolk County, NY

Definitions
- Quarantine is the restriction of persons who are presumed to have been exposed to a contagious disease but are not ill.
- Isolation is the separation of ill persons with contagious diseases.
- Cordon Sanitaire (Community-wide quarantine) refers to closing of community borders or the erection of a real or virtual barrier around a geographical area.


Isolation & Quarantine Authority
- Federal and State authority coexist
- Sometimes this may cause confusion

Federal: Isolation & Quarantine Authority
- Federal quarantine and isolation authority derives from the Commerce Clause of the U.S. Constitution, which states that Congress shall have the power “[t]o regulate Commerce with foreign Nations, and among the several states.”
- Section 361 of the Public Health Service Act

2. U.S. Code art. i, § 8, cl.2

Section 361 of the Public Health Service Act
- Grants the Secretary of Health and Human Services the authority to make and enforce regulations necessary “to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.”

Exec. Order No. 13295
- The diseases currently listed are:
  - Cholera
  - Diphtheria
  - Infectious tuberculosis
  - Plague
  - Smallpox
  - Yellow fever
  - Viral hemorrhagic fevers (including EBOLA)
  - Severe acute respiratory syndrome (SARS)
  - Influenza viruses which have the potential to cause a pandemic.
Transfer of Authority to the CDC

• In 2000, the Secretary transferred certain authorities related to persons, including quarantine authority, to the Director of the CDC.
• Both interstate and foreign quarantine measures are now carried out by CDC’s Division of Global Migration and Quarantine.3

3. See CDC Division of Global Migration and Quarantine home page at http://www.cdc.gov/npid/dqm/q/index.html

CDC: Federal Authority

• Federal regulations authorizing the apprehension, detention, examination, or conditional release of individuals are applicable only to:
  • Individuals coming into a state or possession from a foreign country or possession
  • In addition, Section 361 of the PHS Act authorizes the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a “qualifying stage” and
  • To be moving or about to move from a State to another State; or
  • To be a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State.4


“Qualifying Stage”

• “Qualifying stage” means that such a disease is
  • In a communicable stage or
  • In a precommunicable state, if the disease would likely cause a public health emergency if transmitted to other individuals.5

5. 42 U.S.C. § 264(d).6

U.S. Quarantine Stations

• U.S. Quarantine Stations are part of a comprehensive system that serves to limit the introduction and spread of contagious diseases in the United States. U.S. Quarantine Stations are located at 20 ports of entry and land-border crossings where international travelers arrive.
• They are staffed with medical and public health officers from the Centers for Disease Control and Prevention (CDC) and managed by CDC’s Division of Global Migration and Quarantine. These health officers decide whether ill persons can enter the United States and what measures should be taken to prevent the spread of contagious diseases.

Map of U.S. Quarantine Stations

U.S. Airports

• “We share the genuine concern over the fact that our borders are not impervious to infectious disease, in spite of the best efforts of the CDC and DHHS and its components. Unless draconian health screening techniques are routinely implemented at each port of entry as a standard operating procedure for the millions of people crossing the border, there will always be opportunities for people who are ill to cross our borders undetected.”7


State Police Powers & Quarantine Authority

- The federal government has authority to authorize quarantine and isolation under certain circumstances; however the primary authority for quarantine and isolation exists at the state level as an exercise of the state’s police power.
- Every state has the authority to pass and enforce quarantine laws as an exercise of its police powers, these laws vary widely by state.
- State and local quarantines are authorized through public health orders, though some states may require a court order before an individual is detained.

Court Order Model

- In Louisiana, the state health officer is not authorized to “confine [a person] in any institution unless directed or authorized to do so by the judge of the parish in which the person is located.”

State Health Department Model

- Some statutes only address a single disease.
- In some states, the State Health Department is granted the authority to decide which diseases are communicable and therefore subject to quarantine.

State Quarantine Laws

- A common element is antiquity among these laws.
- A complete list of State quarantine and isolation statutes and where the power resides within the State may be found at [http://www.ncsl.org/research/health/state-statutes.aspx](http://www.ncsl.org/research/health/state-statutes.aspx)

Examples of State Public Health Police Powers via Statues (1)

- **California**
  - Each health officer knowing or having reason to believe that any case of the diseases made reportable by regulation of the department, or any other contagious, infectious or communicable disease exists, or has recently existed, within the territory under his or her jurisdiction, shall take measures as may be necessary to prevent the spread of the disease or occurrence of additional cases. Cal. [Health & Safety] Code § 120175 (Deering 2009).
- **Maryland**
  - The order of the [health official] or the health officer may also contain such other conditions as the [health official] or the health officer believes are necessary to protect either the health of the infected individual or the public health. Md. Code Ann., Health-Gen. § 18-314 (LexisNexis 2009).
Examples of State Public Health Police Powers via Statues (2)

- D.C.
  - Each and every provision of this subchapter shall be construed liberally in aid of the powers vested in the public authorities looking to the protection of the public health, comfort, and welfare and not by way of limitation. D.C. Code § 7-144 (2009).
  - Vermont
  - (TB control statutory provisions) of this title are in addition to any other statutes relating to communicable diseases generally or to tuberculosis specifically and shall not abrogate or repeal those other statutes unless in direct conflict therewith, in which case the provisions of such sections shall control. Vt. Stat. Ann. tit. 18, § 1061 (2009).

Examples of State Public Health Police Powers to Isolate (1)

- California:
  - An order for isolation of persons with infectious tuberculosis disease to their place of residence until the health officer has determined that they no longer have infectious tuberculosis disease. Cal. (Health & Safety) Code § 121365 (Deering 2009).

- New Jersey:
  - If the location of commitment is a private residence, law enforcement may use an electronic device to monitor adherence to the commitment order. N.J. Admin. Code § 8:57-5.11 (2009).

Examples of State Public Health Police Powers to Isolate (2)

- Colorado:
  - In a case of a person with multidrug-resistant tuberculosis, the health officer may issue an isolation order to such person if it is determined that the person has ceased taking prescribed medications against medical advice. Such order may be issued even if the person is no longer contagious so long as the person has not completed an entire course of therapy. Colo. Rev. Stat. § 25-4-507 (2009).

- Maryland:
  - A health officer may require an individual having tuberculosis in a noncommunicable stage to be under medical supervision, which may include physical isolation from others, if the individual refuses to receive adequate chemotherapy. Md. Code Regs. 10.06.01.21 (2009).

- Massachusetts:
  - Minimum period of isolation of patient – pulmonary tuberculosis (also includes mediastinal, laryngeal, pleural, or miliary). Until bacteriologically negative based on three appropriately collected and processed sputum smears that are collected in eight – 24 hour intervals (one of which should be an early morning specimen), and/or until 14 days after the initiation of appropriate effective chemotherapy, provided therapy is continued as prescribed, and there is demonstration of clinical improvement (i.e., decreasing cough, reduced fever, resolving lung infiltrates, or AFB smears showing decreasing numbers of organisms). 105 Mass. Code Regs. § 300.200 (2009).

Legal Challenges to Quarantine Authority

- Dormant Commerce Clause Challenges
- Due Process Challenges
- Auxiliary Potential Challenges

Dormant Commerce Clause Challenges

- Gibbons v. Ogden, 22 U.S. 1, 18 (1824).
Due Process Challenges

- People ex rel. Barmore v. Robertson, 134 N.E. 815, 817 (citations omitted) (Ill.1922); see also Zemel v. Rusk, 381 U.S. 1, 15 (1965)
- Miller v. Campbell, 945 F.2d 348 (10th Cir. 1991)
- People ex rel. Barmore v. Robertson, 134 N.E. 815 (Ill.1922).
Vaccines: Legal and Regulatory Aspects of Development and Deployment

Dr. Jack Snyder
American College of Legal Medicine
February 27, 2015

Acts & Regulations Pertinent to Vaccine Development

- Public Health Service Act (42 USC 262-63) §351
- Food, Drug, and Cosmetic Act (21 USC 301-392)
- Title 21 CFR
  - 21 CFR 600-680: biological product standards
  - 21 CFR 312: investigational new drug application
  - 21 CFR 201-211: good manufacturing practices
  - 21 CFR 50: protection of human subjects

Selected FDA and ICH Guidance

- Manufacturing, product testing, and CGMPs
  - FDA guidance for industry: characterization and qualification of cell substrates and other biological starting materials used in the production of viral vaccines for the prevention and treatment of infectious diseases
  - FDA guidance for industry: development of preventive HIV vaccines for use in pediatric populations
  - FDA guidance for industry: considerations for plasmid DNA vaccines for infectious disease indications
  - FDA guidance for industry: content and format of chemistry, manufacturing and controls information and establishment description information for a vaccine or related product
  - ICH Q3A pharmaceutical quality system
  - FDA draft guidance: process validation—general principles and practices

Lot Release Testing

- Sterility, purity: detects the presence of bacterial or fungal contaminants
- Identity test: verifies that a product induces specific antibodies after vaccination (conducted in small animal models)
- Potency: verifies immunogenicity, antigen content, or chemical composition (in vivo or in vitro)
- Purity: verifies freedom from extraneous materials
- Tests for removal of process contaminants
- Pyrogenicity: detects the presence of fever-inducing substances

Recent CBER Accomplishments

- Approved five seasonal influenza vaccines in 2012 and 2013. The approach include three quadrivalent vaccines, which increase the likelihood of adequate protection against circulating influenza B strains, and the first two targeting technologies offering the potential for faster start-up of the vaccine manufacturing process.
- Continued to optimize the vaccine review and licensing process to help approve or expand indications for many important safe and effective vaccines in recent years such as the Pneumovax 23, Synflorix, Afluria, Adacel, Adenovirus Type 4 and Type 7 vaccine, Menactra, Menveo, and Zostavax.
- November 2012 Advisory Committee met to discuss and make recommendations on the safety and immunogenicity of Q-Pan H5N1, a monovalent adjuvanted pandemic influenza vaccine.
- Published research in a peer reviewed publication about baboons providing an excellent model of clinical pertussis. This model allows researchers to investigate how Bordetella pertussis bacterial disease, spread in a population, and how immunity develops. This research can help inform the development of new pertussis vaccines.
- Obtained redesignation in February 2012 as a WHO Collaborating Center for Biological Standardization and served as a reference National Regulatory Authority for eight prequalified vaccines.
FDA regulatory review process


- Placebo use in vaccine trials: Recommendations of a WHO expert panel
  - Vaccines are among the most cost-effective interventions against infectious diseases. Many candidate vaccines targeting neglected diseases in low- and middle-income countries are now progressing to large-scale clinical testing. However, controversy surrounds the appropriate design of vaccine trials and, in particular, the use of unvaccinated controls (with or without placebo) when an efficacious vaccine already exists. This paper specifies four situations in which placebo use may be acceptable, provided that the study question cannot be answered in an active-controlled trial design; the risks of delaying or foregoing an efficacious vaccine are mitigated; the risks of using a placebo control are justified by the social and public health value of the research; and the research is responsive to local health needs. The four situations are: (1) developing a locally affordable vaccine, (2) evaluating the local safety and efficacy of an existing vaccine, (3) testing a new vaccine when an existing vaccine is considered inappropriate for local use (e.g. based on epidemiologic or demographic factors), and (4) determining the local burden of disease.

CAUSATION ANALYSIS


- Assessment of causality of individual adverse events following immunization (AEFI): a WHO tool for global use.
- Serious illnesses or even deaths may rarely occur after childhood vaccinations. Public health programs are faced with great challenges to establish if the events presenting after the administration of a vaccine are due to other conditions, and hence a coincidental presentation, rather than caused by the administered vaccines. Given its priority, the Global Advisory Committee for Vaccine Safety (GACVS) commissioned a group of experts to review the previously published World Health Organization (WHO) Adverse Event Following Immunization (AEFI) causality assessment methodology and aide-memoire, and to develop a standardized and user-friendly tool to assist health care personnel in the processing and interpretation of data on individual events, and to assess the causality after AEFIs.


- We describe a tool developed for causality assessment of individual AEFIs that includes: (a) an eligibility component for the assessment that reviews the diagnosis associated with the event and identifies the administered vaccines; (b) a checklist that systematically guides users to gather available information to feed a decision algorithm; and (c) a decision support algorithm that assists the assessors to come to a classification of the individual AEFI. Final classification generated by the process includes four categories in which the event is either: (1) consistent; (2) inconsistent; or (3) indeterminate with respect of causal association; or (4) unclassifiable. Subcategories are identified to assist assessors in resulting public health decisions that can be used for action. This proposed tool should support the classification of AEFI cases in a standardized, transparent manner and to collect essential information during AEFI investigation. The algorithm should provide countries and health officials at the global level with an instrument to respond to vaccine safety alerts, and support the education, research and policy decisions on immunization safety.
Vaccine. 2012 Aug 24;30(39):5791-8

- Algorithm to assess causality after individual adverse events following immunizations.

Assessing individual reports of adverse events following immunizations (AEFI) can be challenging. Most published reviews are based on expert opinions, but the methods and logic used to arrive at these opinions are neither well described nor understood by many health care providers and scientists. We developed a standardized algorithm to assist in collecting and interpreting data, and to help assess causality after individual AEFI. An algorithm can assist with addressing these questions in a standardized, transparent manner which can be tracked and reassessed if additional information becomes available. Examples in this document illustrate the process of using the algorithm to determine causality. As new epidemiologic and clinical data become available, the algorithm and guidelines will need to be modified. Feedback from users of the algorithm will be invaluable in this process. We hope that this algorithm approach can assist with educational efforts to improve the collection of key information on AEFI and provide a platform for teaching about causality assessment.

Brighton Collaboration – Vaccine Safety Objectives

- Setting Standards
- Clinical Assessment
- Data Linkage
- Capacity Building
- Addressing Public Concerns

Brighton Collaboration to Classify Vaccine Reactions

- Categories included:
  - Very likely
  - Probable
  - Possible
  - Unlikely
  - Unrelated
- Unclassifiable, based on temporal criteria and evidence of alternate etiological explanation
- Deaths occurring soon after vaccination w/o alternate explanation were classified as “probably related to vaccine.”

Post-Approval Vaccine Safety Activities

- Phase IV Trials
  - 10,000 participants
  - Improving but still limited
- Large-Linked Databases (population-based)
  - VAERS
  - VSD (9.2M MCO enrollees, 3% of U.S. population)
- Clinical Immunization Safety Assessment Network (evaluates individuals)
- Brighton Collaboration

Tort Liability of Parents for Refusing to Vaccinate Their Children?

- No
  - “Best interests of the child” prevails over “community benefit”
  - “Parental right to refuse” (instinct, self-interest)
  - Waivers or exemptions (as legal defenses)
  - Literature questioning effectiveness of immunization (CDC and others)
  - # of lives saved is unknown and unknowable
  - Lack of tests to identify who infected whom
Tort Liability of Parents for Refusing to Vaccinate Their Children?

• Yes
  – Can offer proof of duty (to avoid harm to others), breach, causation, harm (to individuals & society)
  – Herd Immunity needed to protect:
    a) Persons yet to be vaccinated (< 1 y.o.)
    b) Persons who must remain unvaccinated (contraindications, allergies, medical conditions)
    c) Persons who remain or become susceptible despite vaccination
  – No parental duty for persons in groups a, b, and c above

Tort Liability – Possible Role of Public Nuisance Litigation?

• Public Nuisance Claims (under § 821C of Restatement of Torts)
  – Agency files suit to prevent conduct harmful to public (e.g., failure of herd immunity)
  – Person files suit to show conduct substantially interferes with right common to public and person suffers harm different in type or quality from that suffered by other members of public
  – Class rep or person with standing files federal or state “citizen suit”
  – “Prospective nuisance” claim can seek injunction or order of abatement

There’s Gotta Be a Better Way?
There Oughta Be Law?
There Oughta Be a Federal Law?

The National Childhood Vaccine Injury Act (NCVIA)

• Establishes the National Vaccine Injury Compensation Program for adults and children who receive covered vaccines
• Finances compensation for vaccine injury by an excise tax on vaccines
• Provides administrative no-fault compensation for claimants with any injury included in its injury table

The National Childhood Vaccine Injury Act (NCVIA)

• Bars state actions against vaccine makers for injuries that were “unavoidable” even though the vaccine was properly prepared and accompanied by proper directions and warnings
• Prohibits liability by a vaccine maker solely for failing to provide direct warnings to the injured party
• Establishes the Advisory Commission on Childhood Vaccines
Bruesewitz v. Wyeth
131 S.Ct. 1068 (2011)
• Vaccine “design defect” claim preempted by NCVIA (unlike Wyeth v. Levine, where SCOTUS held federal law did not preempt state court actions over drug safety)
• Vaccines are unlike drugs because widely given to healthy children & market less stable
• SCOTUS worried about flood of testimony on a “universe of alternate designs...limited only by an expert’s imagination...” even if FDA usually doesn’t consider whether a safer product design exists when deciding on market approval or retention

“Unavoidable” – The Problem of Textual Ambiguity in the NCVIA §22(b)(1)
• Federal law preempts vaccine claims “if the injury or death resulted from side effects that were UNAVOIDABLE even though [subordinating conjunction!] the vaccine was properly prepared and was accompanied by proper directions and warnings.”
• Conclusion of inherent UNAVOIDABILITY has been “categorically” determined by Congress if (and therefore because) conditions of proper preparation, directions and warnings are shown (a legal truth [not absolute truth] is deemed sufficient here

Holmes v. Merck & Co., 697 F.3d 1080 (9th Cir. 2012) (No. 08-16557)
• Appeal from SJ for vaccine manufacturer on claims brought by parents of child who died after receiving a vaccine
• Trial court held that the parents’ state law negligence and strict liability design-defect and failure-to-warn claims were preempted by the Vaccine Act, and 9th Circuit agreed
• NCVIA requires claims of individuals who receive vaccine to go to Vaccine Court
• Plaintiffs argued that since they did not receive the vaccine, the preemptive sections of NCVIA did not apply to their state law claims

Holmes v. Merck & Co., 697 F.3d 1080 (9th Cir. 2012) (No. 08-16557)
• 9th Cir. held NCVIA expressly preempts all state law design-defect and failure-to-warn claims seeking compensation for injury or death caused by a vaccine’s unavoidable side effects, including claims brought by parties who did not receive the vaccine...
• “[I]f we were to conclude that the parents of those suffering a vaccine-related injury could bring design defect and failure to warn claims outside of [preemptive] limitations, we would be acting contrary to the statute’s central purpose of managing vaccine manufacturers’ liability because our construction would do little to protect the vaccine manufacturers from suit.”

The Public Readiness and Emergency Preparedness Act (PREP Act)
• Provides immunity except for “willful misconduct” to the United States, manufacturers, distributors, program planners, and those who administer “covered countermeasures” when the Secretary of DHHS issues an emergency declaration
• Defines “covered countermeasures” to include a qualified epidemic or pandemic product or drug, biologic products, and devices authorized for emergency use

The Public Readiness and Emergency Preparedness Act (PREP Act)
• Creates an exclusive and limited cause of action in federal court for injuries alleged to be caused by willful misconduct
• Bars judicial review of claims to the compensation fund
• Permits claimants for injury by a covered countermeasure to seek compensation from a fund administered by Health Resources and Services Administration
NVICP Statistics (1989-2011)

Alleged Problems with VICP

- LACK OF JUDICIAL INDEPENDENCE
- LACK OF EQUALITY BETWEEN THE GOVERNMENT AND PETITIONERS
- LACK OF ADEQUATE ACCESS TO EXISTING SCIENCE
- ABSENCE of ESSENTIAL SCIENCE
- LACK OF TRANSPARENCY AND THE PERCEPTION OF ARBITRARINESS

Alleged Problems with VICP

- LACK of DISCOVERY
- LACK of ADEQUATE PROCEDURAL SAFEGUARDS
- GOVERNMENT'S LACK of BURDEN TO PROVE CAUSATION
- LACK of a JURY of PEERS
- INAPPROPRIATELY SHORT STATUTE of LIMITATIONS

Vaccination Rates in U.S.A.

- Rates ≥ 90% for nearly all recommended pediatric vaccines attributed to:
  - Gov't. programs vaccinate uninsured or underinsured children
  - Requirements for attendance in public schools and in state-licensed day care programs

- Immunization Information Systems

• Immunization information systems (IIS) are confidential, computerized, population-based systems that collect and consolidate vaccination data from vaccination providers that can be used in designing and sustaining effective immunization strategies. To monitor progress toward achieving IIS program goals, CDC annually surveys immunization program grantees using the IIS Annual Report (IISAR). Results from the 2012 IISAR, completed by 54 of 56 grantees, indicate that 86% (19.5 million) of U.S. children aged <6 years, and 25% (57.8 million) of U.S. adults participated in IIS. Eight of 12 minimum functional standards for IIS published by the National Vaccine Advisory Committee (NVAC) have been met by ≥90% of grantees.


• Context: Immunization Information Systems (IIS), or registries, were developed to improve effectiveness and efficiency in immunization services. Complex laws that govern IIS and immunization records are developed at the state-level, interact with each other, and may impact utility for all immunization stakeholders. As states develop Health Information Exchange laws they may also interact with IIS laws.

• Objectives: To provide immunization stakeholders an overview of the laws applicable to healthcare providers and health departments. Comparisons are provided to illustrate the trends since the previous studies.

• Methods: IIS relevant statutes, regulations and ordinances of jurisdictions (states, large cities) of 56 “Grantees” receiving funding under the 317b Public Health Service Act were identified via legal databases then systematically reviewed for authorization, reporting and consent requirements. Key provisions were coded and mapped according to 131 variables.

• Results: Including subsections, 984 laws across Grantees relate to immunization records, falling under many administrative sections of state and city government. Most Grantees have more than one law that addresses immunization records reporting, exchange and privacy protections. Not all of these laws are in alignment, but there is a trend toward increased Grantor IIS authorizing laws, mandated reporting and implied consent provisions. Of the 56 Grantees, 37 (66%) had IIS authorizing laws, and 46 (82%) had laws addressing healthcare provider and vital statistics reporting. However, much variation remains, even within the provisions of these laws. The coding instrument received 93.7% agreement and a K-α of 0.791.

• Conclusions: The trend toward laws that encourage participation should continue to improve functionality and value, but inconsistencies among laws should be addressed, both across jurisdictions within states and between different states. They may impair the value of the information that is collected. Greater uniformity could improve the overall usefulness of IIS.
Love them. Protect them. **Never inject them.**

There are NO safe vaccines!

Shaken Baby Syndrome
Chronic Ear Infections
Death
SIDS
Seizures
ADD
Asthma
Arthritis
Asthma
Diabetes
Meningitis
and polio are caused by adverse reactions to vaccine poisons.

Go to: VaccineTruth.com
or call Vaccination Liberation: 1-888-249-1421

http://shotofprevention.com/2014/03/04/rights-of-the-unvaccinated-child-vaccinating-over-the-parents-will/

Anti-Vaccination Providers

The International Medical Council on Vaccination
in an association of medical doctors, registered nurses and other qualified medical professionals whose purpose is to COUNTER the messages asserted by pharmaceutical companies, the government and medical agencies that vaccines are safe, effective and necessary. Our conclusions have been reached individually by each member of the Council, after thousands of hours of personal research, study and observation.
**Anti-Vaccination Tactics**  
*Vaccine 2012;30:3778-3789*

- **Skewing the science:** Denigrating and rejecting science that fails to support anti-vaccine positions; endorsing poorly conducted studies that promote anti-vaccine agendas.
- **Shifting hypotheses:** Continually proposing new theories for vaccines causing harm, moving targets when evidence fails to support such ideas.
- **Censorship:** Supressing dissenting opinions; shutting down critics.
- **Attacking the opposition:** Attacking critics, via both personal insults and filing legal actions.

**Anti-Vaccination Catch Phrases**  
*Vaccine 2012;30:3778-3789*

- **I’m not anti-vaccine, I’m pro-safe vaccines**
- **Vaccines are toxic**
- **Vaccines should be 100% safe**
- **You can’t prove vaccines are safe**
- **Vaccines didn’t save us**
- **Vaccines are unnatural**
- **Choosing between diseases and vaccine injuries**
- **Galileo was persecuted, too**

**Anti-Vaccination Catch Phrases**  
*Vaccine 2012;30:3778-3789*

- **Science was wrong before** You’re in the pocket of Big Pharma
- **So many people can’t all be wrong** I don’t believe in coincidences
- **Skeptics believe....** I’m an expert on my own child

**Hum Vaccin Immunother. Aug 1, 2013; 9(8): 1755–1762.**

**Hum Vaccin Immunother. Aug 1, 2013; 9(8): 1763–1773.**
Pro-Vaccination Providers

Vaccine Safety and Benjamin Franklin

- Benjamin Franklin, persuaded by his brother, was opposed to smallpox vaccine until scientific data convinced him otherwise. Tragically, he had delayed inoculating his favorite son Franky, who contracted smallpox and died at the age of 4, leaving Ben with a lifetime of guilt and remorse.

Quoting Mr. Franklin’s autobiography:

“In 1736, I lost one of my sons, a fine boy of four years old, by the smallpox...I long regretted bitterly, and still regret that I had not given it to him by inoculation. This I mention for the sake of parents who omit that operation, on the supposition that they should never forgive themselves if a child died under it, my example showing that the regret may be the same either way, and that, therefore, the safer should be chosen.”


- Addressing the anti-vaccination movement and the role of HCWs. Tafuri S, et al.

- The main theoretical structures of anti-vaccination ideology in the 19th and 20th centuries are:
  - Vaccines cause idiopathic illness;
  - Opponents against vaccines accused vaccine partisans to be afraid of the "search after truth," they fear unveiling errors;
  - Vaccination laws not only insult every subject of the realm, but also insults every human being;
  - Vaccine immunity is temporary;
  - An alternative healthy lifestyle, personal hygiene and diet stop diseases.


- Proponents against vaccination now have additional means to communicate their positions to the general public, the Internet in particular. Doctors and HCWs constantly have to face parents and patients who search information about vaccination. A lot of these people have previously found data about vaccinations from a lot of sources, such as papers, media or in websites and in these sources most contents come from anti-vaccine movements. For these reasons doctors and HCWs need to have updated knowledge about the vaccinations and to know the contents proposed by vaccine sceptics. Educating the general public cannot be fully effective unless there is a corresponding provision, enthusiasm and commitment by trained HCWs.

EXEMPTION from VACCINATION

We argue that personal belief exemptions to the mandate for childhood immunizations should not be allowed. Parents who choose not to immunize their children put both their own children and other children at risk. Other children are at risk because unimmunized children go to school or day care when they are contagious but asymptomatic, exposing many more children to potentially dangerous infections. The risks to children from disease are much higher than the risks of vaccines. There are, of course, some bona fide reasons why children should not be immunized. Some children have known allergies or other medical contraindications to certain immunizations. Immunization refusals based on parental beliefs, however, do not fall into this category. In those cases, children are denied the protection of immunizations without any medical or scientific justification. By eliminating personal belief exemptions to those childhood vaccines associated with contagious diseases that have high rates of childhood mortality, we would better protect children and would more fairly spread the burdens of this important public health program.

Data on Belief Exemptions

More Data on Exemptions

Current Exemptions by State

Role of Health Care Professionals

- Providers can help to ensure the safety and efficacy of vaccines through proper:
  - Vaccine storage and administration
  - Timing and spacing of vaccine doses
  - Observation of contraindications and precautions
  - Management of vaccine side effects
  - Reporting of suspected side effects to VAERS
  - Vaccine benefit and risk communication
  - Opportunities for questions should be before each vaccination
  - Provision of Vaccine Information Statements (VISs) before each dose of vaccine (required of public and private providers; must be available in multiple languages)
How to Balance Individual Civil Liberties and State Police Powers?

- Medical Necessity v. Practical Necessity Model
  - No alternative v. some alternative to vaccination
  - Nature, communicability, consequences of disease
  - Clear and present danger to community
  - Target of vaccine must be necessary and sufficient to cause the preventable disease

- Level of Scrutiny of Religious Exemption Claim
  - Under Rational Basis (Emp’t. Div. v. Smith, 494 U.S. 872 (1990)), not survive since compulsory vaccine laws have rational basis
  - Under Strict Scrutiny (Sherbert v. Verner, 374 U.S. 398 (1963)), need compelling gov’t. interest to deny, so P tries a “hybrid-rights” claim

- Three responses to “hybrid rights claim”
  - Courts “refusal to recognize” claim
  - Court needs “independently viable” claim to accompany free exercise claim – but independence makes HC illogical
  - “Colorable claim” – “interdependent claims” – must join free exercise claim with colorable (likely success on the merits) claim for violation of another constitutional right

- “Medically necessary vaccinations” (viewed as necessary AND sufficient) but not “practically necessary vaccinations” (viewed as necessary but not sufficient) are likely to withstand strict scrutiny and will meet Jacobson “public necessity” standard to exercise police powers
  - Can argue that not all new vaccines will satisfy compelling gov’t interest test...so some constitutional analytical frameworks may continue to provide basis for allowing religious (and philosophical?) exemptions
GENERAL SESSION V
THE PEER REVIEW “DEBATE”

SATURDAY, FEBRUARY 28, 8:00AM - 8:55AM

Brera 4-5

MODERATOR:
Dale Cowan, MD, JD, FCLM, UH Parma Medical Center
DEFENDING MEDICARE AUDITS AND OVERPAYMENT IN THE UNITED STATES

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DEFENDING MEDICARE AUDITS AND OVERPAYMENT IN THE UNITED STATES

EXECUTION – MAJOR STEPS

1) Selecting the provider or supplier (MAC, RA, ZPIC);
2) Selecting the period to be reviewed;
3) Defining the universe, the sampling unit and the sampling frame;
4) Designing the sampling plan and selecting the sample;
5) Reviewing each of the sampling units and determining if there was an overpayment (the actual overpayment);
6) Estimating the overpayment for the defined universe and determining the demand amount.
7) Demand with statistical extrapolation made
8) Either payment by provider or appellate process
9) If payment not made, offset initiated on all claims paid

NOTICE OF OVERPAYMENT

PJM states that overpayment demand letter should include information about the review and statistical sampling that was followed:

Information about sampling methodology:
– Description of universe, frame, sample design;
– Sample selection procedures, numbers and definitions of strata and size of sample;
– Time period under review;
– Sample results, including overpayment estimation methodology and calculated sampling error as estimated from sample results;
– The amount of the actual overpayment from each of the claims reviewed.

THE ALPHABET SOUP OF PLAYERS

<table>
<thead>
<tr>
<th>Contractor</th>
<th>Claim Types</th>
<th>Claim Selection</th>
<th>Claim Volume</th>
<th>Purpose of Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORT</td>
<td>All claim types Medicare</td>
<td>Random</td>
<td>Small</td>
<td>Measure improper payment rate</td>
</tr>
<tr>
<td>PERM</td>
<td>All claim types for Medicaid</td>
<td>Random</td>
<td>Small</td>
<td>Measure improper payment rate</td>
</tr>
<tr>
<td>MAC (medical review department)</td>
<td>All claims with Medicare fee for service</td>
<td>Targeted</td>
<td>Depends on this fee and amount of improper payments</td>
<td>Prevent improper payments Provider/Education</td>
</tr>
<tr>
<td>RA (formerly RAC)</td>
<td>All claims with Medicare fee for service</td>
<td>Targeted</td>
<td>Depends on the magnitude of improper payments</td>
<td>Demand over payment Provider/Education</td>
</tr>
<tr>
<td>ZPIC</td>
<td>All claim types with Medicare fee for service</td>
<td>Targeted</td>
<td>Depends on the magnitude of improper payments</td>
<td>Demand over payment Provider/Education</td>
</tr>
</tbody>
</table>

MEDICARE, MEDICAID AND TRICARE

• Established in 1965 by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq.
• Reimbursement is governed by statute and by regulations issued by HHS
• Covers the elderly (>65 yrs), the disabled, renal failure and ALS patients
• Administered by private contractors in the states
• Medicaid covers the poor, many children (Title XIX)
• Administered by the Center for Medicare and Medicaid Services.
• TriCare covers the uniformed services and retirees
STATUTES OF LIMITATIONS

- Prior to 2013, for Medicare overpayments, the federal government and its carriers and intermediaries had 3 calendar years from the date of issuance of payment to recoup overpayment. This has been changed to 5 years based on provision in Taxpayer Relief Act of 2012.
- The Statute of Limitations does not apply to recovering overpayments made as result of false pretenses or fraud.

STATISTICAL EXTRAPOLATION

- *Chaves County Health Svcs. v. Sullivan*, 931 F.2d 914 (D.C. Cir.1991)

The Court finds that absent an explicit provision in the statute that requires individualized claim adjudications for overpayment assessments against providers, the private interest at stake is easily outweighed by the government interest in minimizing administrative burdens.

PREREQUISITES TO USING STATISTICAL EXTRAPOLATION

- 42 U.S.C. § 1395ddd(f)(3) (Section 1893(f)(3))
  A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset or otherwise unless the Secretary determines that -
  1) There is a sustained or high level of payment error; or
  2) Documented educational intervention has failed to correct the payment error.

MECHANISMS TO ATTACK ALLEGED OVERPAYMENT

(1) CLAIM VALIDATION:
  - CHALLENGE THE MEDICINE
  - CHALLENGE THE ADEQUACY OF THE MEDICAL RECORD DOCUMENTATION
(2) EXTRAPOLATION CHALLENGE:
  - CHALLENGE THE EVOCATION OF STATISTICAL EXTRAPOLATION
  - CHALLENGE THE STATISTICAL METHODOLOGY
(3) COMBINATION OF THE TWO

WHAT A PROVIDER SHOULD DO

- GET AN EXPERIENCED HEALTH LAWYER!!!!!!
- Administrative Appeals Process:
  - 42 C.F.R. Part 405 Subpart I:
    - Initial Determinations: Medicare overpayment determination and determination of liability
    - **STEP 1** - Redetermination: 42 C.F.R. § 405.940, 948:
      - Contractor independent review of the initial determination.
    - **STEP 2** - Reconsideration by a Qualified Independent Contractor (“QIC”): 42 C.F.R. § 405.904.
ADMINISTRATIVE APPEAL – STEP 3

- ALJ Hearing. 42 C.F.R. § 405.1000.
- In 2005, CMS amended its regulations to explicitly permit CMS or its contractor to participate or be a party to such proceeding where "input from CMS or a contractor will help resolve an issue in a case." 70 Fed. Reg. 11420, 11459 (Interim Final Rule) (Mar. 8, 2005).
- 42 C.F.R. § § 405.1010, 405.1012: participation/party status.
- The ALJ may not draw any adverse inferences if CMS or a contractor declines to participate or invoke party status. 42 C.F.R. § § 405.1010(f), 405.1012(d).

ADMINISTRATIVE APPEAL – STEP 4

- Departmental Appeals Board (Medicare Appeals Council)
- A party to the ALJ hearing may submit a request for review of the ALJ's decision by the DAB. 42 C.F.R. § § 405.1100, 405.1102.
- The DAB may on its own motion review the decision of the ALJ if the decision contains an error of law material to the outcome of the claim and is not supported by the preponderance of the evidence in the record pursuant to 42 C.F.R. § 405.1110.

STEP 4 (CONT.)

- CMS or its contractor may request that the DAB take on own motion review of a case if CMS or its contractor participated in the appeal at the ALJ level and in the CMS’s view, the ALJ's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ abused his or her discretion. 42 C.F.R. § 405.1110(b).
- CMS or any of its contractors may refer a case to the MAC if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. 1d.

JUDICIAL REVIEW

- Judicial Review
- A party has 60 days to request judicial review
- 42 C.F.R. § 405.1006(c)
- 42 U.S.C. § 405(g) – Secretary's findings of fact, if supported by substantial evidence, are conclusive.

AUDIT APPEAL PROCESS

<table>
<thead>
<tr>
<th>120 days</th>
<th>60 days</th>
<th>MAC, RA, ZPIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial-------------------&gt;Request for-------&gt;Redetermination Decision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Determination</td>
<td>Redetermination</td>
<td></td>
</tr>
<tr>
<td>(MSN or RA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>180 days</td>
<td>60 days</td>
<td>QIC</td>
</tr>
<tr>
<td>Unfavorable----------------&gt;Receipt of Reconsideration----------------&gt;Reconsideration Decision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Redetermination Request by QIC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>60 d to file</td>
<td>90 d</td>
<td>No timeframe ALJ</td>
</tr>
<tr>
<td>Reconsideration----------------&gt;Receipt of ALJ----------------&gt;OMHA-ALJ----------------&gt;Case forwarded Decision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Party Initiated 60 d to file 90 d timeframe ALJ Decision Accepts Referral to DAB Hearing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Party Initiated 60 d to file 90 d timeframe ALJ Decision Accepts Referral to DAB Hearing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

POST ALJ REVIEW

<table>
<thead>
<tr>
<th>AdQIC Initiated</th>
<th>10 d to complete</th>
<th>DAB Hearing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sent to DAB</td>
<td>Denies Referral</td>
<td>Effluxation to MAC</td>
</tr>
<tr>
<td>Decision no</td>
<td>30 d to effectuate</td>
<td></td>
</tr>
<tr>
<td>APPELLANT HAS 60 DAYS TO APPEAL TO FED DISTRICT COURT</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| 60 d to file | 90 d timeframe |
| ALJ Decision | DAB Decision |
| 60 d to file | 90 d timeframe |
| ALJ Decision | DAB Decision |
| APPELLANT HAS 60 DAYS TO APPEAL TO FED DISTRICT COURT |
### WAIVERS

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>§ 1870(b)</td>
<td>Rebuttable presumption that providers not liable for overpayments more than 3 (now 5) years after initial determination</td>
</tr>
<tr>
<td>§ 1870(c)</td>
<td>Waiver of recoupment of overpayments where no fault on behalf of provider, where would defeat purposes of Titles II and XVIII, and/or would be against equity and good conscience</td>
</tr>
<tr>
<td>§ 1135</td>
<td>Waiver of enforcement in event of national emergency</td>
</tr>
</tbody>
</table>

### CLAIM VALIDATION DEFENSES

- Medical Record documents alleged deficiency earlier in time
- Level of billing is justified based on earlier documentation
- That MAC or PSC incorrectly portion of the medical record allegedly deficient
- That documentation deficiency is de minimus

### SAMPLING BURDEN OF PROOF

- “CMS Rulings are published under the authority of the CMS Administrator. Consistent with §401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS...” 42 C.F.R. § 405.1063(b).
- CMS Ruling 86-1: the use of statistical sampling creates a presumption of validity as to the amount of an overpayment which may be used as a basis for recoupment. The burden then shifts to the provider. THIS IS A PRESUMPTION UNDER U.S. LAW

### ATTACKING EXTRAPOLATION

- Challenge Burden of Proof (statistical validity)
- Challenge Constitutional Due Process (no property interest in retained overpayments, notice includes solely opportunity to correct payer error)
- Lack of Threshold Determination (no notice requirement as to sustained or high level of payment error)
- Challenge Sample Size (no statistical sample size floor)
- Challenge Precision (no specific level of sampling precision required)
- Challenge Representativeness of Sample (sample does not have to correlate to whole population)

### ATTACKING EXTRAPOLATION

- Challenge Lack of Documentation (no minimum documentation requirement must be produced)
- Challenge Stratification (proportionately stratified design more accurate than random sampling of same size)
- Challenge Procedural Issues (no right to cross examine non-party, carrier need not appear)
- Challenge Waiver of Liability (Hurricane Katrina)
- Challenge Failure to Follow PIM (PIM is not a set of mandatory regulations)

### RECOMMENDATIONS

- Adhere to all appeal deadlines;
- Review the medical record in depth
- Make sure you have all documentation needed to recreate sampling methodology;
- Keep in mind the burden of proof - conclusory allegations are insufficient.
- Make sure your expert demonstrates how the lack of precision, representativeness, etc. prejudices the provider

HIRE AN ATTORNEY WHO'S EXPERIENCED
GENERAL SESSION VI
MEDICAL MALPRACTICE UPDATE

SATURDAY, FEBRUARY 28, 9:25AM - 10:20AM

Brera 4-5

MODERATOR:
Martin J. Stillman, MD JD ,FCLM, Hennepin County Medical Center
Fear of Malpractice and Defensive Medicine in the Emergency Department

Darren P. Mareiniss, MD, JD
Instructor
Department of Emergency Medicine
University of Maryland School of Medicine

The Emergency Department
- Emergency departments in US are stretched near capacity
- ACEP Data – decreasing number of EDs
  - 1997 the total number of EDs was 4,945
  - 2004 the total was 4,017 – decrease of 19%
- ED visits
  - 90.3 million ED visits in 1993
  - 113.9 million in 2003
  - 136 million in 2009 – increase of 50.6% in 16 years!!

2006 IOM Report; ACEP website; CDC report

The Emergency Department
- Challenging environment
- Incomplete information
- Continual flow of patients
- Pressure to see more patients efficiently
- Many interruptions
- Critical cares / traumas
- Safety net for US health care

Malpractice Risk in the ED

http://www.funnygreetings.net/html/Medical-Malpractice.html

ED-Based Malpractice Claims
- 11,529 closed claims reviewed from ED 1985-2007
- Insurer group – 60% physicians
- 19% of claims – Emergency Medicine physician as primary defendant
- Most common claims
  - Error in diagnosis – 37% (4,233)
  - No error identified – 18% (2,091)
  - Improperly performed procedure – 17% (1,935)

Brown et al. 2010
Causes of ED Claims

<table>
<thead>
<tr>
<th>Error</th>
<th>Closed Claims</th>
<th>% of Total</th>
<th>Paid Claims</th>
<th>% Paid</th>
<th>Total Indemnity</th>
<th>Average Indemnity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error identified by insurer</td>
<td>243</td>
<td>16</td>
<td>5</td>
<td>0</td>
<td>$13,820</td>
<td>$900</td>
</tr>
<tr>
<td>Emergency permissibility</td>
<td>229</td>
<td>17</td>
<td>4</td>
<td>0</td>
<td>$5,850</td>
<td>$250</td>
</tr>
<tr>
<td>Failure to diagnose or monitor a condition</td>
<td>445</td>
<td>32</td>
<td>11</td>
<td>0</td>
<td>$24,920</td>
<td>$1,036</td>
</tr>
<tr>
<td>Failure to perform</td>
<td>92</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>$12,920</td>
<td>$1,324</td>
</tr>
<tr>
<td>Medication errors</td>
<td>218</td>
<td>15</td>
<td>6</td>
<td>0</td>
<td>$15,020</td>
<td>$690</td>
</tr>
<tr>
<td>Failure or delay in admission to hospital</td>
<td>299</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>$59,540</td>
<td>$195</td>
</tr>
<tr>
<td>Failure or delay in diagnosis to patient</td>
<td>396</td>
<td>28</td>
<td>0</td>
<td>0</td>
<td>$132,660</td>
<td>$4,395</td>
</tr>
<tr>
<td>Treatment complications</td>
<td>758</td>
<td>52</td>
<td>0</td>
<td>0</td>
<td>$331,780</td>
<td>$4,426</td>
</tr>
<tr>
<td>Total</td>
<td>11,528</td>
<td>75</td>
<td>31</td>
<td>0</td>
<td>$2,831,280</td>
<td>$244,618</td>
</tr>
</tbody>
</table>

ED Malpractice Claims

- Most common pathology
  - 6% – fracture (vertebra, ulnar/radius, tib/fib)
  - 5% – AMI
  - 2% – appendicitis
- Outcome
  - 64% of cases dropped or dismissed
  - 29% closed with settlement
  - 6% verdict for defendant
  - 1% verdict for plaintiff

Claim Resolution Numbers

- Most claims dropped or dismissed
- Most frequent claim – missed diagnosis
- Acute myocardial infarction – highest paid ratio – 42%
  - Average indemnity $317,281 for chest pain – higher than most
  - Error in diagnosis in majority of claims for AMI

Risk by Specialty

- 40,916 physicians covered by a large nationwide insurer
- Reviewed claims made and payment by specialty
- 7.4% of all specialties sued per year; 1.6% paid
- 78% of claims did not result in payment
- Consistent with Brown et al. – 70%

Summary

- Most claims dropped or dismissed
- Most frequent claim – missed diagnosis
- Acute myocardial infarction – highest paid ratio – 42%
  - Average indemnity $317,281 for chest pain – higher than most
  - Error in diagnosis in majority of claims for AMI

Brown et al. 2010

Brown et al. 2010

Jena et al. 2011
Annual Risk of Suit by Specialty

- Neurosurgery – 19.1%
- Cardiothoracic Surgery – 18.9%
- General Surgery – 15.3%
- Family Medicine – 5.2%
- Pediatrics – 3.1%
- Psychiatry – 2.6%
- Emergency Medicine – around 7.5%

Malpractice Risk by Specialty

- 5 lowest-risk specialties – 75% expected to be sued by age 65; 19% to make indemnity payment
- For highest-risk specialties – 99% expect lawsuits by age 65; 71% will make payment

Defensive Medicine

- May 2003 survey – 824 PA physicians in high-risk fields:
  - Orthopedic Surgery
  - General Surgery
  - OB/GYN
  - Emergency Medicine
  - Radiology
- 93% of surveyed physicians sometimes or often engage in defensive medicine tactics
Defensive Medicine

- 92% of survey used Assurance Tactics
- 70% EM vs. 59% group “often order” more tests than indicated (P < .05)
- EM least likely to avoid high-risk patients – 13% vs. 32%
- Self identified areas of defensive medicine:
  - w/u for atypical chest pain
  - CT abd for unlikely appendicitis
  - CT head for minor trauma

Does Fear of Malpractice Correlate with Defensive Tactics?

- 1,134 patients with possible ACS
- 6-question survey
- Low (<15), mod (15-20), high (>20) litigation fear by answers
- Separate risk-taking survey – no significant correlation

Katz et al. 2005

Survey Questions

Results – Low Fear versus High

- 51% discharged vs 42.2% discharge OR .56 (CI, .4 to .9)
- Low-risk patient discharge – 80% vs 64% high fear group – OR .34 (CI, .12 to .99)
- Test troponin 74.3% vs 80.4% high fear group – OR 1.9 (CI, 1.2 to 2.9)
- Admission to tele – 51% vs 42%; OR 1.7 (CI, 1.2 to 2.4)

Summary

- Fear of litigation appeared to correlate with increased testing and number of admissions for ACS
- Limitation:
  - Small study only involving one institution
  - Potential benefit to increased testing not evaluated
  - Malpractice history of providers not evaluated

Waxman et al – NEJM October 2014

- Study 1997-2011 – 5% of Medicare patients randomly surveyed in acute care visits
- GA, TX and SC before and after enactment of gross negligence standard in the ED
- Compare – per visit expenditures, MRI/CT ordering and admissions
- Controlled with surrounding states – regression analysis
Comparison of GA, TX & SC – Before and After Malpractice Standard Reform

Results

• Compared to control states, malpractice reform was not associated with decreased CT or MRI utilization
• Admission rates were not affected
• In Georgia, reform was associated with 3.6% reduction in per visit charges (95% CI (.9 to 6.2); P=0.01)
• TX and SC had no reduction in per visit charges

Effects on Testing, Admissions & Total Charges in the ED

<table>
<thead>
<tr>
<th>Test</th>
<th>Total</th>
<th>GA</th>
<th>SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>1000</td>
<td>950</td>
<td>1050</td>
</tr>
<tr>
<td>MRI</td>
<td>200</td>
<td>190</td>
<td>210</td>
</tr>
</tbody>
</table>

Does This Mean That Defensive Medicine Doesn’t Really Exist?

form states do not believe that they are fully protected. This is true to some degree, but the
issue may be applied to any other low, for example, some have advocated for “safe harbor”
laws, which would provide specific protections to physicians who adhere to evidence-based
guidelines. If physicians do not believe that they are adequately protected by a legal
standard of gross negligence, then they also might not believe that they are protected by a
statute that provides a safe harbor for evidence-based guidelines. Indeed, a recent
study showed that evidence-based guidelines would be applicable to only a minority
of malpractice claims.

What...That’s the Argument?

Why Waxman Fails to Disprove Defensive Medicine

• ED physician surveys report engaging in defensive medicine
• Fear of malpractice may be linked to defensive practice
• Waxman does not show that legal protections diminished fear in GA, SC or TX or that providers are aware of the protections
• All that is shown is that malpractice reforms failed to decrease testing, admissions and costs in GA, SC and TX
• We do not know why (ignorance, persistent fear, habit?)
Summary

• ED is a challenging environment
• Risk of malpractice suit is high, but success rates are low
• Fear of malpractice may increase defensive practice
• Waxman does not appear to disprove defensive medicine
• Further research is needed

References


Example of Legal Ignorance

• If a lawyer can show that I breached the standard of care, I can be sued regardless of patient outcome
• True 23/38 – 60.5%
• False 15/38 – 39.5%
GENERAL SESSION VII
INNOVATORS AND ENTREPRENEURS IN LEGAL MEDICINE

SATURDAY, FEBRUARY 28, 10:45 - 11:45 AM

Brera 4-5

MODERATOR:
Monique Anawis, MD, JD, FCLM, Annual Meeting Co-Chair
Rapid Assessment of Entrepreneurial Ventures

Raymund C. King, MD, JD, FCLM

Law Offices of Raymund C. King, MD, JD, PLLC
Plano, Texas

2015 ACLM Annual Meeting – Las Vegas, NV
The Cosmopolitan Hotel
February 29, 2015

The Medical Economics

- The “Baby Boomer Effect” will increase healthcare demands in this country by 80% in the next 6 to 9 years
- The cost of running a medical practice is increasing 3X faster than Medicare is adjusting reimbursements to keep up with inflation
- Increases in medical revenue are actually due to increased patient volumes

To the Entrepreneur: Does your business make the world a better place?
Are you an Entrepreneur?

What Kind of Entrepreneur Are You?

Is There Market Validation for your Good or Service?
...and if so, who are your competitors?

Is There Technical Validation for your Good or Service?
...i.e., Can you actually do or accomplish what you say you’re going to do or accomplish?

Is Your Business Scalable?
...i.e., Can you deliver the same quality good or service to ten people as you can to ten thousand people, etc.?
War Stories...

• The investment banker and undercapitalization
• The retiring partner
• Purchasing a business from a retiring founder with potential health issues
• Purchasing a business from the widow of a deceased business owner

The Bottom Line

THE END

Raymund C. King, MD, JD
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(972) 381-2792
What is Innovation?

Innovation can be a bit tricky to classify. It is typically thought of as the creation of better or more effective products, processes, services, technologies or ideas.

However, although it is a concept related to creativity, invention, and improvement of existing systems or modes of thought, it can be subtly differentiated.

“Innovation differs from invention in that innovation refers to the use of better and, as a result, novel idea or method, whereas invention refers more directly to creation of the idea or method itself. Innovation differs from improvement in that innovation refers to the notion of doing something different rather than doing the same thing better.”

Outline of this Presentation

- What is Innovation?
- Canadian and American Approaches to Health Care
- Accountability and Rights of Action: Denied or Delayed Health Coverage
- Malpractice Litigation

Single Payer vs Multi Payer

- **Canada** is composed of provinces and territories, each having its own single angle health plan to cover its residents. This is a single-payer system.
- Physicians charge the respective province territory for the medical-related service provided. Canada provides a basic level of universal coverage to all its residents.
- It covers about 75% of expenditures.
- Basic public coverage can be supplemented with private insurance to offset many non-covered medical treatments.
- **Canada Health Act** requires coverage for all medically necessary hospital and physician care.

Single Payer

- A multi-payer system with a diversity of coverage options.
- It is a mix of public and private insurers.
- Residents may have eligibility requirements to receive funding (e.g. income).

Eldridge v British Columbia (Attorney General) [1997] 3 SCR 424

- **Eldridge** argues that the right to receive a test for a communicable disease is a human right under Section 7 of the Charter of Rights and Freedoms. It allows the state to protect the health of the community without violating the individual’s rights to bodily harm.

Accountability and Rights of Action: Denied or Delayed Health Coverage

- Public funding for sign language interpretation services in hospitals is denied or individuals receiving insured health services.
- ‘Better’ in the eyes of one individual may be ‘worse’ in the eyes of another individual.
- **Eldridge** argues that an interpretation program was denied as “unfair” and the hearing impaired were denied access to a “treasure” or valuable resource, even though it would consume only a small portion of the provincial health care budget.
- The Supreme Court of Canada was critical of the Ministry of Health’s ad hoc decision making process.
Cherubí v Québec (AG) [2008] 2008 SCC 15
- Prohibitions of in-hospital medical insurance in the face of long wait times violated the Québec Charter of Human Rights and Freedoms

Auton (Guardian of Blem et al) v British Columbia (AG) [2004 SCC 76
- Unsuccessful challenge has related to the issue of paying novel and/or innovative treatments beyond pre-approved standard treatments.
- Government funding for "extra-care" medically necessary treatments is now required under section 19(1) of the Charter.

Malpractice Litigation

Caps on Damages
- Canadian courts cap damage awards to reflect conservative pre-determined calculations of necessary medical costs.
- This ensures consistency and legitimacy of court awards.

Evidentiary Threshold
- Ediger v Johnston, 2013 SCC 16
  - Application of "the fair" test.
  - Defendant was found to have breached standard of care as negligently caused brain damage in a newborn and did not have medical support available for recognition in which would likely have reduced effects of the injury.
  - durch court breached standard of care and injury of cost to state.

Malpractice Litigation

Innovations in approach to expert evidence
- R. v. Mother
- The evolving evolution of jurisprudence to deal with the "hired gun"
- New Rules of Civil Procedure
- Some disclosure of work product
- Duty of the Expert to be objective, impartial and assist the court

Conservation of Resources
- Early Mandatory Mediation
- Focus on discovery of disputed material facts rather than opinion evidence
- Summary Judgments – Pilot Trials
- Judge or Jury Trial

Canadian Medical Protective Association (CMPA)
- The CMPA’s mission is to provide medical liability advice and assistance for physicians in Canada.
CYRIL WECHT LUNCHEON
THE SEVEN HABITS OF HIGHLY EFFECTIVE DIs: KEY COGNITIVE FACTORS IN PSYCHOLOGICAL AUTOPSIES

This lecture made possible through a grant from the ACLM Foundation

SATURDAY, FEBRUARY 28, 12:00PM - 1:00PM

Brera 2

Katherine Ramsland, PhD, Program Director, Master of Arts in Criminal Justice, and Professor of Forensic Psychology, DeSales University
Objectives
At the end of this presentation, participants should be able to:

- Describe cognitive influence on decisions
- Recognize basic logical errors
- Explain the value of psychological evidence
- Clarify best practices for awareness
- Apply awareness to psychological autopsies

“There are known knowns: things we know that we know. There are known unknowns: things that we now know we don’t know. But there are also unknown unknowns – things we do not know we don’t know.”

-Donald Rumsfeld

We absorb more than we think

Default Mode

I-Contact
Three Issues
1. Cognitive interference
2. Attentional drain
3. Personality frames

Cognitive Interference

Myth
Our thinking process is transparent.

Information
2 Concurrent Systems of Processing
- Controlled-rational
- Emotional/intuitive
Aware of #1, but not #2
Effects
- Bias perception and memory
- Insert info into judgments

Amodal Completion
We fill in what’s missing

Congruency Effect
- Subjects viewed video clip that aroused anger
- Read description of accident
- Blamed defendants more than subjects who watched neutral clip
- Subjects watched sad clip
- Read same description
- Did not blame
2005 Detective Study
- Murder suspect photos: some looked guilty, others did not
- Ambiguous witness evidence
- Result: Guilty appearance, assumption of guilt

Outside Influences
- Irrelevant factors affect decisions
  - People pay up to 60% more for junk food if item is presented over a picture
  - Rate same detergent as “better” in a mixed-color vs. plain box
  - German or French background music influences desire to purchase German vs. French wine
  - Different price makes same beer taste different

MIT Study
- People asked to write the last 2 digits of SS#
- Submit mock bids on wine and chocolate
- Those with higher numbers submitted far higher bids

Story-Telling Heuristic
- We embrace chronology
  - Beginning/middle/end
  - Plausibility can undermine analysis
  - Expectations influence listening
  - Fill in gaps
Base-rate Bias
Expectations lead the brain

Attentional Drain

Attention!
A Limited Resource

Concurrent Tasks
Each task detracts from the other
Brain does NOT assess reduced performance
Confidence does not signal proficiency

Blindsight
We think we experience our entire subject frame
No intuitive awareness of limitations

Inattentional Blindness
We overestimate what we actually see
This influences what we think we know

**Personality Frames**

Our Cognitive Maps
We become habituated to our perspective

**HNC/LNC**
1. I don't like uncertainty.
2. I prefer to make decisions quickly.
3. I don’t second-guess.
4. People who question my decisions annoy me.
5. I usually go to the same restaurants.
6. My friends are predictable.

7. I need to understand why things occur in my life.
8. I don’t like surprises.
9. In most conflicts, I can easily see which side is right.
10. I dislike people who cannot make up their minds.

**Study**
Criminal investigators and undergraduates read facts from preliminary investigation of a homicide case.

Participants' initial hypothesis was manipulated with information implying that 1) prime suspect had a jealous motive or 2) there was an alternate suspect.

Students ascribed guilt to suspect only when a potential motive was presented.

Investigators did so regardless of hypothesis
- less sensitive to alternative ideas
Closure

“High NFC” investigators were less likely to acknowledge inconsistencies when presented with a potential motive, but did so when told of possible alternative perpetrator.

High NC

- Prefer gut instinct
- Tend to accept cultural narratives
- Don’t like to leave a hypothesis hanging
- Urgency and permanence

Myth

Always Trust Your Gut

Dissecting Gut Instinct

What is Gut Instinct?

How Brain collects and stores information for recognized situations
- Unconscious reaction - bias
- Evolved for protection
- Lack of information = lack in gut instinct
Other HNC Notions
- If it ain’t broke, don’t fix it.
- Argument from ignorance
- Cherry-picking

Our minds are not wired for uncertainty.
Sense of Closure = “I’m Right”

Mental Flexibility

Ohio, 2010

Investigative Narratives
Creating a narrative is unavoidable in law enforcement
Good narrative = Good story
Respects logic
Explains evidence
Interprets motive and goals
Good-looking Narrative

- Based on simplistic cultural narratives
- Ego investment
- Plays off prejudices and mindsets
- Deflects from its weaknesses
- Exploits attentional limits

Default vs. Reflection

Brain will make its choices: It likes what it likes
- Defaults to certainty
- But, we can choose to keep perspective

Key Points

1. Diagnose momentum
2. Confirmation bias
3. Superficial logic
4. Emotional congruency
5. Cognitive interference
6. Attentional drain
7. Pressure from past experience

Resist Blindspots & Biases

1. Recognize impact of ego & heuristics.
2. Form and analyze competing hypotheses.
3. Create a case-specific checklist of key assumptions.
4. Spell out areas of uncertainty or ambiguity as attractants for assumptions.
5. Remind yourself of limitations.

Psychological Autopsies

Purpose

To discover victim's state of mind preceding death, when circumstances can be interpreted in more than one way.

Psychologists can compile information retrospectively about behavior, psychological state, and motive.
Purpose

- Motive/Intent
- Reconstruction
- Strategies
- Improve database

Problem

Psychological elements often overlooked or treated superficially

Ridley Case

1961 – Edwin Shneidman coined term, “Psychological Autopsy”
Identified 16 categories
Suicidology
Victimology

1. Gather Information
2. Organize Data
3. Reconstruct sequence of probable events
4. Generate psycho-biographies of parties involved

Suicidology

- Empirical Criteria for Determination of Suicide
  - (a 16-item scoring system, 92% accuracy)
- Know the myths
- Consult databases (vs. experience)
- Recognize range of human acts

The Role of Psychology

Type of intent
Degree of lethality
- “Psychache”
  - Knowledge about suicide method

Psychache Evaluation

* Idea
* Substance abuse
* Purposelessness
* Anxiety
* Trapped
* Hopelessness
* Withdrawal
* Anger
* Recklessness
* Mood swings

NOTEPAD

“Learn as if you were to live forever live as if you were to die tomorrow.”
Summary

- Quick decisions harbor subtle influences.
- “Good-looking” narratives can pass as good narratives.
- Education about cognitive factors can help decision-makers perform solid investigations.
- See more anomalies
- Remain mindful to observe and listen better
- Think flexibly

Autoerotic Accidents

Thank you

KATHERINE.RAMSLAND@DESALES.EDU

Selected Resources


GENERAL SESSION VIII
HEALTHCARE REFORM — THE ACA TODAY

SATURDAY, FEBRUARY 28, 1:15PM - 2:45PM

Brera 4-5

MODERATOR:
David Donnersberger, Jr., MD, JD, MA, FCLM, ACLM Annual Meeting Co-Chair
America ranks worst on cost-related problems

Percent of patients who "did not fill a prescription, skipped recommended medical test, treatment or follow-up, or had a medical problem but did not visit a doctor or clinic in the past year because of cost."

Source: The Commonwealth Fund

America has the least efficient health care system

Percent of patients who reported spending a "lot" of time in paper/worker disputes related to medical bills.

Source: The Commonwealth Fund

America’s health care system is the least equal

Percent of patients who “did not get recommended test, treatment, or follow-up because of cost in the past year.”

Source: The Commonwealth Fund

Waste in U.S. Health Care System

Source: The Institute of Medicine
**International Comparison of Spending on Health 1980–2011**

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Note: $US PPP = purchasing power parity.


**U.S. Health Spending 1962 to 2022**

(in billions)

**Federal Spending 2013**

(percent of $3.5 Trillion budget)

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**Medicare Enrollment 1970-2035**

(in millions)

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**Projected Medicare Spending 2013-2023**

(in billions)

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**Number of Workers Per Beneficiary & Medicare Beneficiaries**

(in millions)

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<td>2035</td>
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General Revenue Transfers to Social Security and Medicare

Deficit Spending per Household vs. Median Household Income

U.S. National Debt 1970-2013 (in trillions)

Source: Congressional Budget Office, Long-Term Budget Outlook, Alternative Fiscal Scenario, June 5, 2012

Deficits if Spending Per Household Is On This Side of the Zero Deficit Line

Surpluses if Spending Per Household Is On This Side of the Zero Deficit Line

Source: 2009 Social Security and Medicare Trustees Reports.
Three Goals of the ACA

- Insure the Uninsured
- Make Insurance Better
- Make Medicine Better

Individual Mandate

- All U.S. citizens must have health insurance
  - Extended dependent coverage up to age 26
  - Employer, Individual, or Medicaid health insurance
  - Penalty for those without insurance:

Health Insurance Exchanges

Medicaid

- Several levels of coverage with varying cost-sharing requirements based on income level.
- Monthly premiums vary depending on the level of coverage.
- Premiums are based on the family's income and available assistance.
Constitutionality of Medicaid Expansion

  - Medicaid expansion is constitutional as a VOLUNTARY option for the states
  - Medicaid expansion is NOT constitutional as a mandate for the states
  - HHS may NOT withhold future federal funding for existing Medicaid programs if a state refuses to expand its Medicaid program

State Medicaid Expansion (2014)

Insure the Uninsured

Three Goals of the ACA

- Insure the Uninsured
- Make Insurance Better
- Make Medicine Better

Make Insurance Better

- Guarantee issue
  - Eliminates pre-existing condition exclusion
  - Eliminates lifetime limits on coverage

- "Essential benefits" coverage

- Medical loss ratio

- Independent Payment Advisory Board

Essential Health Benefits
**Three Goals of the ACA**

- Insure the Uninsured
- Make Insurance Better
- Make Medicine Better

**Make Medicine Better**

- Accountable Care Organizations
- Medical Home
- Primary Care Raikes
- Center for Medicaid & Medicare Innovation
  - Bundled Payments
  - Hospital value-based Purchasing Program
- Pay for Performance
- Patient-Centered Outcomes Research Institute (PCORI)
  - Comparative Effectiveness Research
- Medical Malpractice Reform
- National Quality Strategy
- Financial Disclosure Requirements
- National Strategy for Prevention & Wellness
- Wellness Program
- Nutritional Information Labeling Requirements
- Independence at Home

**Triple Aim**

**Make Medicine Better**

- Accountable Care Organizations
- Medical Home
- Primary Care Raikes
- Center for Medicaid & Medicare Innovation
  - Bundled Payments
  - Hospital value-based Purchasing Program
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- National Strategy for Prevention & Wellness
- Wellness Program
- Nutritional Information Labeling Requirements
- Independence at Home
Obamacare Design Flaws

- Significantly increases administrative burdens
- Does not curb federal healthcare spending
- Does not control pharmaceutical costs
- Does not achieve universal health insurance
Pharma Spending per Capita vs GPD per Capita

Profit Margin by Industry 2010 (percent)

Uninsured Population with and without Obamacare (in millions)

Source: Anthem 360 Industry Grouping: IDC States

Source: Anthem 360 Industry Grouping: IDC States

Source: Anthem 360 Industry Grouping: IDC States

Pharma Spending per Capita vs GPD per Capita

Profit Margin by Industry 2010 (percent)

Uninsured Population with and without Obamacare (in millions)
**The Affordable Care Act 2015: Where Have All the Failures Gone?**

John P Conomy, MD JD FACLM  
Health Systems Design, Inc.  
and  
Case Western Reserve University  
Cleveland, Ohio  
American College of Legal Medicine  
Las Vegas Meeting 2015
Luke Fildes, “The Doctor”
Tate Museum, London

Ezekiel Emanuel, MD

USA Health Care Costs in My Professional Lifetime
“Omnia ad Stellae”

These Features Compel Consideration of Health Care Reform

- Education
  - The Substrate, The ACA
- The Economy
  - On the Way to 25% of GDP for Health?
  - On the Way to 65 million with Inadequate Care?
- Immigration
  - We Live in a New USA
- Wealth Distribution
  - 1% have 20%, 20% have 80%

Distorted Wealth Distribution = Poor Health

Immigration, USA: Then and Now
(I) Shipwreck? Trainwreck? Where Have All the Failures Gone?

- The Number of Uninsured Americans Has Declined from 20% to 15% since 2013
- The Greatest Increases Occurred in States With Medicaid Expansion
- 85% of Newly Covered Persons Received Insurance Premium Subsidies
- Over 7,000,000 Enrolled, 6,000,000 Applied
- Health Insurance Companies Are Profitable

(II) Shipwreck? Trainwreck? Where Have All the Failures Gone

- Personal Satisfaction with Obama Care Plans is Very High-75% of Exchange Plans
- By 2017, CBO Estimates 26million in Plans
- Coverage for Pre-Existing Conditions plus Mental Health Services and Inclusion in Parental Plans to Age 26 years are pluses
- There is a >20% drop in uninsured 19-25 yr. old person since 2010

(III) Shipwreck? Trainwreck? Some Areas of Lingering Concern

- Does the ACA Control Health Care Costs? It may, or may not. Program Costs ????
- Is the ACA Inclusive Enough? States without Medicaid Expansion are Among the Poorest in the Nation and Have Large Vulnerable Groups
- Will the ACA Suffer Death By 1000 Cuts?

Transcendent Global Issues Affecting Health Care Reform

- Lack of Recognition of the Rights of Man
  - The French National Assembly, Declaration of the Rights of Man, 1789
- Growing Disparity in the Distribution of Wealth
- Decay and Degeneration of Social, Political and Economic Institutions
  - Francis Fukuyama, Political Order and Political Decay, Farrar, Strauss & Giroux, 2014

The Problem of a National USA Health Care System has a History…
SANDY SANBAR LECTURE
THE UNBEFRIENDED: A NEW PROTECTED CLASS OF PATIENTS?
This lecture made possible through a grant from the ACLM Foundation

SATURDAY, FEBRUARY 28, 3:15PM - 4:30PM

Brera 4-5

David Ozar, Professor, Department of Philosophy, Loyola University Chicago; Clinical Ethics Consultant, NorthShore University HealthSystem
ANNUAL AWARDS BANQUET
GAMBLING DISORDER AND HEALTH LAW

SATURDAY, FEBRUARY 28, 7:00PM - 9:00PM

Gracia 1-2

SPEAKER:
Stacey A. Tovino, JD, PhD, Lincy Professor of Law, Lehman Professor of Law, Wil- liam S. Boyd School of Law, University of Nevada, Las Vegas
GENERAL SESSION IX
INTERNATIONAL TOPICS IN LEGAL MEDICINE

SUNDAY, MARCH 1, 8:00AM - 9:15AM

Brera 4-5

MODERATOR:
Alejandro Moreno, MBBS, MPH, JD, FCLM, University of Texas Southwestern Residency Programs, Austin, TX
MEDICAL MALPRACTICE FREE ZONE?
REFLECTIONS FROM NEW ZEALAND’S ACCIDENT COMPENSATION SCHEME

Professor Kate Diesfeld, JD
Conference of the International College of Legal Medicine, Las Vegas, February 2015

Overview
• Disciplinary case
• Why NZ adopted ACC
• Significance of ACC for medical malpractice
• Overview of patients’ rights and disciplinary regime

The case of Dr N
• Dr N administered unapproved medicine Novielle Gel Plus as dermal filler without informed consent regarding its: unapproved status and side effects
• Patient experienced swelling, inflammation and formation of granuloma
• Dr N did not ensure it was safe to use as dermal filler
• Failed to refer to specialist in timely fashion
• Without justification, prescribed further medication and treatment
• Failed to adequately document
• www.hpdt.org.nz  Med 12/225

Legislation
• Health Practitioners Competence Assurance Act 2003
  • S 100 malpractice and negligence
• Health Practitioners Disciplinary Tribunal
• Medicines Act 1981
  • Patient was not known or identifiable to Dr N under the requirements regarding unapproved medicines by the Medicines Act 1981

Section 100 HPCAA 2003
• Two step process for discipline
  1. Whether acts/omissions reasonably regarded by the HPDT as constituting malpractice or negligence, or otherwise meets standard of having brought or was likely to bring, discredit to the profession
  2. Whether the HPDT was satisfied that acts/omissions require disciplinary sanction to protect the public and/or maintain professional standards and/or punish the practitioner

Dr N’s penalty
• Censured
• Subject to conditions on practice for 3 years
  • Medical consultation
  • Ensuring compliance with medication regime
• Fine $8000 NZ ($5972 US)
• Costs $9400 ($7020 US)
• What would be the likely result in the US?
Accident compensation

- Sir Owen Woodhouse chaired the Royal Commission on Accident Compensation 1966-67
- Two key principles
  - Community responsibility
  - Comprehensive entitlement

- Comprehensive and equitable scheme of social insurance that would enable personal injury claims to be managed “speedily, consistently, economically and without contention”.

Woodhouse Report

Comprehensive and equitable scheme of social insurance that would enable personal injury claims to be managed “speedily, consistently, economically and without contention”.

However, currently, 2 to 3 year back log of cases in District Court appeals, in part due to number of adverse decisions issued by ACC (Peart, 2014).

ACC progression

- Came into force in 1974
- Medico-legal system influenced by Cartwright Inquiry and Cull Report

- How do patents who experience treatment injury caused by a registered health practitioner obtain accident compensation?

Accident Compensation Act 2001

Treatment injury

1. Treatment injury means personal injury that is—
   (a) suffered by a person—
      (i) seeking treatment from 1 or more registered health professionals; or
      (ii) receiving treatment from, or at the direction of, 1 or more registered health professionals; or
      (iii) referred to in subsection (7); and
   (b) caused by treatment; and
   (c) not a necessary part, or ordinary consequence, of the treatment, taking into account all the circumstances of the treatment, including—
      (i) the person’s underlying health condition at the time of the treatment; and
      (ii) the clinical knowledge at the time of the treatment.

(cont)

2. Treatment injury does not include the following kinds of personal injury:
   (a) personal injury that is wholly or substantially caused by a person’s underlying health condition;
   (b) personal injury that is solely attributable to a resource allocation decision;
   (c) personal injury that is a result of a person unreasonably withholding or delaying their consent to undergo treatment.

3. The fact that the treatment did not achieve a desired result does not, of itself, constitute treatment injury.

What ACC scheme achieved

- Reduced tension between compensation and accountability
- Separated compensation from complaints and disciplinary regime
- With establishment of “treatment injury” category, fault-finding removed from accident compensation scheme under ACA 2001
- ACC designed for accident compensation and rehabilitation, not fault-finding
How to redress patients’ complaints regarding personal injury?

- Compensation: ACC since 1974
- Other protections/responses through:
  - Health and Disability Commissioner Act 1994
  - Code of Health and Disability Services Consumers’ Rights (10)
  - www.hdc.org.nz
  - Health Practitioners Disciplinary Tribunal www.hpdt.org.nz
  - Human Rights Review Tribunal with residual claims for exemplary damages
  - Criminal justice system
  - Employment law

Critique: Wallis 2013

- Accountability via compensation decreased following the 2005 ‘no-fault’ compensation reforms, contributing to an overall decrease in medical professional accountability for harm.

Counter-argument
Collins and Brown 2009

- The Cartwright Report instigated a profound change in thinking about patient-doctor relationships and the need for public involvement in the processes by which doctors are censored. It was also the key catalyst to legislative reforms designed to ensure the accountability of practitioners to their patients. Perhaps contrary to expectations, the statistics show a pronounced decline in disciplinary hearings. The authors argue this should not necessarily be considered an adverse outcome; the statistics in fact reflect the working of multi-layered, more constructive and open processes for regulating doctors and holding them accountable.

Discussion

- Does this type of medico-legal regime achieve:
  - Speedy, efficient and comprehensive compensation?
  - Preferable legal response to medical malpractice and negligence?
  - Adequate patient safeguards?
  - Is New Zealand’s response the solution?

We welcome debate. kdiesfel@aut.ac.nz

HPDT statistics:
registered health practitioners to 23/1/15

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References

• Peart, H. (2014) Promises and Perils of a No-Fault Scheme: Lessons from New Zealand. Conference presentation, see hamish@schmidtpeart.co.nz
• Tennent, D. Accident Compensation and Older People. In K. Diesfeld and I. McIntosh (Eds) Elder Law in New Zealand, Thomson Reuters: Wellington.

Cont.

DEVELOPMENT OF HEALTH LAW IN NIGERIA

- The Open Season Of Malpractice Suits

Olaolu A. Osanyin, LLM
President, Center for Medical Law Research & Development
Course Director for Medico-legal, Medical Tutors Ltd (Accredited C.M.E provider for the Medical & Dental Council of Nigeria)
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The Open Season Of Malpractice Suits

- There is a steadily growing medicolegal environment in Nigeria, with a total of 190 judgments of professional negligence against Doctors between year 2000 and 2007 this represents a 200% increase from the previous records of only 92 petitions from 1963-1999.
- This is because for several years the Nigerian Doctors appeared immune from liability.

SOME OF THE REASONS FOR THE “PERCEIVED IMMUNITY” OF NIGERIAN DOCTORS

- Patients’ ignorance due to a large illiterate population.
- The years of military dictatorship in Nigeria which restricted access to justice.
- Belief in “The Act of God”.
- Apathy for the courts leading to lack of faith in judicial process.
- The reverence Patients had for their doctors.

Existing Legislations Regulating Medical Practice in Nigeria.

- Medical and Dental Practitioners Act, 2004.
- Code of Medical Ethics 2008
- The Criminal and Penal Codes
- Other laws regulating other allied professions relevant to medical practice in Nigeria and
- Regardless of these existing legislations regulating medical practice in Nigeria, there were a paucity of malpractice suits in contra-distinction to the plethora of allegations of malpractices by Doctors from patients.

The New Medicolegal Environment

- In the past 15 years, there has been a steady and consistent increase in litigations and petitions against Nigerian Doctors which has brought about a new medicolegal environment. Some of the reasons for this new trend include:

Some Reasons for Patients’ Awareness.

1. The increase in literacy level and the advent of internet into Nigeria.
2. Existence of democratic dispensation in the past 16 years and access to the courts.
3. Medical Tourism: About 30,000 Nigerians spend $1 bn annually on medical Tourism into other countries.
4. Pecuniary considerations with respect to litigious patients.
5. Increase in the living standards of Middle Class Nigerians and their readiness to challenge infringements of their rights.
A Review of Some Malpractice Cases in Nigeria.

- **THE CASE OF NAVY CAPT/DR. OLOWU:** who failed to personally examine the patient having complications in pregnancy for 15 hours, he merely wrote a letter of referral when the situation had already become bad as she was already bleeding profusely from the vagina. She was later operated upon in another facility where it was discovered that the baby died about 24 hours with several complications and inability to further conceive. The Federal High Court, Lagos, awarded N100 million ($900,000) damages against the Nigerian Navy and Captain C.T Olowu, for negligence.
- The court martial consequently demoted him from the rank of captain to commander, a four-year reduction in seniority.

The Case Of Dr. Samuel Wokoma:

- Who neglected to see and monitor the management of the patient who was in a severely ill condition, thus conducted yourself infamously in a professional respect contrary to Rules 29 and 43 of the Code of Medical Ethics in Nigeria 2008 he was subsequently suspended from practice for a period of three(3) months.
- **State v Ozegbe:** A nursing orderly who paraded himself as a doctor and proceeded to surgically excise a lump. The court convicted him for manslaughter.

The Case Of Dr. Robert Akintade:

- Who carried out a major surgery on a 65 year old patient who was obese without testing the patient for diabetes. The patient developed post operation complications arising from her diabetic status and died shortly afterwards. The Doctor was suspended from practice for displaying inadequate knowledge and skill.

The case of Dr. Vital Eseihien Uhomebhi

- Who in the process of attending to a female patient related indecently with the said patient in the consulting room and on several occasions in the Teaching Hospital had related indecently with other female patients. He was also reported to have conducted vaginal examination on several female patients in the same Teaching Hospital with ungloved fingers.
- He was found guilty of professional misconduct and his name struck-off the register of Medical and Dental Practitioners in Nigeria.

CASE of Dr. Afam Ezendiugwu

- Who did a caesarian section on a patient without the necessary consent form. The tribunal held amongst other things that payment of surgical fee and knowledge of operation are not enough evidence for consent. He was suspended from practice for 6 months.

The National Health Act 2014

- The open season of malpractice suits is one of the major factors that compelled the National Assembly of Nigeria to pass the National Health Bill which was assented by the President into an act of the Federal Republic of Nigeria as the National Health Act 2014 on the 8th of December 2014.
Objective of the National Health Act 2014

(a) encompass public and private providers of health services;
(b) promote a spirit of cooperation and shared responsibility among all providers of health services in the Federation and any part thereof;
(c) provide for persons living in Nigeria the best possible health services within the limits of available resources;
(d) Set out the rights and obligations of health care providers, health workers, health establishments and users; and
(e) Protect, promote and fulfill the rights of the people of Nigeria to have access to health care services.

Some of the Provisions of the NHA

1. Compulsory annual Certificate of Standards for all health facilities.
2. Compulsory emergency treatment for Patients.
4. Informed Consent and Confidentiality.
5. Regulation on Research and Experimentation.
7. National Health Insurance Scheme.
8. Prohibition of State Sponsored Overseas Medical Treatments.

SANCTIONS WITHOUT DOUBLE JEOPARDY

- The Nigerian Doctors can be sanctioned severally without the defense of double jeopardy being applicable;
  a). Administrative Panels of Organizations
  b). The civil courts can award compensation.
  c). MDCN disciplinary organs can sanction practitioners.
  d.) Criminal Prosecution.

Conclusion

- It is evident that there is a direct correlation between democratic governance and the increase in malpractice law suits.
- Nigerian Patients have become aware of their rights and they are willing to assert these rights and can easily become litigious particularly with the prospect of monetary compensation.
- The reality is that a whirlwind of petitions and litigations against Doctors are already existing in Nigeria.
- Consultants, Supervising Doctors, Hospital Administrators etc will always be called to question when allegations of negligence is made against them or any of their subordinates.

Recommendations

1. The Medical Law Seminar series has produced modules for training of Doctors in Medical Law as a C.M.E requirement for renewal of Doctors' annual practicing licenses, we also collaborate with Colleges of Medicines and Teaching Hospitals all over Nigeria with an effort to introduce Medical Laws as a course in our Medical Schools.
2. COMPULSORY PROFESSIONAL INDEMNITY INSURANCE FOR HEALTH CARE PRACTITIONERS

THE END

Thanks for coming.

ACLM 55th Annual Meeting Program Book
Regulatory Reforms on doctor-patient relationship in India: Need of a new comprehensive Law to govern medical liability.

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Background and Rationale

- Ushering in of consumer protection of law: phenomenal rise in cases and many settled principles of law (e.g., informed consent, diligence, secrecy, death certificate, etc.)
- Corporate expansion of medical services and health consciousness
- Persons at total bay at both ends due to lack of awareness of rights and obligations: patients and professionals
- The risk of professional failure added with risk of litigation and compensation
- Minimal standards of reasonable care in case of Medical negligence: to be set by courts or by professionals?

Background and Rationale

- Key Concepts in CPA traced and connected: Profession, Negligence, Professional negligence, Professional Liability
- Linking them to context and multiple rules of medical negligence in India
- Concept of medical negligence as on today in India in the backdrop of Bolam and Bolitho
- Tracing the exception of error or mistake
- Deficiency in Service vis a vis Medical Profession (shortcoming, inadequacy, incorrect, refusal to treat, use of faulty instruments)
- Service as main, inclusionary and exclusionary

Objectives

1. To study the concept of medical Negligence as a whole under various Indian laws
2. To identify and analyze the Changing Trends in the Law of Medical Negligence in India and its impact.
3. To study the comparative position of the law in this regard with reference to foreign laws, to explore the linkages with the International approach towards Medical Negligence.

Literature Review:

- Consumer Rights:
  Patient as Consumer and Medical Professional or Healthcare establishment as Service Provider
Trend: a pattern of gradual change in the law (CPA), its applicability (Medical Negligence) and impact on various stakeholders (patients, professionals, hospital administrators) in opinion, in outcome of cases at different levels
- Dearth of any specific extensive study with all these concepts is proved by literature review once these concepts are identified

Literature Review:

- National and international models in defining and applying the concept of medical negligence
- The implications of the Bolam and Bolitho principles
- The role of the courts in resolving medical negligence cases
- The impact of medical negligence on patients and healthcare providers
- The current status of medical negligence cases in India
- The role of technology in medical negligence cases
- The importance of patient education in preventing medical negligence
- The role of medical ethics in preventing medical negligence

Literature Review:

- Key Concepts in CPA traced and connected:
  - Profession, Negligence, Professional negligence, Professional Liability
  - Linking them to context and multiple rules of medical negligence in India
  - Concept of medical negligence as on today in India in the backdrop of Bolam and Bolitho
  - Tracing the exception of error or mistake
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2. To identify and analyze the Changing Trends in the Law of Medical Negligence in India and its impact.
3. To study the comparative position of the law in this regard with reference to foreign laws, to explore the linkages with the International approach towards Medical Negligence.
Research Questions

1. How is the Concept of Medical Negligence defined under various laws in India and abroad?
2. What are the various trends visible in the approach towards Medical Negligence in India and abroad?
3. What are the parameters of Consumer Protection that determine the nexus between Medical Negligence and its consequences under Consumer Protection Act? Should the Consumer Protection Act continue to govern it in India?

Research Methodology

- Mixed Methodology: combination of doctrinal and empirical methods
- Triangulation of methods and data: Convergence Variant
- Criteria were developed from study of doctrinal data to define trends and applied to case analysis
- Quantitative Analysis of Primary legal Data: Case Laws Analysis and Interrelationships on Judicial Response to Medical Negligence: 40 Cases from Supreme Court and 300 Cases from National Commission

Data Analysis and Interpretation

Judicial Response to Medical Negligence

- 40 Supreme Court case laws and 300 National Commission case laws
- Duration 1987 to March 2013
- Study and Analysis of Case Laws using 31 variables
  - Selected variables
    - Patient’s Education and Profession
    - Involvement of hospital
    - Judge’s version
    - Bolam Principle
    - Deficiency in service

Analysis of Local Trends at Pune

- Analysis of the 10 cases from Pune District Consumer Forum pending with State Commission of Maharashtra and National Commission
- Interrelationships between the two based on variables and Medical Negligence:
  - Selected variables
    - Patient’s Education Status
    - Involvement of hospital
    - Judge’s version
    - Bolam Principle
    - Deficiency in service

Data Analysis and Interpretation Of Empirical Study

- Analysis of awareness amongst Doctors
- Themes of Survey findings based on 40 Questions Community
- Themes of Survey findings based on 13 Questions Interviews and Opinions amongst Doctors and Community Summary
- **Triangulation Matrix**
  - Triangulated Doctrinal Study and Empirical Study
  - Triangulation of Case laws analysis with Doctors and Community Response
  - Comparison of selected variables
  - Doctor’s specialty
  - Patient Education
  - Bolam Principle
  - Deficiency in service- Informed consent
  - Second Opinion

- **Critical Evaluation : Changing Trends**
  - Identified Trends in Case Law Analysis: (Diagrammatic Representation)
    - principles,
    - deficiency,
    - methods of judging,
    - evidence,
    - compensation
    - Overview of Changing Trends

- **Overview**
  - Impact on profession and on consumer/patient
    - Change in the doctor patient relationship
    - Increased practice of defensive medicine
    - Rising cost of the treatment
    - Loss to the students
    - Deficiency in the number of specialists

- **Implications for the FUTURE**
  - Assistance and awareness
    - Among Doctors
    - Among Community
    - About Good Doctor Patient Relationship
    - About limitation of medical science
    - Efforts to reduce enmity
    - Information about new Act

- **Specific Findings**
  - Concept of Medical Negligence under various Laws in India and Consumer Rights in landmark cases, laws including CPA: predominance of fault liability, requires alternative because current remedy inadequate
  - Development of Criteria for Trends and observing the trends for Case Law analysis show correlation at all levels leaving gaps

- **Assistance and awareness**
  - Among Doctors
  - Among Community
  - About Good Doctor Patient Relationship
  - About limitation of medical science
  - Efforts to reduce enmity
  - Information about new Act

- **Exploring amendment or new Act**
  - Feasibility of law reform
  - Regulation by profession or community
  - Exclusive health tribunal or medical board

- **Regulation by profession or community**
  - Exclusive health tribunal or medical board
Specific Findings

- Observed the Changing Trends by triangulating Case Law analysis with Empirical study shows
- Uncertain movement from Bolam to Bolitho and other (10) factors;
- Counter productive nature of CPA due to dismal statistics of proving medical negligence (36 to 60%), hence alternatives are suggested

Suggestions for Existing Mechanism: Amending current Act

- Stronger Role of Medical Councils
- Screening Committees
- Medical Professional on Consumer Panels
- Nursing Homes Regulations
- Punishment for false cases
- Orientation Programs for New Doctors and Community

Suggestions for new Act

- Patient Protection and Safety Act (Proposed): New Comprehensive Law Governing Medical Liability
  - Chapter 1 Preliminary: bases of a limited fault liability and b. fast track settlement. Patient interest in the center
  - Chapter 2 Patient Protection Councils
  - Chapter 3 Health Tribunals: Medical Boards
  - Chapter 4 System of Expert Medical Evidence: Daubert criteria
  - Chapter 5 Miscellaneous
  - Scope for Future Research: rural district as the universe, larger sample, study of awareness via mass media

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GENERAL SESSION X
STUDENT WRITING AWARDS

SUNDAY, MARCH 1, 9:40AM - 10:35AM

Brera 4-5

MODERATOR:
Robert W. Buckman, PhD, FCLM, President ACLM Foundation
HIRSH AWARD FOR STUDENT WRITING COMPETITION IN LAW, MEDICINE & BIOETHICS

Hirsch Award Winner
Author: Stuart Portman
The George Washington University, Milken Institute School of Public Health
AN ETHICAL ANALYSIS OF IN-HOME HEALTH COVERAGE BY ILLINOIS’S MEDICAID PROGRAM

Introduction:

In-home health services are a benefit for many Social Security Disability Insurance (SSDI) beneficiaries in state Medicaid programs. For the physically disabled population, the ability and decision to live in the community can be integral to maintaining a meaningful and productive life. This paper seeks to analyze how considerations of cost can impact beneficiaries’ autonomy and whether such decisions differ when the beneficiary has reduced autonomy due to physical disability. Analyses of ethical issues are complex by design; state actors must make hard choices on a daily basis, but this does not mean that the resolutions they develop should be acceptable based on the difficulty in decision-making. Only by comparing specific State actions to ethical principles—such as respect for autonomy, beneficence, and justice—can potentially improper State action be judged fairly. These principles have been outlined in The Belmont Report and Beauchamp & Childress’s Principles of Biomedical Ethics.12

Although the two ethical analyses were developed as research and clinical guidance for ethical treatment, they combine universal and normative beliefs similarly to the confluence of the issues addressed here. In regards to Medicaid coverage, a decision to change or exclude a preexisting benefit is perceived more severely by the beneficiary than the governing body overseeing that benefit. While not directly human subject research or clinical care, understanding how normative beliefs impact value-laden decisions inherently guides policy development.

Determinations of benefit coverage vary between state Medicaid programs\(^3\). While benefit decisions are a state matter, the inclusion of cost as a condition for certain benefits may fluctuate between states in their acceptability and appropriateness\(^4\). To that end, consider the following scenario: A young woman has been physically disabled since birth. She receives SSDI benefits from her state’s Medicaid program, but she is capable of rational thought (meaning that she does not have a legally-defined mental disability). Her parents have served as her primary caregivers, and the state has provided in-home health services as part of her benefit package. However, one of the girl’s parents died and the other is no longer able to lift the girl, who is over the age of 21. In determining whether to offer a more robust package of in-home health services, the state considers the cost to the state of in-home health care in comparison with care in a nursing facility. The final decision of where the fully-cognizant girl will be allowed to live with the support of the state Medicaid program lies with the state’s Medicaid program, not with the girl or her family, regardless of the girl’s input. This situation may seem extreme, but recent changes to the Illinois Medicaid program resulted in this exact scenario.

In the state of Illinois, a person with a physical disability seeking Medicaid SSDI in 2014 must meet the following requirements: U. S. citizen or legal alien; Resident of the State of Illinois; Under age 60 at time of application; Medicaid eligible or enrolled in the Health Benefits for Workers with Disabilities program; Medical determination of a diagnosed, severe disability, which is expected to last for 12 months or for the duration of life; Be at risk of nursing facility placement as measured by the Determination of Need (DON) assessment; Estimated cost to the State for home care is less than estimated cost for institutional care; Can be safely maintained in

the home or community-based setting with the services provided in the plan of care. From these requirements, there are need-based waivers to allow home and community-based care, and there are different requirements for each category of Medicaid services based on the waiver for those services. Here, the focus is on the Medicaid Home and Community-based Services waiver (DHS 4243 waiver).

In June of 2012, the Illinois Department of Healthcare and Family Services released an informational notice explaining changes to the state’s Medicaid program. Specifically, it explained that Governor Pat Quinn had signed Public Act 097-0689 (dubbed the SMART Act) into law. This implemented a series of policy changes into the Illinois Medicaid program, including a requirement specifically for waiver programs for home and community-based care. When new applications for home and community-based services waivers are reviewed initially or during an annual eligibility determination performed by the Department of Human Services, resource reviews must be conducted by the Office of the Inspector General. This is the formal addition of cost as a consideration for home health benefits.

In the context of this analysis, physical disability does not include clinically-proven mental illness. The disabled population is capable of lucid thinking and desires to be free and independent, not viewed as a financial burden to the state. Like other rationally-thinking people,

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independence offers decision-making to lead a free and fulfilling life\textsuperscript{9}. For many people with physical disabilities, there is no need for rehabilitative care due to the permanent or degenerative nature of their diseases\textsuperscript{10}. However, maintenance of care is still integral to the person’s well-being, and caregivers and home health nurses and aides allow for that maintenance in the person’s own home.

**Context:**

What compels a state to desire cost-neutrality in its entitlement programs? The answer is complex and multifaceted. To start, benefit changes are federally mandated to be cost-neutral (in the absence of specific legislation) to maintain the integrity and viability of state programs\textsuperscript{11}. Additionally, there are fears of the woodwork effect, which is a policy term for the insurance concept of moral hazard. This means that, in the state’s perspective, if too many people sign up for coverage and benefits without an increase in the state’s revenues, it will not be long before the state experiences cost overruns in its budget\textsuperscript{12}.

The beliefs of this analysis hinge on the notion that having reduced autonomy via physical disability is different than other variances between individuals. This is not a Rawlsian belief that difference requires making policies for the least among members of society, but rather that treating home health and MRIs in the same way is inconsistent with the ideals that society should uphold\textsuperscript{13}. An MRI is a diagnostic tool with life-saving capabilities; home health services are ways of existing in a meaningful way. Home health is not a diagnostic tool or test, and therefore, it must be considered by the state of Illinois in a different light. Even with budget


\textsuperscript{10} Ibid.


\textsuperscript{12} Ibid.

constraints, it is incorrect to view a person’s existence as a lifestyle choice because of convenience to the State.

Cost of services in Illinois—and other states—has been a recurring issue. In 2012, there was a funding shortfall in the state accounting for a $2.7 billion loss for Fiscal Year 2013. This required immediate action to work with state and federal departments to cut costs to return to a budget-neutral program. A compounding factor here is the aging population in Illinois, which means more elderly people will be getting sicker and require Medicaid benefits in addition to their Medicare benefits\(^\text{14}\). Between that and the Medicaid Expansion of the Patient Protection and Affordable Care Act (ACA), the population likely to receive benefits from the state program is rapidly increasing. Due to concerns of increased churning from a larger population of beneficiaries, the state must find ways to reduce its overall costs of providing Medicaid benefits\(^\text{15}\). As such, considering cost for benefits remains a practical challenge.

While the policy implications of cost-neutrality are important, they are often factors in situations that do not directly involve a person’s autonomy\(^\text{16}\). The ethical principles of The Belmont Report, which outlines principles for ethical research with human subjects, expand autonomy into two categories of respect for persons: acknowledging individual autonomy and protecting those with diminished autonomy\(^\text{17}\). Because the physically disabled need assistance with at least one “activity of daily living”—the basic tasks of everyday life such as bathing,


eating, dressing, or transferring—their autonomy is, arguably, reduced\(^{18}\). There is a necessary dependency on another person or a mechanism to allow that person participation in daily activities, thereby creating a sense of reduced autonomy for the individual\(^{19}\). Despite this approach to individual treatment, the state also has a moral obligation to the entire population to run a program within its means. Although the population that it serves may be medically needy, all parties will suffer if the revenues are not large enough to meet the projected expenditures.

The previously discussed components of independence are policy-driven concerns for individual autonomy; however, there are ethical concerns that do—and should—impact decision-making regarding benefit determination. For instance, determining whether a certain diabetes treatment should be covered by state Medicaid funds may include a consideration of the cost to the state for providing that treatment. While it may impact a group of beneficiaries if the diabetes treatment is not covered, there would still be other treatments to accomplish the same medical goals. The impact on a person with reduced autonomy is not necessarily the same since there may not be alternatives that maintain the person’s independence; the alternative is institutionalization, which results in a highly different life experience than home and community-based care\(^{20}\). As such, the moral quandary of including cost as a factor for benefit must be analyzed further.

An additional aspect of the scenario with the physically disabled girl is that of the individual’s role in her own care. Just because a person is physically disabled does not mean that


\(^{19}\) Ibid.

the person has lost all of her rights\textsuperscript{21}. When considering what type of care is best for a person—community-based with family and home health services or institutional care—state decision-makers often forget that the beneficiary also has opinions about the course of care that she is to follow. Physical disability benefits are ordered by providers based on medical necessity; as such, they should be treated like other medical decisions where the patient can influence her own course of care\textsuperscript{22}. To discuss in-home health services requires a respect for the individual so that determinations are made with respect to both individuals and state priorities.

\textbf{Ethical Impacts:}

By defining what is right for the beneficiary and what is practical for the state, there is more at stake than benefit determinations. How the decision is made matters, especially in how that decision impacts individual autonomy. The beneficiary who has lost her primary caregiver and is awaiting a state determination of whether or not home health services will be provided is at the mercy of the state. Does being physically disabled exert a dependency on the state? It appears so, especially in regards to how benefits are dispensed. However, does that dependency remove the girl’s rights? Practically, a blanket determination is easier than making case-specific decisions for whether home-health can be continued. Morally, it seems that doing what is best for each beneficiary in each situation is preferable. But in a world of limited resources, broad policies seem to dominate. This effectively creates a scale where equity is valued over equitable care.

In this scenario, the girl is capable of rational thought. That means that the physical disability does not prevent her from contributing to society. She could hold a job that is


accessible to her abilities, as well as interact with the community’s economy and spur economic growth. Furthermore, she can contribute in non-economic terms to the well-being of her community and family. These traits are the same as a physically-able-bodied person. To treat her differently simply because of her disability could be viewed as an unreasonable accommodation by the standards of the Americans with Disabilities Act\textsuperscript{23}. Just because someone requires assistance to complete tasks should not alter what is normative; rather, the ability to complete the same responsibilities must be treated as judged on its own merits.

This example delineates two seemingly competing objectives from policies surrounding the physically disabled: The policy objective is to concurrently increase quality and decrease the cost of services while the ethical objective is to promote social justice and empower individuals with reduced autonomy. Illinois operates with a system where there are limited funds, so trying to understand the minimal level of care that the state must provide is difficult when considering autonomy and social justice.

To elaborate on this, those that do not object to cost being a factor in home health service determinations argue that the state must provide some type of care, but since it is a form of welfare, the beneficiaries do not get to choose what service best fits their needs. This viewpoint contends that welfare, as a gift to those who have a physical disability, have no choice or do not need a choice from the government entities involved with their decision-making. It might be sad that the physically disabled girl cannot get everything she wants, but is it truly unfair? What this viewpoint misses is that the role of government intervention in a person with reduced autonomy’s life is not to provide the bare minimum. If the girl needs a wheelchair to survive, is

\begin{footnote}{23} Americans with Disabilities Act of 1990. One Hundred and First Congress: S. 933. http://www.dol.gov/ofccp/regs/statutes/ada.htm.\end{footnote}
the government’s role simply to make the least expensive wheelchair option available to her/her family, and then let them figure out whether that chair fits their home, vehicle, and other practical needs? If the government provides a single option (institutionalized care), has it met its obligation to those with reduced autonomy and increased dependence on a non-self-actor? This is not to say that limited budgets do not create burdens for decision-makers, but that society has moved past a standard of providing minimal services and calling it good enough\(^\text{24}\). This analysis of the environmental scan of long-term supports and services by the Center for Health Care Strategies was developed through interviews with state health department leaders and state health policy makers, so the derived data provides insight into the beliefs and practices of the states themselves.

**Ethical Standards:**

There are specific criteria that should dictate a decision where a Medicaid beneficiary’s autonomy is at risk. These standards, as explained in The Belmont Report, include respect for persons, beneficence, and social justice. These must all be analyzed in the context of a limited budget and financial constraints. By setting forth criteria for comparisons, decision-making around whether benefits impacting autonomy can be altered can be more standardized. Each type of care will be analyzed according to these standards in relation to the individual.

**Institutional Care:**

The care provided in institutional settings is important, and it provides care to over 58% of the population requiring long-term care\(^\text{25}\). There are diseases, illnesses, and conditions that


require monitoring and treatment to occur at all times, often with specialized equipment. It is in the interests of the individual to have those services available.

In regards to respect for persons, institutional care plays a conflicting role. If the person selects institutional care him/herself, then it appears as though the person made an autonomous choice to be there and receive care in that setting based on his/her needs. If personal input was not provided or considered, the individual seems to have ceded his/her autonomy. For a population that has reduced autonomy, State actors should not assume that they are incapable of self-determination. If that occurs, a decision that is destructive to both autonomous decision-making and respect for those with reduced autonomy occurs. The Belmont Report even explains that “The extent of protection afforded [by the government] should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations”26. This means that institutional care has great potential to be abused, which should cause individuals to be worried and vigilant.

Beneficence comes from the notion of doing no harm to the individual and maximizing possible benefits while minimizing harms. Institutionalization seeks to monitor the individual, and thus reduce harms. However, long-term care in a nursing home is not a remedial source of care; rather, the idea is to maintain care and give a sense of independence. This means that while harms are minimized, there is very little action to maximize benefits to the individual. If that were the case, why would individuals share rooms with others in a place where infections can be transferred so readily between people with weaker immune systems27? Therefore, only half of the goal of beneficence is upheld for individuals in institutions.

Justice refers to the allocation of resources and who bears the burdens of such distributions. The goal is to ensure that each person receives what he/she is entitled to, without exploiting a particular population due to convenience. Due to the many definitions of justice, The Belmont Report synthesizes this principle into addressing one or more of the following principles: justice is giving each person an equal share, or justice is giving each person according to his/her individual needs, or justice is giving to each person according to his/her individual effort, or justice is giving to each person according to social contribution, or justice is giving to each person according to his/her merit. Therefore, justice here requires the physically disabled to be helped by the care programs developed, and that the programs do not show a bias towards one program over another.

In the case of institutional care, an argument for justice can be maintained. Social distribution of justice principles shows that giving everyone an equal share of the available resources is a form of justice, and here, it appears to be upheld. If someone needs institutional care, that is available. By treating the physically disabled population as a community, all members have access to the same location of care services, even if it is not individually ideal. This, in effect, is a form of justice.

Home Health & Community Services:

Despite the impacts of institutional care on convenience to the State, home and community-based service can provide more fitting care to a segment of the population. A 2012 study by Sands et. al. concluded that, when young, disabled people received more hours of paid

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home health care services they were less likely to transition to nursing homes. In fact, in this randomized and controlled study, the closer the number of hours of home health services approached 24 hours/day, the less likely physically disabled people were to seek nursing home services. Multiple studies also conclude that the cost of home health services is less than nursing home care. Therefore, making an investment in more home health services actually can lead to decreased costs.

In terms of respect for persons, home and community-based services are more likely to uphold standards of self-determination in daily living, as the individual remains in his/her home. Even with aides and nurses, the decision-making activities are those of the individual, so there is inherent respect for the individual’s autonomy. Relating this to the principle of protecting those with diminished autonomy, this source of care operates under the belief that protection does not mean stepping into the shoes of the physically disabled. State officials should seek input of the affected communities, but it is even more important that they protect the autonomy of those with diminished autonomy to allow them to make decisions in the face of opposition. This shows more respect to the individual, is much less prescriptive, and treats the physically disabled like other members of society, which they are.

The concept of beneficence applies here by seeking to secure the well-being of the physically disabled individuals. Beneficence is an interesting standard, as it inherently applies to the individual but also requires an action by the State. To be beneficent, a policy must recognize the long-term risks and benefits of a particular action, and such a response should be in the

30 Ibid.
interests of the physically disabled person. Home and community based services seek to do no harm and maximize benefits to the individual. It is possible, however, that some decisions to receive care in a particular location could be biased for or against institutional care, and ethical decisions should be made devoid of internally held biases. Despite this, it is important to note that beneficence is generally upheld by this care option.

Finally, the analysis surrounding home health and justice shows that it is better to look at the population from an individual need perspective rather than as a singular community. Home health prioritizes individual needs over community needs since the care provided occurs in a way that inherently values independence for the physically disabled. The principle of justice cannot be biased, and including more than one option is an effective way to counter bias towards having a singular option for care. This relates to arguments about treating physical disability as a diagnostic test rather than a form of existence. Claiming that all people receive the same minimal level of care (e.g. institutional care which places the physically disabled in a setting that allows State actors or medical personnel greatest ease in dispensing treatment) ignores the differences in individual needs. Cost should not be a factor in determining the guiding principles of a system that automatically incorporates competing interests for action, and the objectives of State action should be compared to cost, not analyzed as a factor of cost.

**Discussion of Autonomy and Policy**

With these ethical standards in mind, consider how both a person with a physical disability and a state Medicaid agency should proceed. Home health services are focused on the individual and his/her needs, and study after study has proven its cost-benefit indications\(^\text{32}\). Therefore, the level of care provided is above the level of care from nursing facilities in that

respect. However, institutionalized care facilities allow for quicker interaction with care professionals, many of whom are on staff or on-call for the facility. The required accreditation reveals more scrutiny for institutionalized care, so the practitioners are more likely to have been trained more rigorously to adapt to specific scenarios. Additionally, home health nurses and aides tend to be younger, so their exuberance for helping people may not equate to their skill at their profession.33

Finally, the desires of the individual must be taken into account. If their conditions allow it, home health services are preferred since it allows individuals to remain integrated with their families and communities34. Therefore, home health services as a policy decision reflect two of the three ethical criteria for analysis, compared to the training and expertise of institutionalized care. By defining autonomy in the context of this policy decision to consider cost, it is important that the state of Illinois not limit access to home health services because it deems its financial interests more important than the criteria outlined above. Cost matters, but creative thinking can allow for a more adaptive and meaningful approach.

Conclusion

The autonomy of the physically disabled individual is of the utmost importance; both the individual and the state have an interest in protecting that person’s rights and freedoms. However, the constraints of budgetary battles have caused home health benefits to be threatened in certain states. The fact that there is little in the current body of research knowledge about this situation suggests that the public agrees with the state’s responses due to the budget constraints,

or that the current definition of justice is a community-based approach which disregards individual protections and does not respect individual autonomy. Cost-neutrality is important, but ethically, a person’s life matters more than a politicized budget. The significance of this decision should not be lost, and the conversation must continue to develop policies more amenable to all parties.
LOLETTA M. ORR POSTDOCTORAL STUDENT WRITING COMPETITION

Loletta M. Orr Award Winner
Author: Philip Eskew, DO, JD, MBA
Heart of Lancaster Regional Medical Center
DIRECT PRIMARY CARE: A LEGAL AND REGULATORY REVIEW OF AN EMERGING PRACTICE MODEL

Abstract

Direct Primary Care ("DPC") practices are a type of retainer practice where physicians directly charge patients a periodic fee and avoid any third party fee for service payments. These physicians have been small and overlooked group for many years, but the recent growth of the model demands attention. Previously tacit insurance commissioners have taken notice. Laws enacted by six state legislatures and the Affordable Care Act provides a background from which a legal framework can be developed. This article will articulate “business of insurance” concerns encountered by DPC physicians including recommended contractual provisions to minimize this risk, compare state laws written chiefly to address this concern, consider the DPC provisions of the Affordable Care Act, and briefly consider tax and scope of practice policy implications of the DPC model.

A Definition & Introduction

A retainer practice model involves a contract between the physician and patient whereby ongoing primary care services are provided in exchange for a periodic fee. For the practice to qualify as a direct primary care practice (a subset of the retainer category) the practice must 1) charge a periodic fee, 2) not bill any third parties on a fee for service basis, and 3) any per visit charge must be less than the monthly equivalent of the periodic fee. Billing third parties on a

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fee for service basis in addition to the periodic fee is formally called the fee for “non-covered” services model, a practice commonly described as “double dipping,” commonly used by practices many describe as “concierge.” The fee for non-covered services model is used by groups such as MDVIP and SignatureMD. In a DPC practice third parties may pay the periodic fee on behalf of the patient, but traditional third party fee for service billing is strictly prohibited. If the per visit charge were larger than the monthly fee, the practice would be considered a cash pay urgent care facility. Figure 1 demonstrates terminology describing retainer practice subsets.

The DPC model was originally used by only a handful of pioneers. Garrison Bliss, MD, (of Qliance in Seattle) Vic Wood, DO, (of Primary Care One in Wheeling, WV) and Brian Forrest, MD (of Access Healthcare in Apex, NC) are the three physicians credited most with growing the DPC model in its earliest stages. DPC pioneers were present in other locations over a decade ago as well, and these include John Muney, MD (of AMG Medical Group in New York City) and Robert Fields, MD (in Onley, Maryland). Each of these individuals was faced with inquiries from their respective state insurance commissioner regarding their practice models. Some physicians were threatened with criminal prosecution for the unlawful sale of insurance.


4 Wu, WN., Bliss, G., Bliss, EB., Green, LA., Practice Profile A Direct Primary Care Medical Home the Qliance Experience, Health Affairs, 2010 May;29(5):959-62.,
Six states have legislation designed to address this concern, but dispositive case law remains absent.

A History of the “Business of Insurance” Concern

When Vic Wood, DO and Garrison Bliss, MD established their practices, they received letters from their respective state insurance commissioners informing them that they would need to discontinue this model or face criminal prosecution for engaging in the unlawful sale of insurance.9 Similar insurance commissioner inquiries in many states slowed wide adoption of the DPC model, but eventually Dr. Bliss and Dr. Wood were able to convince the Washington and West Virginia legislatures to pass legislation clarifying that the DPC practice model was not considered insurance. Similar motivations led to legislation in Utah and Arizona, where DPC physicians were threatened, only to successfully obtain legislative protection. Louisiana, through the efforts of Greg Waddel of the Louisiana State Medical Society10, and a persuasive white paper,11 appears to be the only state that proactively passed DPC legislation without any individual physicians receiving insurance commissioner threats. While it is fortunate that state legislatures have been receptive to physician concerns, each individual DPC physician’s decision to avoid a courtroom battle with the insurance commissioner has led to a lack of dispositive legal precedent.

Insurance commissioners argued that by offering full scope primary care to patients for a fixed monthly fee, too much risk was being transferred from the patient to the physician. What if too many patients required care on the same day and the care could not be delivered as promised? To analyze this argument one must begin by agreeing on a common definition of insurance. Each state is able to define this term individually. The Iowa Supreme Court’s definition of insurance is a helpful example. Insurance “denotes a contract by which one party, for a compensation called the ‘premium,’ assumes particular risks of the other party and promises to pay to him or his nominee a certain ascertainable sum of money on a specified contingency.”

In a 1978 case reviewed by the Supreme Court of Iowa (Huff v St. Joseph’s Mercy Hospital of Dubuque Corporation) a hospital developed a prepaid obstetrical contract plan where the hospital would agree to furnish all necessary hospital services for seven days relative to childbirth for the mother for $400 paid at least fifteen days prior to delivery. If the hospital stay exceeded seven days, the regular rate would be charged beginning with the eighth day. If the patient’s charges were less than $400, or she did not enter the hospital she would be given a partial or full refund. The hospital used portions of the $400 to pay any physician service fees and lab fees, and discussions why the agreement did not amount to a health maintenance organization were included in the court opinion as well. The Court held that these contracts were not subject to insurance because “they do cover the risks of assorted complications but the principal benefit or effect is the hospital care as opposed to a minimal indemnity feature. Additionally, the contracts in their operation are not insurance because there is [an] express provision for refund or additional charge depending on the actual hospital expense incurred.”

12 State v. Timmer, 260 Iowa 993, 999, 151 N.W.2d 558, 561 (Iowa 1967).
Winning the Business of Insurance Argument

If the DPC practice contracts between physicians and patients are structured correctly, the DPC physician has an excellent legal argument against an aggressive insurance commissioner. An insurance commissioner will focus chiefly on risk in their analysis of whether a DPC practice is engaged in the unlawful sale of insurance.14 Steps can be taken to reduce risk transfer in the patient-physician DPC contract, easing the concerns of insurance commissioners. Here are ten reduce-your-risk suggestions for physicians concerned about the possibility of an aggressive insurance commissioner: 1) limit the number of patients in your panel, 2) define your scope of practice (list services covered by the periodic fee and others at additional cost), 3) include contractual and marketing disclosures that your DPC practice is NOT insurance, 4) recommend that patients purchase comprehensive insurance coverage, 5) permit patients to terminate the arrangement at any time with a pro-rated refund, 6) hold any funds paid more than one month in advance in a separate escrow account, 7) require that all patients visit the practice at least annually, 8) require that each individual patient sign a contract with the practice (even if an employer is paying the periodic fee on behalf of the patient) 9) consider listing a contractual cap on the number of office visits and/or charging a per visit fee (in addition to the periodic fee), and 10) consider billing the patient at the end of the service period rather than the beginning.

When describing and defending the practice model, remember to articulate that the greatest value of a DPC practice is ongoing continuity of care for all member patients. While the ability to rely on the DPC physician to minimize emergency department or urgent care usage is important, “being available” for these contingent events is not the central feature of the DPC

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model. Do not speak in terms of patient “utilization” of your services. Do not advertise or name your practice “unlimited care,” which implies more than standard primary care services. Require that all patients have a physical visit at least once per year. This allows the practice to demonstrate that the periodic fee is for ongoing care.

Patient panel sizes vary widely across DPC practices. Many have publicly stated that they have around 600 patients in their panel, while others are known have as many as 2,000 patients in a panel. No number is dispositive, but simply listing a panel cap is a helpful defense technique. A practice may select a higher cap to provide more flexibility. An individual physician is free to decide how much he would like to work, and panel size will likely vary based on the age and acuity of the patients in each panel.

State By State Comparisons – Beginning to Define Direct Primary Care

Most state insurance commissioners have not documented official stances on the limited number of DPC practices in operation and continue to take a watchful waiting approach. While DPC practices have been located in most states, DPC related legislation has been enacted in only six states: Washington\(^\text{15}\), West Virginia\(^\text{16}\), Oregon\(^\text{17}\), Utah\(^\text{18}\), Louisiana\(^\text{19}\), and Arizona\(^\text{20}\). A summary of elements in each enactment is provided below in Table 2. Each of the six states that enacted DPC legislation wanted to encourage DPC practices to grow by reassuring them that

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\(\text{17}\) ORS § 735.500, 735.510 (2011). Available at: http://www.oregonlaws.org/ors/735.500 (last accessed on July 6, 2014).


they would not be regulated as insurers. Some states achieved this aim more effectively than others, but the goal of any state legislation should be more than merely addressing “business of insurance” concerns. Providing a clear definition of the DPC model, an appropriate DPC scope of practice description, and alignment with federal ACA provisions are issues that have generally been unaddressed. Only three of the state acts attempt to define direct primary care, while the other three fail to reference the term at all. Fortunately a definition can be found in the Affordable Care Act which contains a provision to permit direct primary care medical homes to participate in insurance exchanges with wrap around health plans.21

The DPC model went by many names prior to the passage of Washington state legislation in 2007. Washington’s law states that “a direct practice must charge a direct fee on a monthly basis” and does “not accept payment for healthcare services provided to direct patients from any entity” subject to the state’s insurance code.22 Louisiana’s legislation contains similar provisions without specifying a monthly basis as the specified payment period, and was clearly modeled after Washington’s law.23 On its face, these provisions in the Washington and Louisiana laws appear to prohibit the usage of a third party insurer to pay the periodic fee on behalf of the patient, and this discrepancy will need to be addressed as large cohorts of patients seek to enter a DPC relationship in a bundled payment fashion through healthcare exchange purchases (per the ACA – to be discussed below) or in Medicaid managed care pilots, activities that are already taking place in Washington.24 Arizona defines a direct primary care provider plan as a “practice that collects on a prepaid basis fees to conduct primary health care for enrollees,” a generally vague and unhelpful definition that effectively forbids the physician from billing after the

24 Bliss, G – Personal Communication, June 2014.
services have been provided (at the end of the month). Each of these three definitions is a poor attempt to define DPC, but represents a better effort than West Virginia, Oregon, or Utah which omitted the phrase DPC entirely from their laws addressing retainer practices.

Poor or absent definitions combined with decisions to lump various types of retainer practices together (namely DPC and concierge) have created confusion. Both Washington\textsuperscript{25} and Oregon\textsuperscript{26} provide a list of qualified practices, but their listing of retainer practices demonstrates that they have lumped together DPC and concierge practices. Separate laws should be authored for each of these different retainer models. Concierge groups are less likely to gain the attention of insurance commissioners because they charge a periodic fee \textit{in addition} to traditional third party fee for services charges. Concierge practices face more traditional legal risks in the form of False Claims Act cases along with stark and anti-kickback laws.

\textbf{Affordable Care Act Provision for DPC Participation in Insurance Exchanges}

The Affordable Care Act contains a provision in Section 10104 stating that HHS “shall permit a qualified health plan to provide coverage through a qualified direct primary care medical home plan that meets criteria established by the Secretary…”\textsuperscript{27} In later announcements in the Federal Register, HHS defined a Direct primary care medical home plan as “an arrangement where a fee is paid by an individual, or on behalf of an individual, directly to a medical home for primary care services, consistent with the program established in

\begin{flushleft}
\footnotesize
\textsuperscript{27} The Patient Protection and Affordable Care Act, Pub. L. No. 11-148, 124 Stat. 119, § 10104 (Mar. 23, 2010).
\end{flushleft}
Washington.” 28 HHS applied an appropriately broad definition of primary care services as “routine health care services, including screening, assessment, diagnosis, and treatment for the purpose of promotion of health, and detection and management of disease or injury.” 29 Each state considering passing DPC legislation should take note of this broad definition and scope of practice description. States should ensure that their legislation does not enact any barriers for DPC practices that wish to obtain patients via the insurance exchanges. Model legislation has been discussed by many leaders in the DPC field, and states could start here when considering potential legislation. 30

Finally, federal IRS treatment of DPC practices remains unsettled. In spite of the ACA language defining DPC practices as independent of “health plans,” current IRS interpretation is that DPC practices are another “health plans,” a decision that means that periodic fees are currently not deductible as a health expense or available for health savings account usage. 31 Efforts are underway to change the IRS treatment of DPC practices (no longer treating them as “health plans”) so that expenditures in this area may be appropriately treated as health expenses. 32 A change from the IRS health plan designation will likely result in DPC scope of practice guidance designed to restrict the types of DPC services eligible for favorable tax treatment.

Summary

Family physicians electing to operate a DPC practice should be aware that legal, policy, and regulatory issues are continually evolving. Risk averse physicians should follow the ten recommendations listed above to minimize the risk that their practice will face unlawful “business of insurance” accusations. The lack of legislation the majority of states should not dissuade informed physicians from considering the DPC model. Only three out of six states with legislation aimed at encouraging DPC practices made any attempt to define DPC or similar terms, and the three that attempted a definition largely missed the mark. Physicians wishing to educate policy makers about the DPC option should look to the three part definition above and model legislation. Monitor the anticipated debates about the tax treatment of DPC periodic fees, and anticipate the scope of practice discussions that are likely to follow.
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Figure 1 Membership Medicine Hierarchy

Retainer Medicine / Membership Medicine

- Direct Primary Care
- Split / Hydbrid
- Concierge / Boutique
<table>
<thead>
<tr>
<th>State</th>
<th>Washington</th>
<th>West Virginia</th>
<th>Oregon</th>
<th>Utah</th>
<th>Arizona</th>
<th>Louisiana</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Direct Patient-Provider Primary Health Care</td>
<td>Preventive Care Pilot Program</td>
<td>Requirements for Certification as Retainer Medical Practice</td>
<td>Medical Retainer Agreements</td>
<td>Direct Primary Care Provider</td>
<td>Direct Primary Care Practice</td>
</tr>
<tr>
<td>Phrases Defined</td>
<td>Requires that a &quot;direct fee&quot; be charged on a monthly basis, no definition or use of term periodic fee</td>
<td>&quot;primary care&quot; poorly defined using terms basic and simple</td>
<td>&quot;primary care&quot; = outpatient, nonspecialist, &quot;retainer medical fee&quot; poorly defined</td>
<td>&quot;Routine&quot; health care services</td>
<td>Poor definition of &quot;DPC Provider Plan&quot;, Poor definition of &quot;Primary Care Provider&quot;</td>
<td>failed to define periodic fee, vague definition of &quot;direct fee&quot;</td>
</tr>
<tr>
<td>&quot;Not Insurance&quot;</td>
<td>Yes (&amp; HMO)</td>
<td>Yes</td>
<td>Unclear - the only time the phrase &quot;not insurance&quot; is used is in the mandatory disclosures section</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Reporting Obligations</td>
<td>Yes</td>
<td>Yes - Severe</td>
<td>Yes</td>
<td>None</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Mandatory Disclosure</td>
<td>Yes</td>
<td>No</td>
<td>Yes (in both contracts and marketing materials)</td>
<td>Brief &quot;not insurance&quot;</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Discontinue Care Provision</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>None</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>&quot;Double Dipping&quot; Prohibition</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Marketing Restrictions</td>
<td>No</td>
<td>Severe</td>
<td>No, only via disclosure requirements</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Inadvertent Pilot/Exchange Ban</td>
<td>Potentially</td>
<td>No</td>
<td>Likely</td>
<td>Potentially</td>
<td>No</td>
<td>Potentially</td>
</tr>
<tr>
<td>Mention DPC as option in exchange</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Scope</td>
<td>Mild restrict, primary care is broadly defined</td>
<td>Narrow</td>
<td>Narrow</td>
<td>Broadly defined</td>
<td>Broad</td>
<td>Mild restrict, primary care is broadly defined</td>
</tr>
<tr>
<td>Policing Authority</td>
<td>Must submit annual statements to WV state &quot;Health Care&quot;</td>
<td>Dept of Ins - may investigate and subpoena,</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>LA State Medical Board</td>
</tr>
<tr>
<td>Appendix A: Model Legislation Checklist</td>
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</table>
Define “Direct Primary Care”
Specifically and explicitly state that DPC is NOT insurance (reference the state insurance code)
Discourage any formal registration with the state
Oversight from the medical board rather than the insurance commissioner
Require an individual contract with each patient, which must contain:
   Mandatory disclosures
   A phrase specifically stating that “this is NOT insurance”
   Discontinuation of care provisions
Avoid an overly narrow primary care scope of practice interpretation
Include a provision promoting the formation of “Wrap around” health insurance in the state exchange
Appendix B: Additional State Issues Worth Considering

Vermont – Passed Act 48 in May of 2011. This law is designed to implement a single payer health system in the state as of 2017. The Green Mountain Care Board will have the authority to set all health care prices, and thus may effectively ban all private medicine through price setting measures. DPC practices might be forced to change their prices or leave the state entirely.33

West Virginia – The requirements to participate as a DPC practice within their “Preventive Care Pilot Program” are rigid. Any DPC practice would likely prefer to market itself freely to potential patients, avoid certificate of need-like applications for operational decisions and pricing approvals, and avoid strict reporting requirements. This means that a DPC practice would likely operate outside the Preventive Care Pilot program, without the guaranteed protections from the insurance commissioner’s office.

Oregon – Legislation related to DPC is especially poor, containing onerous reporting requirements and technically failing to provide any assured protection from the insurance commissioner. Physicians planning to operate a DPC practice in Oregon should not register in the state program, and instead defend the DPC practice on its merits in the event of a business of insurance argument from the insurance commissioner.

Arizona – This state passed DPC legislation defining DPC as “not insurance,” but due to poor language and the failure to include multiple provisions related to patient (consumer) protections, it is unlikely to survive any judicial scrutiny. DPC physicians in the state of Arizona should continue to practice as if they were in a state with no DPC “business of insurance” protection laws.

Maryland – A former Maryland Insurance Commissioner issued harsh guidance in 2009.34 Fortunately numerous practices are persisting in Maryland in spite of this aggressive guidance, and the current commissioner is using the all too common “wait and see” approach.

New York – AMG Medical Group was threatened by an insurance commissioner using state HMO laws, and the group agreed to increase the amount of their per visit fee to appease regulator concerns.35

GENERAL SESSION XI
MEDICAL AND LEGAL ETHICS

SUNDAY, MARCH 1, 10:45 - 11:45 AM

Brera 4-5

MODERATOR:
Karin Waugh Zucker, MA, JD, LLM, FCLM, Prof., US Army - Baylor University Graduate Program in Health and Business Administration, Ft. Sam Houston, Texas
ACLM ETHICS 2015

“Doing What’s Right When No One Is Looking”

Mitchell D. Forman, D.O., FACR, FACP, FACOI
Dean & Professor
Touro University Nevada
College of Osteopathic Medicine

Weldon (Don) Havins, MD, JD, FACS, FCLM
Professor & Director, Medical Jurisprudence
Touro University Nevada

Objectives

Using a series of vignettes portraying interactions between clinicians and their patients, participants will:

• Identify inappropriate professional behaviors
• Define ethical dilemmas
• Discuss legal aspects of clinician/patient/commercial third party interactions

Urine or You’re Out!

When Privacy is a Social Thing
Your Hair
or
Down There!

If Looks Can Kill,
What Can a Phone Call Do?

... Well they did have access!
Telemedicine
State law variation
  – ATA report September 2014
  – Oklahoma vs. Nevada example

Marketing
- Individuals
- Hospitals
- Through corporations
- Insurance substitutes

Consultation Problem?

Privacy Trade-off?
Duty to Disclose Substandard Care
Confidentiality Issue?
HIPAA Violation?

Herbal Options
Who Benefits?
Stark Self-Referral Violation?

U Care
About Medicare?
I’d rather have a bottle in front of me, than a frontal lobotomy
DENTAL SESSION I

FRIDAY, FEBRUARY 27, 1:30 - 3:00 PM

Brera 3

MODERATOR:
Chester Gary, DDS, JD, FCLM
Evidence Based Dentistry
What Why and Where
Russel Christensen DDS
Diplomate American Board of Endodontics

"The difference between the public library and the medical/dental library is that the public library clearly separates fiction from non-fiction"

Dr. Herbert Schilder
A Search For Truth

What is Evidence Based Dentistry?

A Search For Truth

What is the Truth?

Breast Cancer and Root Canals

Price-Pottenger

THE LANCET

Wakefield's article linking MMR vaccine and autism was fraudulent

The evidence of falsification of data should now close the door on this damaging vaccine scare
Aren't we all using the best available evidence in our practice?

- “For each of the past 10 years an average of 6,700 articles about dentistry have been published. This accounts only for journals that are abstracted in the more common databases such as Medline and PubMed. Thus even if a dentist has read one or two peer reviews journals every month for the past 5 years they would still have missed more than 33,000 articles”. Glick JADA 2012
- “There are more than 500 oral health clinical trials published each year in each clinical specialty, in more than 30 journals. This is more than 1 article per day, 365 days per year!
- To stay current, each day, a clinician would need to identify, obtain, read, appraise, and implement 1 new article – an impossible task”. Niederman, R. Director EBD Center Forsyth Institute

What about Evidence Based Medicine?

- “30–40% of medical patients do not receive care according to the best evidence and 20–25% of care provided is not needed or potentially harmful”. McClynn NEMJ 2003
- How many established standards of medical care are wrong? It is not known. Medical practice has evolved out of centuries of theorizing, personal experiences, bits of evidence, expert consensus, and diverse conflicts and biases. Rigorous questioning is difficult and trials mostly deal with trivialities or are efforts to buttress product sales. It is possible that some entire medical subspecialties are based on little evidence. Their disappearance probably would not harm patients and might help salvage health budgets. V. Prassad, MD JAMA January 2012

Dental Practice of EBD

- Derek Richards DMD editor of EBD Journal 2006
- “6–7% of dental treatment is EBD
- More than 60% of general dentists turn to friends and colleagues for evidence rather than read a text or journal

Where do we get our evidence?

Experts–Prophets–Vendors

Experts–Prophets–Vendors

Science or Sales?

Unfortunately the most read dental publications are similar to these. They tend to fill their pages with the proclamations of the prophets experts and vendors often with minimal or no disclaimers and some actually claim they are peer reviewed journals.

EBD requires questioning what we think we know

- Are 6 month prophy recalls actually necessary?
- Does flossing actually prevent caries?
- Are pit & fissure sealants effective, who when where?
- Do you need to wait 6 months following a myocardial infarction for dental care?
- Bisphosphonates–Actual Risk– Drug holiday before surgery?
- Do implants have a higher success rate than RCTs?
- Amalgam–What is the truth?
- Antibiotics: Which, when, how long?
Origins of Evidence Based Medicine

- **Archie Cochrane** - A British Physician in 60–70’s who was a strong advocate of randomized clinical trials (RCT’s) and the dissemination of this information for clinical practice
- **The Cochrane Center** at Oxford was founded in 1992. It is an international collaboration of 28,000 people in 28 countries tasked with developing Cochrane Systematic Reviews of RCT’s. Cochrane Reviews are considered the gold standard of systematic reviews
- **David Sackett** - A Canadian Physician coined the primary definition of EBM at McMaster University in the 90’s
  - "Conscientious, explicit and judicious use of the best evidence in making decisions about the care of individual patients"

What is EVIDENCE-BASED DENTISTRY?

According to the ADA...

Evidence-based dentistry (EBD) is an approach to oral health care that requires the judicious integration of systematic assessments of clinically relevant scientific evidence, relating to the patient’s oral and medical condition and history, with the dentist’s clinical expertise and the patient’s treatment needs and preferences.

Three Components of EBD

- Is an approach to oral health care
- Is a method to acquire, understand and apply the most current science
- Includes the patients needs and preferences

Evidence-Based Dentistry Is NOT....

- Cookbook dentistry
- A standard of care
- A mandate of what must be done
- A substitute for clinical judgment

"Evidence alone is never enough to make a clinical decision”  
Vicori Monturi – Mayo Clinic

“External Clinical evidence can inform but can never replace individual clinical expertise”  David Sackett

How much is enough?

Do we need an RCT to answer this question:

Will using a parachute save lives?

Group 1: Jump with parachutes
Group 2: Jump without parachutes

![Image of a person jumping with a parachute]

Systematic Reviews - Strong

- RCT’s
- Cohort study
- Case control study
- Case series
- Case report
- Expert opinion
- Animal research
- Bench-top research - Weak
Evidence Based Dentistry/Medicine Resources
- ADA Evidence Based Dentistry
  www.EDB.ada.org
- Cochrane Collaboration www.cochrane.org
- Center Evidence Based Medicine
  www.cebm.net/
- JAMA Evidence www.jamaevidence.com/
- This is a short list of available resources

How to Practice EBD
Always be questioning what you think you know.
- What is the evidence?
- What is the level of evidence?
- What is the quality of evidence?
- Does this apply to this patient?

Use your own judgment
- Based on your experience and judgment should you recommend this?
- How does this patient's needs and preferences influence this choice?

What is the Truth?
DENTAL SESSION II

FRIDAY, FEBRUARY 27, 3:30 PM - 5:30 PM

Brera 3

MODERATOR:
Frank Riccio, DDS, JD, FCLM
DENTAL SESSION III

SATURDAY, FEBRUARY 28, 8:00 AM - 9:45 AM

Brera 3

MODERATOR:
Joseph Graskemper, DDS, JD, FCLM, DABMM
The Requirement for a CBCT Report

Structuring a Solution

Dale A. Miles
BA, DDS, MS, FRCD (C)
Dip. ABOM, Dip. ABOMR

Why?

1. Dentists must look at all of the scan data
2. Dentists must “re-tool” (anatomy especially)
3. Medico-legal requirement for “records” (chart notes, report, etc…)
4. Reportable/referable findings
5. Risk and liability reduction
6. Appropriate referral to physicians and specialists

“Diagnostic Responsibility”

Radiographs and the Responsible Dentist

Areas that must be examined if captured

1. Paranasal sinuses
2. Nasal cavity
3. Airway
4. Cervical structures
5. Temporomandibular joints
6. Dental findings
7. Other findings

A Failing Implant Won’t Kill You, But a Carotid Plaque May!

Carotid plaques
Narrative Vs. Structured Report?

1. Dentists are not real good at “records”
2. Many dentists do not know what they are seeing their scans
3. Dentists like “cookbooks”
4. Dentists want it “simple”

Even medical radiologists have this debate


"The patient should be referred to her primary care provider for evaluation of hypertension and stroke risk as well as possible dysglycemia and/or renal problems."
Causes for trigeminal nerve injury
- Anesthesia
- Teeth extraction
- Dental implants
- Root canal treatment
- Surgical procedures
- Maxillary floor augmentation

THE WISDOM TRIANGLE MANAGING THE RISK OF 3RD VS. 5TH
Rood criteria, cbct and coronectomy
N. Givol DMD OMFS
Soroka university medical center
A. Ilgynaev DMD OMFS
Israel Defense Force

Me worry?
100% give anesthesia
41% insert dental implants
34% extract impacted wisdom teeth
24% perform augmentations
21% perform periodontal surgery

M.R.M data base for causes to trigeminal injury
- 27% of trigeminal injuries are due to wisdom teeth extractions

Injury due to wisdom tooth extraction
- 1-0.5% permanent injury
- Lingual or IAN
- 5000 - 10000 patients a year in USA

Wisdom teeth extraction
- The most common procedure in oral surgery
- About ten million teeth each year in USA
**Injury due to wisdom tooth extraction**

Injury to ian
- Happens during root removal
- The operator should understand the relation between the roots and the mandibular canal and identify the risk

**Back to bases**
- The best treatment is prevention
- Consider the indications
- Avoid myths:
  1. There is more pathology around wisdom teeth.
  2. Extraction at early age is less traumatic
  3. Anterior crowding is a result of third molar eruption

**Root criteria**

Seven radiographic signs of the relations between the root and the mandibular canal

Root related:
- Darkening of the root
- Deflection of the root
- Narrowing of the root
dark bifid root apex

Canal related:
- Narrowing of the canal
- Diversion of the canal
- Interruption of the white line

**In surgical procedures**

Main cause to injury is wrong interpretation of the imaging

**Deflection of the root**

**Darkening of the root**
Interruption of white line is well known
The other signs are not known enough
Cbct is the Gold standard in oral imaging. Several issues are associated with the use of CBCT.

BMJ May 2013
- Study of patients 0-19 years old
- Had CT exams between 1985-2005
- A year post CT 24% more cases of malignancies un the study group
- 5-10 years post CT more malignancies

Study of patients 0-19 years old
Had CT exams between 1985-2005
A year post CT 24% more cases of malignancies, than the study group
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Minimize the risk
- Justification: “whether the benefits outweigh the risks”
- Each patient should be considered an individual. Routine protocols of imaging are not compatible with this.”

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Medical exposure … shall show a sufficient benefit, weighting the total potential diagnostic of therapeutic benefits it produces … against the individual detriment that the exposure might cause, taking unto account the efficacy, benefits and risks of available alternative techniques…”

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“Each patient should be considered an individual. Routine protocols of imaging are not compatible with this.”

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Minimize the risk
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Traditionally dentist make their own interpretations of the imaging
CBCT: Enlarges the scope of imaging
In the field of imaging
In the resolution of imaging
Some of the dentists lack the knowledge for proper interpretation

Example

Degenerative changes in cervical vertebra

Interoperation of imaging

Summery
- Indications
- Risk evaluation
- Understanding panoramic X-ray
- CBCT benefits and risks
- Alternative modes of treatment

PARTIAL ODONTOECTOMY
- Direct relation between the roots and the canal
- Removal all parts of the crown below bone height
- Re-entry is needed in 2-6%
- If infection occurs the root migrates far from the canal

THANK YOU
Informed Consent

Toan Foeng (Bill) Tham, DDS, JD
Assistant Professor
University of Nevada, Las Vegas
School of Dental Medicine

So What is Informed Consent?

- Informed Consent (IC) is a process of providing people with sufficient information so they can make intelligent informed decisions about whether to accept or refuse treatment, care, activity, etc.

Concept-Autonomy

- Patient’s right to determine what to do with his or her own body - patient has the right to decide what risks to take

Let take a look at the case of Mary Schloendorff (1914) which clearly demonstrate the concept of autonomy

- Agreed to be examined under anesthesia to determine if a diagnosed fibroid tumor was malignant
- Specifically told the surgeon *not* to remove it
- He examined her ... and did remove it
- She sued him

The Court found that the operation to which the patient did not consent constitute medical battery

Battery is defined at common law as any unlawful touching of the person of another without consent

Here is the quotation from the opinion of Justice Cardozo in Schloendorff which rooted in the principle of autonomy

“Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages...”
What are the functions of Informed Consent?

First legal requirement: Adult of Sound Mind. ‘Adults’ are generally considered to be “of sound mind”
- Unless they are obviously impaired by drug, alcohol, or mental or physical disease. Further, patients under the influence of narcotic painkillers or other psychotropic drugs are likely to be considered “impaired” by the courts even though they may appear lucid.

What are the legal requirements when you provide patient with informed consent?

IC: Second Legal Requirement
- Has been presented with all the material facts that a reasonable person would consider in making the decision to accept or refuse care.

Standards of Disclosure

Professional
- What reasonable professionals tell patients
- This is the standard under Nevada law

Reasonable Person
- Asks what the reasonable patient would want to know, rather than what the MD thinks the patient should know

Subjective
- Maximizes the right of an individual patient to learn how the procedure will impact her personally

How do you effectively convey the “diagnosis”?
- This needs to be explained on the patient’s level of understanding.
- dialogue with the patient on her own level of understanding, and listening to her as well as talking to her.
- If she does not speak English well, consider using Medical interpreter to maximize understanding.
- Avoid family members, medical explanations are difficult to interpret.
- It’s okay to use technical terms as long as follow immediately with a lay explanation.
Third Requirement: No Material Misrepresentations

- Include any misstatements or omissions of facts made to obtain informed consent.
- Misrepresentations can also be implied—for example, offering to perform a procedure in your office while knowing you lack of optimal equipments. Likewise failure to disclose the fact that you seldom perform a difficult proc.

Professional Negligence

- "Professional negligence" means a negligent act or omission to act by a provider of health care in the rendering of professional services, which act or omission is the proximate cause of a personal injury or wrongful death. The term does not include services that are outside the scope of services for which the provider of health care is licensed or services for which any restriction has been imposed by the applicable regulatory board or health care facility. (NRS 41A.015)

Nevada Malpractice Law

- "Malpractice" means failure on the part of a dentist to exercise the degree of care, diligence and skill ordinarily exercised by dentists in good standing in the community in which he or she practices. As used in this section, "community" means the entire area customarily served by dentists among whom a patient may reasonably choose, not merely the particular area inhabited by the patients of that individual dentist or the particular city or place where the dentist has an office. (NRS 631.075) (2011)

Lack of Informed Consent

- Can be a battery – an intentional wrong
  - Classic Intentional Tort
  - Elements:
    - Intent (Can prove an intent by lack of consent)
    - Harmful or Offensive Touching
    - Harm (can be physical or emotional)

Lack of Informed Consent

- Most courts see it as malpractice – negligent behavior
- In both cases, the physician or dentist does not need to perform the procedure negligently. Merely need to violate the patient’s right to consent to the procedure and to risks of the procedure.
A dentist has conclusively obtained the consent of a patient for a surgical or dental procedure if s/he has done the following:
- Explained to the patient in general terms without specific details, the procedure to be undertaken;
- Explained to the patient alternative methods of treatment, if any, and their general nature;
- Explained to the patient that there may be risks, together with the general nature and extent of the risks involved, without enumerating such risks; and
- Obtained the signature of the patient to a statement containing an explanation of the procedure, alternative methods of treatment and risks involved, as provided in this section. (NRS 41A.110) (2011)

Full disclosure is impossible.
Complete understanding is unattainable.
Belief that patients don’t wish to be involved in decision making.
Harmful effects of informing patients.
It takes too much time.

A consent to any dental procedure will be implied if:
- In competent medical judgment, the proposed dental procedure is reasonably necessary and any delay in performing such a procedure could reasonably be expected to result in death, disfigurement, impairment of faculties or serious bodily harm; and
- A person authorized to consent is not readily available. (NRS 41A.120) (2011)

Provide ample opportunity for consideration
Minimize coercion/undue influence
Use simple & clear language so the patient understands
Explain risks and alternatives
Get signed, written consent

Questions?
MINIMIZING MALPRACTICE LAWSUITS AND PATIENT COMPLAINTS RELATED TO DENTAL IMPLANT TREATMENT

American College of Legal Medicine 55th Annual Meeting
The Cosmopolitan Hotel, Las Vegas, Nevada
February 27-28, 2015

Rollin M. Matsui, B.Sc., D.D.S., LL.B., F.C.L.M.

DISCLAIMER

- This presentation is intended to provide information of a general nature only and is not to be taken as legal advice upon which you are to rely for specific situations.
- Appropriate legal advice should be obtained from your own lawyer prior to taking any action.
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Topics

- Legal liabilities Related to Implant Dentistry
- Key essentials for rendering appropriate Implant Dentistry
- Ways to minimize and deal with Dental Implant misadventures and patient complaints

Legal Liabilities

Malpractice Lawsuits

- Patient seeking compensation from the dentist for harm suffered arising from the dentist’s dental treatment.
- Are independent, separate from and unrelated to a Regulatory complaint or investigation.
- Not unusual for civil proceeding to be commenced by patient in addition to other legal proceedings (eg. regulatory).
- Due to high costs of implant dentistry, civil legal proceedings not uncommon.

Legal Liability: Bad Things That Can Happen to Dentists

- Malpractice Lawsuit
- Regulatory Complaint / Investigation
- Criminal Investigation
- Other Regulatory Investigations
Professional Misconduct, Complaints and Investigations

- A formal investigation by the Provincial / State Regulator when a patient files a written complaint against a dentist.
- Can be initiated by the Regulator if reasonable and probable grounds exist.
- Professional misconduct can include failing to obtain informed consent, meet the standards of practice.
- If misconduct proven, dentist can be suspended from practicing dentistry.

Criminal Liability

- Certain dentist conduct can attract criminal sanction.
- Allegations related to assault (no consent to touching), sexual assault, billing fraud can arise.
- Sanction can be imprisonment.
- May see increase in criminal sanctions if public dissatisfaction increases.
- Typically not common in implant dentistry.

When Does Liability Arise in Implant Dentistry?

Unsatisfactory Dentistry

- Implant Dentistry
  - Bone lost around implant causing chronic bleeding gums
  - Surgical Implant Placement Into Mandibular Canal Causing Paraesthesia
Legal Aspects of Incorporating Dental Implants in the GP Practice

January 22, 2010

Dr. Rollin Matsui

Unsatisfactory Dentistry

Patient presents with radiating pain. Dentist suspects bluspid. Substandard Implant treatment?

Unsatisfactory Dentistry: The failed Implant prosthesis

Paraesthesia?

Is this Substandard Dentistry?

Is this Negligence? Was Sinus Lift / Bone Graft Performed?
Key Essentials for Rendering Appropriate Implant Dentistry

Key Essentials
- Recognition of necessary elements integral to successful Implant Dentistry
- Educational Requirements
- Diagnosis and Treatment Planning Parameters
- Practitioner and Team Member Responsibilities

Key Essentials
- Proprietary Implant Systems
- Standards of Practice
- Informed Consent to Treatment
- Post-operative Management

Standards of Practice
- There is no printed standard of practice for the practice of implant dentistry in Ontario.
- Dentists must rely on continuing education courses, dental literature, colleagues and expert witnesses.
- Ontario Solution: Rely on Implant Guidelines published by the Provincial Regulator (Royal College of Dental Surgeons of Ontario).

Guidelines Evolve Over Time
- Latest edition issued by the College in May 2013.
- www.rcdso.org

RCDSO GUIDELINES May 2013
Educational Requirements & Professional Responsibilities for Implant Dentistry
**Importance of Guidelines**
- Are not deemed to be standards of practice of practice of the profession regarding implant dentistry.
- Guidelines may be used by the College in determining whether appropriate standards of practice and professional responsibilities have been maintained.

**Key Requirements**
- Key: Implant dentistry is about the creation of an implant supported prosthesis.
- Dentists utilizing dental implants in their practices require specialized knowledge and clinical skills related to both the surgical and prosthetic phases of treatment.
- Guidelines outline recommended educational and professional responsibility requirements for those practitioners wishing to use dental implants for their patients.

**Limitations of Guidelines**
- The Guidelines do not attempt to provide comprehensive information relating to the clinical steps necessary in providing dental implants.
- Onus is on the dentist to seek requisite knowledge prior to performing implant dentistry.

**KEY EMPHASIS**
- Guidelines require that even if you only perform the surgical placement of the implant, you must be knowledgeable about the prosthodontic aspects of the implant treatment and vice versa.
- The prosthetic dentist should be the "quarterback" of the implant case.

**Reality Check**
- For the surgeon, temptation is to just place the implant and let the prosthetic dentist "take it from there".
- For the prosthetic dentist, temptation is to just send the patient to the surgeon and let him/her do the surgery without input from the dentist.
- Miscommunication can lead to bad outcomes with great stress and high costs and Regulatory sanctions.

**Guidelines Recognize 2 Levels of Implant Dentistry Complexity**
- "Straightforward" placement and/or restoration of dental implants.
- "Complex" placement and/or restoration of dental implants.
- Incumbent on dentist to identify the type of implant case being considered when deciding if he or she is competent to render the implant treatment.
Initial Educational Requirements

- Prior to performing any implant procedure, dentists must have undertaken comprehensive training by means of a course(s) which adhere closely to specified criteria in the Guidelines.

- Course instructors should have had recognized comprehensive formal, preferably university-based, training and significant experience performing dental implant procedures.

Required Course Criteria

- Have didactic and clinical-related components with formal evaluation.

- Have a hands-on clinical simulation component with formal evaluation.

Course Content

- Teach methods and systems that have been shown to be successful and safe based on published scientific research preferably supported by longitudinal clinical studies that demonstrate the efficacy and effectiveness of the method and biocompatibility of the materials.

Course Duration

- Guidelines state if you provide both surgical and prosthetic phases of implant treatment, you must successfully complete a course or courses involving not less than 35 hours of instruction for each of the surgical and prosthetic phases, or 70 hours of combined instruction so that dentists learn the requisite information as set out in the Guidelines.

- If you limit practice to one phase only (surgical or prosthetic), you must successfully complete a course or courses involving not less than 35 hours of instruction for the phase practiced and 14 hours of instruction for the phase not practiced.

- If you provide surgical phase, you must be competent and experienced in dentoalveolar surgical procedures.

Importance of Communication

- Understand the importance of effective communication and shared responsibility between the various members of the dental implant team and other providers, and especially with the patient.

CAVEAT: This is critical if you want to minimize miscommunication and misunderstanding leading to a very unhappy patient.
Purpose of Educational Requirements

- The minimum educational requirements suggested in the Guidelines are adequate for most practitioners to begin “Straightforward” implant cases.
- Additional training and education should be completed before undertaking “Complex” implant cases.

New Technology

- It is the responsibility of each dentist to evaluate any new technology, products and techniques to ensure that their use is supported by valid scientific data and long-term studies, and that necessary Health Canada approvals are in place. www.mdall.ca.
- Caution is advised in extrapolating results from one system to another.

Professional Responsibilities

- Preliminary Evaluation and Treatment Planning by the prosthetic dentist.
- Pre-Surgical Assessment by prosthetic and surgical dentist.
- Finalization of Treatment Plan and Informed Consent by the prosthetic dentist (Guidelines set out details of what to be discussed with patients).

Professional Responsibilities

- Surgical Treatment by surgical dentist.
- Post-Surgical Follow-up by surgical dentist and prosthetic dentist.
- Post-Surgical Pre-Prosthetic Assessment by prosthetic dentist.
- Prosthetic Treatment.
- Long-Term Follow-up and Maintenance.
- Management of Complications.

Recordkeeping for Implant Cases

- Essential for defending yourself if sued or confronted with College investigation.
- Guidelines set out details required for surgical and prosthetic records.
- Very useful for risk management purposes.

Ways to Minimize and Deal with Dental Implant Misadventures and Patient Complaints

- Essential for defending yourself if sued or confronted with College investigation.
- Guidelines set out details required for surgical and prosthetic records.
- Very useful for risk management purposes.
Ways to Minimize Implant Misadventures and Complaints

- Understand true complexities of implant dentistry before rendering surgical or prosthetic implant dentistry or both.
- Obtain sufficient education for both surgical and prosthetic aspects of implant dentistry.
- Recognize your responsibilities and obligations for both surgical and prosthetic aspects even if you only perform one component of implant treatment.

Caveat

- Be critical when reviewing dental literature related to implant dentistry.
- Expert panel of periodontists designed a safety checklist for implant placement.
- Note: Focus of study was on surgical issues, less emphasis on role of the prosthetic dentist in implant placement.
- Consider using Ontario Implant Guidelines as a general guide if no implant guidelines are available in your jurisdiction.

Comprehensive training programs in the utilization of dental implants protect the public as well as the dentist.

Lack of adequate and/or inadequate clinical treatment and records may place the dentist at risk for civil proceedings and allegations of professional misconduct if there are adverse results due to the treatment rendered.

Activate Your Action Plan

- Notify your malpractice insurer and seek advice if patient seeking or could be seeking compensation or refund.
- Seek legal advice if complaint filed or could be filed with State Regulator.
- Seek advice from circle of competent specialists with whom you consult and refer to regarding implant cases as necessary.
- Maintain patient privacy and confidentiality.

How To Deal with Dental Implant Misadventures and Patient Problems

- In Ontario, compliance with the RCDSO Implant Guidelines will help provide basis for sound defence against allegations of dental malpractice or professional misconduct related to the provision of implant dentistry.
DENTAL SESSION IV

SATURDAY, FEBRUARY 28, 10:15 AM - 12:15 PM

Brera 3

MODERATOR:
Daniel L. Orr, II, DDS, MS, PhD, MD, JD, FCLM, DABLM
Dentists and the law: Headlines we’d rather not see

Irene Bober-Moken, DMD, MPH
Department of Comprehensive Dentistry
University of Texas Health Science Center
San Antonio, Texas 78229
February 28, 2015

Objectives
• Appreciate media’s role with professions’ reputation
• Know story behind dentists’ unsavory endeavors
  – Menace to society
  – Drug dealing
  – Torture
  – Murder
  – Desecrating bodies
  – War crimes

Dentist Pleads Guilty to Drug Distribution

AIDS Patient Infected by Dentist Dies

• Dr. David Acer
  – Full-blown AIDS 1987 (died 1990)
  – 6 patients contract AIDS
  – 2001: CDC – transmission unclear

Defrocked Dentist In Semen Suit

2004

– John Hall: injected semen into 7 women’s mouths
– Lost his license
– Jail-time

UK Dentist Struck off for Offering Female Genital Mutilation

“...conduct fell short of the standards expected of a registered dental practitioner...performed intimate exam...and talked with her about and planned to perform FGM on two children”

Dentist The Menace

Pediatric patients forcibly restrained
– Red marks on head “allergic reaction”

Al Qaeda’s Dentist

Terrorism

• Dr. Sohail Qureshi
  – Terrorist training in Pakistan
  – UK for fundraising
  – Convicted in 2008

Defrocked After Terrorist Material Found on Computer

• Dr. Umer Farooq pleaded guilty
  – 14 charges: possessing material useful in terrorism
  – Convicted: 2 years in jail (2012)
Dentist Pleads Guilty To Not Paying Taxes On Cocaine Profits

Dental school graduate: 1981
- Drug ring: Larry Lavin & “Yuppie Conspiracy”
  - Cocaine syndicate (1978-1984)
  - 20-yr term, fines & a 5-year probation
- Gov’t seized: $20M value cocaine
- Guilty (1986)
  - Operating criminal enterprise
  - Conspiracy w/ intent to distribute
  - Tax evasion

“Organ Grinder”

- Non-hospital recoveries w/o consent
- 1,077 bodies dismembered
- Parts in 10,000 surgeries (bone, skin, heart valves)
  - Recipients: HIV, Hep-C, syphilis and septic shock
- Charge: body stealing, unlawful desecration of human remains, conspiracy & abuse of bodies
- 18-54 year jail term
- Forfeit: $4.68 M

“The West’s Deadliest Dentist”

- Graduate Pennsylvania College of Dental Surgery 1872
- Killed two men and shot eight
- Arrested four times; attempted extradition to AZ

“I found him a loyal friend and good company. He was a dentist whom necessity had made a gambler; a gentleman whom disease had made a vagabond; a philosopher whom life had made a caustic wit; a long, lean blonde fellow nearly dead with consumption and at the same time the most skillful gambler and nerviest, speediest, deadliest man with a six-gun I ever knew.”

– Wyatt Earp

“Murder by Mercedes”

- 2002: struck husband, running him over multiple times
  - Having an affair with their former receptionist
- 1st-degree murder w/ finding of “sudden passion”
- Fined: $10,000 and 20 year jail term
- Dental license revoked

Torture

Papuan student from the highlands killed by two dentists
War Crimes

**War Crimes**

- Concentration camps
  - Sachsenhausen (10,000 died)
  - Buckenwald (16,000 died)
  - Mauthausen (119,000 died)

- Extermination camps
  - Auschwitz II (Birkenau) (1,125,000 died)

**Dental Gold**

- Amounts
  - Buchenwald: 182-504 grams every month
  - Mauthausen: 25 Kg
  - Treblinka: 8-10 Kg/week
  - Auschwitz-Birkenau*: 6 tons (up to 12 Kg/day)
  - Oranienburg-Sachsenhausen: 80,000 teeth found on in boxes after liberation

- Estimation:
  - 5 teeth extracted/individual
  - 3 gms. 22 carat gold/tooth

**War Crimes**

- Dr. Hugo Blaschke ( Brigadier General)
  - Responsible for dental treatment for SS, police & Gestapo
  - Treated Hitler, Goring, Goebbels, Borman and Himmler
  - Charge: exploitation of dental gold extracted from the dead
  - 10 years imprisonment but released 1948

- Dr. Hermann Pook (Colonel)
  - Heads dentists in concentration camps
  - "No conservation or restorative treatment. Only extractions, and with no anesthesia."
  - Ordered to gather dental gold
    - "On the feasibility of the re-using the gold from the mouths of the deceased" (Doctoral thesis of dentist Wiktor Scholz 1940)
    - Sept 1940 – extract gold from "survives & teeth that could not be cured"
    - Decree reinforced Dec. 1942 – "Profit" of about 4,000,000 reichsmarks annually
  - Ten years prison time (pardoned 1951)

**Wilhelm Henkel**

- Mauthausen: 61% mortality rate
- Trial at Dachau: March 1946 (U.S. vs. Hans Altfuldisch, et al)
  - 61 former camp personnel and prisoners
  - "Common Design" criminal charge
  - Charge: "violation of the laws and usages of war," as well as with subjecting foreign nationals to killing, beating, torture, and starvation
  - Execution: hanging May 1947
- Torture and murder of allied nationals

---

*Note: All sources are from the camp: Mauthausen - NS-experiments" and "Mauthausen - 61 former camp personnel and prisoners. (Class in camp)
“To make the work more rational, a cross was marked on the chest of those who had gold dental work.”

“After the execution, the S.S. dentists, Capt. Henkel and Franz Jutmann, removed the gold teeth.”

“...dental pulled out the golden teeth and golden crowns with pincers and hammers.”

“Dr. Walter Sonntag
– Dentist and physician
– Mustard-gas poisoning at Sachsenhausen
– 4th Ravenbruck’s Trial
• Mistreatment and torture
• Sending women of Allied nationalities to gas chamber
– Executed: September 1948

He particularly enjoyed extracting healthy teeth without anesthesia.”

Dr. Willi Frank (Lieut.)
• Trial held 1963-1965
• SS Dentist Auschwitz II (Birkenau)
• “Hungarian Action” (summer 1944)
  – Selection >6,000 for gas chambers
• Canisters of Zyklon B poison gas
• Sentence: 7 yrs. imprisonment

Yugoslavia
• Ethnic cleansing, murder, torture & eviction
  – Pleaded guilty; indicted in 2004 at the Hague
  – Commits suicide - 2006

“The U.N. plan to send...peacekeeping troops to Croatian trouble spots has won...support from all parties to the Yugoslav conflict, except for one bespectacled dentist who controls the angry enclave of Krajina.”

Virginia Dentist Sentenced for Scheme to Over-bill Medicaid and Insurance Companies

West Virginia Dentist Sentence for Tax Evasion

A dentist who authorities say was practicing without a valid license was arrested

Questions?
Teaching dental students legal reasoning: Case studies in fee splitting

Concerning Fee Splitting
There are three readily identifiable sources of relevant rules:
(a) Massachusetts General Laws
(b) The ADA Code of Professional Conduct
(c) Regulations issued by the Mass. Board of Registration in Dentistry

MGL Ch.112 §52A
"If a registered dentist contracts with a referral service and a fee is required for the registered dentist to be part of the referral service network, the referral service shall disclose the existence of the fee arrangement in any newspaper, radio or television advertisement, or in any display sign, personal solicitation or other manner of advertising. The disclosure shall plainly state the existence of the fee arrangement between the referral service and the dentists belonging to the referral service network and shall further state that only dentists who pay a fee are participants in such service."

American Dental Association Principles of Ethics and Code of Professional Conduct.

SECTION 4 – PRINCIPLE: JUSTICE

4.E. REBATES AND SPLIT FEES.
Dentists shall not accept or tender "rebates" or "split fees."

Mass. Incorporation by reference
Regulations issued by the Board of Registration in Dentistry of the Commonwealth of Massachusetts

234CMR §5.20
"Principles of Ethics and Code of Professional Conduct. All dentists licensed by the Board and all practices providing dental services shall comply with the Principles of Ethics and Code of Professional Conduct, January 2004 of the American Dental Association...."
Advisory Opinion
4.E.1. Split Fees In Advertising And Marketing Services. The prohibition against a dentist’s accepting or tendering rebates or split fees applies to business dealings between dentists and any third party [ Cf. to Mass. Statute], not just other dentists. Thus, a dentist who pays for advertising or marketing services by sharing a specified portion of the professional fees collected from prospective or actual patients with the vendor providing the advertising or marketing services is engaged in fee splitting. The prohibition against fee splitting is also applicable to the marketing of dental treatments or procedures via “social coupons” if the business arrangement between the dentist and the concern providing the marketing services for that treatment or those procedures allows the issuing company to collect the fee from the prospective patient, retain a defined percentage or portion of the revenue collected as payment for the coupon marketing service provided to the dentist and remit to the dentist the remainder of the amount collected.

What if dentist would charge $100 for a coupon patient, but now charges $115 & gives $15 to rebate company. Why not just charge $100 & have patient pay company $15

American Dental Association Principles of Ethics and Code of Professional Conduct.
SECTION 5 – PRINCIPLE: VERACITY (“truthfulness”)

5.F.4. REFERRAL SERVICES.
There are two basic types of referral services for dental care: not-for-profit, and the commercial. The not-for-profit is commonly organized by dental societies or community services. It is open to all qualified practitioners in the area served. A fee is sometimes charged to the practitioner to be listed with the service. A fee for such referral services is for the purpose of covering the expenses of the service and has no relation to the number of patients referred. In contrast, some commercial referral services restrict access to the referral service to a limited number of dentists in a particular geographic area. Prospective patients calling the service may be referred to a single subscribing dentist in the geographic area and the respective dentist billed for each patient referred. Commercial referral services often advertise to the public stressing that there is no charge for use of the service and the patient may not be informed of the referral fee paid by the dentist. There is a connotation to such advertisements that the referral that is being made is in the nature of a public service.

Case 1.
Jim Dentist has a practice of general dentistry located in a large office building. He rents an office to Gloria Endodontist within his premises that he leases from the owner of the building. This arrangement includes Gloria’s right to use Jim’s telephone equipment and all office equipment; a common waiting room and receptionist for her patients and Jim’s; an operatory equipped with all necessary equipment to treat patients; and the assistance of a hygienist proficient in her practice. Gloria pays Jim a set monthly fee, plus 10% of all fees which she collects. Gloria does not disclose her financial arrangement with Jim to her patients. Should a dentist engage in this conduct?

ADA Advisory Opinion
4.E.1. Split Fees In Advertising And Marketing Services. The prohibition against a dentist’s accepting or tendering rebates or split fees applies to business dealings between dentists and any third party [ Cf. to Mass. Statute], not just other dentists.

May a board rule or regulation supersede a statute? May it ban referral fees to a third party referral company? And if it does?

Commercial referral services often advertise to the public stressing that there is no charge for use of the service and the patient may not be informed of the referral fee paid by the dentist. There is a connotation to such advertisements that the referral that is being made is in the nature of a public service. A dentist is allowed to pay for any advertising permitted by the Code, but is generally not permitted to make payments to another person or entity for the referral of a patient for professional services. While the particular facts and circumstances relating to an individual commercial referral service will vary, the council believes that the aspects outlined above for commercial referral services violate the Code in that it constitutes advertising which is false or misleading in a material respect and violates the prohibitions in the Code against fee splitting.

234CMR §5.21
Prohibited Practices. Licensees are prohibited from engaging in the following practices:
(1) (Intentionally deleted)
(2) Paying or accepting fees in any form or manner as compensation for referring patients to any person for professional services, written work orders, or other services or articles supplied to the patient...."
Case 2.
Jim Dentist has a practice of general dentistry. Gloria Endodontist has a practice down the hall (in an office which she rents independently from their common landlord.) Gloria was graduated from the Harvard School of Dental Medicine within the previous twelve months, and Jim (who is old enough to be her father) has been a professor of clinical practice there for too long. Most of Gloria’s patients are referrals from Jim. Generally, Jim confers with Gloria about their patients. Gloria pays Jim’s practice a “consulting fee” which is not shown on any invoice to a patient or to an insurance company; i.e., she pays that fee out of her own pocket. Should a dentist engage in this conduct?

Case 3.
Jim does business with an out-of-state lab. Prior to April 15th of every year, that lab sends to Jim a check equal to 10% of all sums paid by his practice to the lab in the previous calendar year, and all sums collected by the lab from other dentists who Jim has referred to the lab. Should a dentist engage in this conduct?

Case 4.
Gloria Endodontist is just beginning her practice as an endodontist. She participates in a web service which refers patients to her. The financial relationship is simple: She is obligated to pay an amount equal to ten percent (10%) of her total gross billings to that firm, for all services provided. The firm also provides her with useful “management manuals” and software for financial and patient record keeping. Has Gloria done anything wrong? Under what standard?
DENTAL SESSION V

SATURDAY, FEBRUARY 28, 1:30 PM - 3:00 PM

Brera 3

MODERATOR:
Rollin Matsui, BSc, DDS, LLB, FCLM
THE “SUNSHINE” ACT: RELEVANCE TO DENTAL PRACTICE AND RESEARCH

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Why the Sunshine Act?

1. Lack of definitive resource for patients regarding physician-industry relationships;
2. Physicians had limited insight into potential conflicts of thought leaders, article writers, and speakers
3. The inability of research institutions to effectively monitor potential conflicts of employee researchers
4. Only few states have disclosure/transparency laws
5. Companies required to comply with different (sometimes contradicting) state law requirements
6. Most state laws do not address medical device companies
7. In most states where law exists, information is not public
8. Anticipated overall effect of the various potential conflicts on healthcare cost

OUTLINE

Timeline evolution of the Physician Payments Sunshine Act (PPSA)
Reporting requirements (clinicians and Researchers)
Potential impact on Dental Practice and Research
Suggested Steps to manage own public profile vis-à-vis physician-industry relationship and PPSA

“Sunlight is said to be the best disinfectant.” – Justice Brandeis.

“The sunshine law is expected to enhance transparency into the relationship between industry and healthcare providers in a form publicly accessible to patients and the population at large.

Does not prohibit/restrict industry-physician interaction, including payments/TOVs
Requires TRACKING and REPORTING!

Antecedent:
1993-2011: Six jurisdictions passed some form of the Sunshine Act
- Vermont; D.C.; Massachusetts, Maine, Minnesota; West Virginia. Maine repealed its law in 2011.

2003-04: Survey of physicians across 6 specialties shows 94% of respondents admitting to some degree of physician-industry relationship:
- Gifts; industry provided food in workplace; drug samples (50%)
- Reimbursement costs for professional meetings/CEs (33%)
- Consulting, lecturing, enrolling patients in clinical trials (24%)
Timeline Evolution of the Sunshine Act II:

- **2007:** The Physician Payments Sunshine Act (PPSA) of 2007 (senators Charles Grassley and Herb Kohl)
  - To "shed light" on financial relationships between industry and physicians (researchers) in order to discourage COI capable of compromising clinical integrity and interfering with patient care
  - Increased cost in healthcare (Failed to pass)

- **2009:** The Institute of Medicine (IOM) Conflict of Interest (COI) Report
  - Identified risks posed by financial conflicts:
    - Withholding reports of negative (research) results
    - Erosion of trust, harm to patients
    - (e.g. Systemic review of trial of BMP in adjacent to spine surgery, 2011). Authors:
      - Underestimated adverse effects
      - Failed to disclose financial relationships with sponsors
      - Non-disclosure of lucrative consulting arrangements

The PPSA as a Component of the Patients Protection and Affordable Care Act, 2010

- **March 2010:** POTUS signed into the law the Patients Protection and Affordable Care Act (ACA), incorporating the PPSA.
  - Public disclosure of payments to physicians from the industry
  - Report of certain ownership and investment interests held by physicians and immediate family members from manufacturers and Group Purchasing Organizations (GPOs)

PPSA: Who Must Report?

- The PPSA requires "applicable manufacturers" to disclose "payments or other transfers of value (TOV)" to "covered recipient" as a physician or a teaching hospital.
- "Applicable Manufacturer:" Manufacturers (including certain wholesalers/distributors) of drugs, devices, biological materials/medical supplies (participate in any fed. Healthcare prog)
- Group Purchasing Organizations (GPO) and manufacturers also must report ownership and investment interests held by physicians and/or family members.
- "Physician:" MD; DDS; OD; Podiatrist; Optometrist; Chiropractor; Fellows
- Physicians are not required to Self-Report!
- Payments/TOVs to Residents and Allied Health Professionals are not reportable

PPSA: Reportables

- Payments and TOVs:
  - Of $10 or more
  - If < $10 and if aggregate (sum) over a year is >$100
  - Direct and indirect payments/TOVs
  - Made via 3rd parties at request/on behalf of physician
  - Provided to physician owner/investor

- Ownership and Investment Interests
  - In GPOs and Manufacturers: $ amount of investment; value; terms of ownership/investment
  - Does not include interest in publicly traded securities/mutual funds

PPSA: Details for Reportables

- Manufacturer/GPO:
  - Name
  - Business Address
  - Amount of Payment
  - Date(s) of Payment
  - Mode/form of Payment
  - Nature of Payment

- Physician:
  - Name
  - Specialty
  - Address
  - NPI
  - Professional license #

PPSA: Reportables II

- Payment categories:
  - Consulting fee
  - Faculty/speaker fee for accredited/non-accredited CE
  - Honoraria
  - Entertainment/Gifts
  - Food and Beverages
  - Travel/Lodging (specifying destination)
  - Education/Research
  - Charitable contribution
  - Royalty/License
  - Ownership/investment interests (current/prospective)

Report is to Center for Medicare and Medicaid (CMS)
**PENALTIES FOR NON-COMPLIANCE**

- Non-willful: $1000 - $10,000
- Willful ("knowingly" failing to report): $10,000 - $100,000 with a max of $1 million (annually)
- *for each payment/TOV not reported!

**REPORTING RESEARCH-RELATED PAYMENTS**

- Research related payments are to be reported separately:
  - Usually, to be submitted the year payment occurs
  - Delayed Publication by CMS may be requested where sensitive (e.g., proprietary items) are involved to avoid premature disclosures

- **Final rule:** For a range of pre-clinical and FDA phase research, publication of reported research payments related to new products are delayed for four years or until FDA approval date, whichever comes first.
  - However, payments for research on new applications of existing products may not be subject to delayed publication.

**DENTISTS and PPSA**

- Anticipate inquiries from manufacturer/GPO related to reporting:
  - TVOs and other types of payments incurred toward the required reporting of Sunshine Act transfers of value, including certain payments, entertainment costs, gifts, meals and travel costs

- Some dental related companies offer advance notification regarding reportable TOVs to you with an opportunity to decline transfer. If Dentists agrees to TOV company will request information listed:
  - NPI number, dental license number, dental specialty, etc.
  - Be aware that final rule creates an exemption for compensation for speakers at ADA, accredited CE program provided event is:
    - ADA CERP event during which the dentist is speaking;
    - Manufacturer does not pay the dentist (recipient) speaker directly;
    - Manufacturer played not part in selecting the dentist speaker for the CE program.

  **Caution!!! Beware of IRS!!**

**IMPLEMENTATION TIMELINE FOR PPSA**

Aug. 1, 2013: Manufacturers begin collating information about payments, transfers of value, and ownership interests.

Feb. 18, 2014 – Mar. 31, 2014: (Phase 1 Data Submission)**
  - Manufacturers & GPOs submit aggregate 2013 payment data to CMS. Submission to be completed by March 31, 2014.

May 2014 + 30 days or more: (Phase 2 Data Submission)**
  - Manufacturers and GPOs submit detailed 2013 data (for the period August – December 2013)

August 2014 (May, in subsequent years): Physicians and Teaching Hospitals access their data online for accuracy/corrections:
  - 45 days for reviews and initiation of disputes
  - 15 days to resolve any disputes

September 30, 2014: 2013 data published on CMS public website (June 30 in subsequent years)

The 2-phase approach applies on 2014. subsequent reports will cover entire calendar years

**DENTAL ORGANIZATION ROLE: ADA?**

- Dentistry’s relationship with industry is essential for maintaining scientific progress in dentistry
  - Properly managed partnership needed
  - Develop and institute policies in the dental community to ensure that support from industry has no influence on:
    - Clinical documents (practice guidelines, etc);
    - Contents of CE courses

- Overall goal is to ensure full transparency and the highest ethical standards

- Proposed Guide Areas:
  - Advertising; charitable donations; clinical document development; CE; grants and foundation support; sponsorships

  "With strict and carefully constructed relationships that prevent bias or commercial interest, why should industry not share some responsibility for education that requires funding and life-long learning for the (dental) professionals?"

**JUSTIFYING VOLUNTARY AND AVOIDABLE PHYSICIAN-INDUSTRY RELATIONSHIP: Myths**

1. “I was just there to Teach”
2. “Nobody told me what to say”
3. “I always disclose my conflicts of interest”
4. “The money won’t influence me because I know what they’re trying to do”
5. “I don’t ever remember who bought me dinner”
6. “I need to network with industry leaders”
7. “My department can’t get along without industry money”
8. “Being on an industry advisory committee lets me see what’s going on in the inside”
9. “Companies need my advise and that’s why they pay me”
10. “Since I consult for many different companies, conflict of interest is a moot point”
11. “A company can’t influence me to change my prescribing"
3 STEPS YOU NEED TO TAKE TODAY!

**STEP 1**
Complete CMS e-Verification Process Today

**STEP 2**
Register with CMS Open Payment System

**STEP 3**
Review and dispute Data by Sept 8

Step 1: CMS requires a two-phase registration process:
- Phase 1, now open, physicians/dentists complete CMS’ e-verification process via the CMS Enterprise Portal (EIDM). Access detailed instructions at AMA Wire.
- Step 2: On gaining access to EIDM, physicians/dentists register in CMS Open Payments System via EIDM. Access detailed instructions at AMA Wire.

Step 3: Request individual report, review and flag disputes. Physicians/Dentists must initiate disputes by Sept 8 in order to have potentially erroneous entries flagged in the initial public release. CMS does not resolve disputes, but errors can be reported to manufacturers through the Open Payments System/Open Payments contacts.

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**Final Question!**

Is Physician-Industry Relationship Dispensable?

No
- Some have advocated absolutely no financial ties with industries
- Scarcity of public funding for research and publications, high cost of education makes this above position untenable.

Indeed, industry, in addition to its role in developing new drugs and devices, has an “obligation and expectation” to provide funding for the education of practitioners as part of its social contract with patients, clinicians, and the society.

“What is needed is strict and carefully constructed relationship to prevent bias or commercial interest”

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**GOOD AFTERNOON!**

And
Thank You All for Listening

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SELECTED REFERENCES

ABANDONMENT AND TERMINATION

Joseph P Graskemper DDS JD DABMM
FAGD FAES FICOI FASO FACLM
Associate Clinical Professor
Stonybrook School of Dental Medicine

This book integrates dental law, risk management, professionalism, and ethics, as all are interrelated in everyday practice. True cases show real examples of professional and ethical issues facing the practicing dentist. Integrates various aspects of professionalism, ethics, law, and practice management. Written by a practicing dentist with a law degree. Offers perspectives on both the legal and dental aspects of ethical and professional questions.

Professional Responsibility in Dentistry
A Practical Guide to Law and Ethics
Joseph P Graskemper

Order your copy today at wiley.com

Doctor – Patient Relationship

- Contractually based relationship with a fiduciary duty to the patient
- Starts when the doctor gives an opinion upon which the patient would reasonably rely on.
- Abandonment cannot occur without a valid Dr-Pt relationship


Dentist has duty to complete the services agreed to
Can not withhold completion of treatment agreed upon (when pt. at critical stage of tx)
Be available for patients after hours or arrange for coverage
Failure to send a promised “recall” card upon which the patient has relied on (possible new)

Abandonment


ADA Code of Ethics
Section 2.F

Once a dentist has undertaken a course of treatment, the dentist should not discontinue that treatment without giving the patient adequate notice and the opportunity to obtain the services of another dentist. Care should be taken that the patient’s oral health is not jeopardized in the process.
Also the refusal to initiate treatment may be seen as abandonment. (untimely delay to start treatment or to continue treatment)

It does not occur when termination is by mutual consent or when the relationship is ended by the patient.

Inadvertent Abandonment

- Occurs through:
  - misunderstandings about insurance coverage,
  - after-hours coverage,
  - poor follow-up,
  - failure to give proper after care instructions
  - refusing patient to talk to doctor,
  - scheduling appointment so far in advance that patient is further injured (scheduling system failure)

ADA Statement on Patient rights and Responsibilities

- The patient has a responsibility to participate in health care decisions, to inquire about treatment options, ask questions if you are uncertain about your dental treatment or plan and for consequences resulting from...not following the agreed upon treatment plan

Constructive Abandonment

- Doctor intends to terminate the relationship without the patient’s knowledge or consent
  (Intentional Abandonment - Failure to pay but not end dr-pt relationship, possible punitive damages)
- Doctor found to have failed to attend to the patient as frequently as due care in treatment would demand. (not responding to calls)

Causes of Action

- Negligence
  - Failure to see patient as required
  - Improperly concluded that patient did not require further treatment
  - Both, of course, require the patient sustained damages
- Breach of Contract

Chase v. Clinton County, 217 N.W. 585 (Mich. 1928);
Thomas v. Corso, 265 Md. 84, 288 A. 2d 379 (1972)

Must Have All 5 Elements

1. Health care treatment was unreasonably discontinued
2. The termination of health care was contrary to the patient’s will or without the patient’s knowledge
3. The health care provider failed to arrange for care by another appropriate skilled health care provider
4. The health care provider should have reasonably foreseen that harm to the patient would arise from the termination of the care (proximate cause).
5. The patient actually suffered harm or loss as a result of the discontinuance of care.

Patient must prove that the doctor ended the relationship without good reason or without sufficient notice to allow the patient to find another doctor and the patient was injured as a result.

**Doctor – Patient Relationship**

**When Does It End**

- Treatment completed
- Patient goes to another dentist
- Dentist or patient breaches contract
- Dentist and patient agree to end it
- Dentist or patient dies or disabled/illness
- Dentist terminates practice
- Dentist terminates relationship

**Patient Dismissal**

1. Patient did not fulfill payment agreement
2. Not showing up for appointments
3. Openly displays hostility to doctor and/or staff
4. Not complied with home-care instructions and jeopardizing treatment outcome
5. Lied on the health history
6. Break down in the interpersonal doctor-patient relationship

**Patient Termination**

1. Give date as to when termination begins (“as of”)
2. Give reason as to why patient terminated (state reason in an objective, non-inflammatory manner such that it will not inflame the patient—loss or breakdown of trust, failure to fulfill financial obligations, numerous missed appointments affecting care, etc.)

NOT just a phone call or not allowing patient to make an appointment
3. Must cover emergencies for a reasonable time (2 weeks to 2 months depending on location of practice)
4. Inform patient of his or her current condition and treatment needs and patient should be in a stable condition. (Prevent abandonment and ethically non-malfeasance)

5. How to find new dentist (don’t give names rather a referral to the local dental society)
6. Willing to transfer necessary records (only copies and a treatment summary [per state] if necessary with a signed authorization)
7. State how any financial balance will be handled (terms for payment expected/written off/refund)

Must not terminate patient for something covered by law (age, race, disability, HIV, AIDS, etc.)
Must finish any treatment started to a point that no harm to the patient (no temps without a fully documented informed consent)
Must continue care if only reasonable (skill and/or distance) source of care till safely transferred to another
Must continue care if patient is on pre-paid health plan till 3rd party payer is notified and safely transferred

If in a group practice, be sure patient is terminated from the entire group practice and not just the selected provider
May reasonably charge for reproduction of records
Must not refuse transfer of records if money is owed
Be sure to send certified, return receipt mail

Patient Refunds
- Must have an express written Release of Liability/All Claims with an anti-defamation clause.

Anti-Defamation Clause
Non-Disparagement Clause
- “Disparage” shall mean any negative statement, whether written or oral, about [Dentist/Dental Office] to cast doubt and made to or tends to influence the public not to buy.

Black’s Law Dictionary
“Defamation” – Holding up a person to ridicule, scorn or contempt in a respectable or considerable part of the community; includes libel and slander.

A communication is defamatory if it tends to harm the reputation of another as to lower him in the estimation of the community or to deter third persons from associating or dealing with him. (Black Law Dictionary)

During the time and thereafter, [Employee/Patient] agrees to take no action (written or oral) which is intended, or would reasonably be expected, to harm [Dentist/Dental Office] its/their reputation or which would reasonably be expected to lead to unwanted or unfavorable publicity to the [Dentist/Dental Office].

Take Patient Back

- Pt. cured financial problem
- Pt. apologized for behavior

What would you do?

Mrs. Good Patient calls and requests her records be transferred for herself and her family (4 children and husband). The family balance is about $600 of which she pays $50 a month because the ins. co. did not cover as much as estimated. She is a little upset that the ins. co. did not cover $800 of the treatment you did and was not told that there would be so much owed. She finishes with “I should let my Facebook friends know”